

UNITED STATES INTERNATIONAL TRADE COMMISSION

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In the Matter of

Investigation No.

CERTAIN DERMATOLOGICAL TREATMENT

337-TA-1356

DEVICES AND COMPONENTS THEREOF

-----X

OPEN SESSIONS

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EndyMed Ex. 1047 Page 1 of 12
EndyMed v. Serendia
IPR2024-00386

1 UNITED STATES INTERNATIONAL TRADE COMMISSION

2 Washington, D.C.

3 Before the Honorable MaryJoan McNamara

4 Administrative Law Judge

5 -----X

6 In the Matter of Investigation No.

7

8 CERTAIN DERMATOLOGICAL TREATMENT 337-TA-1356

9 DEVICES AND COMPONENTS THEREOF

10 -----X

11

12 International Trade Commission

13 500 E Street, SW

14 Washington, D.C.

15

16 Evidentiary Hearing

17 Tuesday, December 12, 2023

18 Volume VI

19

20 The parties met remotely pursuant to notice of
21 the Administrative Law Judge at 9:14 a.m. Eastern.

22

23

24 Reported by: Linda S. Kinkade RDR CRR RMR RPR CSR

25

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2

3 [All participants appeared via videoconferencing or
4 telephonically.]

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15 **Index appears at end of transcript**

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1 experimentation required.

2 Q. Moving to slide 39, what do the passages of the
3 '836 patent you've shown here teach a person of ordinary
4 skill in the art?

5 A. Well, I've highlighted four passages from the
6 '836 specification here on the screen to just identify the
7 parameters that control the energy field, for example, the
8 voltage, current, frequency applied to the needles, the on
9 and off time of the radiofrequency signal during the cycles
10 as well as the deployed depth of the needles.

11 And so regulation of the voltages to needles in
12 addition to their -- the polarity and pattern and shape and
13 adjacent distance and frequency all go to specific ways in
14 which the invention can be practiced.

15 And, finally, on the lower right I'm highlighting
16 that the invention may employ needles with particular
17 lengths and thicknesses so that geometry is also called out
18 specifically.

19 Q. Moving to slide 40. Does the '836 patent provide
20 a person of ordinary skill in the art with any information
21 about the parameters you were just discussing?

22 A. Yes, it does. I've listed a range of parameters
23 with specific ranges around them that the '836 patent
24 teaches to one of skill, including ranges of voltage,
25 frequency ranges as well as specific frequencies to try,

1 many of which, incidentally, were found in Respondents'
2 products. So that's consistent. Needle separation range
3 between 1.3 and 3 millimeters also consistent. And further
4 examples about needle separation and frequency of 2
5 millimeters with a 2 MHz frequency. And then very specific
6 time ranges that I'm showing as well as specific needle
7 diameter ranges and length ranges, which are also consistent
8 with many of Respondents' products I observed.

9 Q. Did you try to analyze every conceivable
10 embodiment that would satisfy claim 1 of the '836 patent?

11 A. No. That wasn't necessary for me to reach my
12 conclusions.

13 Q. Why not?

14 A. Well, because, as I mentioned previously, these
15 are smoothly varying functions, if you will, that one of
16 skill can understand by making small changes you can get
17 predictable results. And so there are no ranges of these
18 parameters in which one would get unexpected results,
19 especially in view of the very high level of skill of one of
20 ordinary skill in the art, and understanding that these are
21 getting applied to different areas of a patient's body so
22 that you wouldn't plunge a 4 millimeter needle into an
23 eyelid, for example. That wouldn't make any sense at all.
24 And you wouldn't have needles spaced by a meter, because
25 that wouldn't even cover the breadth of the patient. So, I

1 mean, it's -- it's obvious that there's some common sense
2 and understanding about how to apply this invention.

3 Q. How does the fact that lots of small variations
4 are possible relate to your opinion that the full scope of
5 the claims is enabled?

6 A. Well, one can artificially expand the number of
7 possibilities by, you know, finer and finer slicing and
8 dicing of the parameter space. You can change the frequency
9 by 1 Hz out of one MHz, that's one in a million. You can
10 create for yourself an enormous amount of work, which just
11 isn't necessary. So, in my opinion, one of skill is very
12 well informed by the ranges and the numbers of parameters to
13 be chosen to be able to practice the full scope of the
14 inventions.

15 Q. Let's move now to slide 41. With reference to
16 column 6, lines 43 to 55 of the '836 patent, can you explain
17 whether the patent provides any guidance to a person of
18 ordinary skill in the art about how adjusting parameters
19 will affect how the energy is distributed in the tissue?

20 A. Yes. Not only is the patent very explicit about
21 the number of parameters and certain ranges of those
22 parameters to practice its inventions, but it also explains
23 to one of skill how changing, for example, frequency will
24 change the broad -- the breadth of the energy field applied.

25 And so it notes, as I highlighted, that at a

1 frequency below .5 MHz it's a broad energy field that may
2 cause scarring in adjacent epidermis, whereas, if you go to
3 a source energy frequency of 10 MHz or above, the energy
4 field formed around the needles or electrodes may be too
5 narrow. So it's giving you more than just guidance about
6 the range of frequencies. It's telling you what's
7 happening.

8 Q. Now on slide 42. With reference to column 6,
9 lines 57-62, can you explain whether the '836 patent teaches
10 how changing one parameter affects other parameters?

11 A. Yeah, it not only explains what's happening in
12 the physiology with respect to changing frequency, but it
13 also speaks to the interdependence of some of these
14 parameters, importantly, the spacing between needles, which
15 is important for achieving the desired results versus the
16 source frequency.

17 So I think the -- it's remarkable that the patent
18 describes that interdependence in this language. And,
19 moreover, it actually uses a correlation, as I'll show in
20 the subsequent slide, to make that even more explicit.

21 Q. Let's go to slide 43. What guidance, if any, do
22 the equations in the '836 patent provide to a person of
23 ordinary skill in the art?

24 A. Well, as Dr. Na testified repeatedly, and I
25 agree, this is not meant to be mathematically understood as

1 much as it is a correlation among different parameters.

2 So what this equation or relationship is showing
3 is that the distance between needles is proportional to
4 power, energy, needle thickness, and conductivity of skin
5 and inversely proportional to quantities like resistance,
6 frequency, penetrated needle depth. So this is a very
7 succinct summary of the many experiments that Dr. Na
8 performed in order to condense his understanding into
9 something that can be communicated succinctly to one of
10 ordinary skill in the art.

11 Q. Moving to slide 44. How does Dr. Woloszko's
12 testimony that you've shown on this slide relate to your
13 opinion on Wands factors 1 and 2?

14 A. Well, highlighting the agreement that
15 Dr. Woloszko and I have that a POSITA was well positioned to
16 use the guidance provided in the '836 patent specification.
17 For example, he states in response to a question, he agrees
18 it was well-known that the energy dissipated in tissue is a
19 function of the voltage applied and the tissue impedance. I
20 agree with that. And he agrees with that.

21 He agrees that in 2011 one of skill in the art
22 would have known what temperature is needed in the skin to
23 achieve coagulation. And he agrees that time and
24 temperature would have been known. He agrees that among
25 other parameters the frequency range of the source can be

1 chosen for desired effects on various types of tissue and
2 its influence on lesion size and geometry based on the
3 intended application. And he and I both agree on that.

4 Q. Let's move to slide 45. Can you explain the
5 significance of the additional testimony from Dr. Woloszko
6 that you've included on slide 45?

7 A. Again, more points of agreement between us. I've
8 highlighted that a person of ordinary skill in the art would
9 have known how to adjust the thickness or diameter of the
10 needles to adjust the coagulation zones, and Dr. Woloszko
11 agreed to that question.

12 He also agreed that one of skill in the art would
13 have known how to adjust the needle length or depth to
14 obtain coagulation at the right depth, which is something I
15 also agree with. And, furthermore, that one skilled in the
16 art would have known how to adjust the distance between the
17 needles to create more isolated zones of coagulations, and
18 he says obviously, and I agree with that as well.

19 Q. On slide 46 now, have you seen any evidence in
20 this investigation of any attempt to practice the '836
21 patent claims that was unsuccessful or required excessive or
22 undue experimentation?

23 A. No, I have not.

24 Q. Do you recall that the '836 patent states,
25 determining the parameters to enable the desired energy