that the Accused Products meet the additional limitation recited in claim 4 of the ’812 patent.

6. The Accused Products Practice Claim 5 of the ’812 Patent

a) “The method of claim 4, wherein the needle assembly includes a translucent section and further including energizing the least one embedded LED to illuminate the plurality of needles via the needle assembly translucent section.”

The Accused Products practice this limitation because “the needle assembly includes a translucent section and further including energizing the least one embedded LED to illuminate the plurality of needles via the needle assembly translucent section.” The needle assembly in the Potenza Accused Products, depicted below in blue, includes portions that are translucent, illustrated below by pink outlines.

Figure 32: Crosby Demonstrative Depicting Translucent Section of the Needle Assembly



(CDX-0001C.0067; Tr. (Crosby) at 617:10-618:10; *see also* CX-3089C-3158C, CX-3257C-3295C, CPX-0124-0133C, CPX-0140C-0147C (Inspection Photos/Videos); CPX-0162-0183 (physical portions of Accused Products).).

For the Potenza Accused Products, the [redacted]. (Tr. (Crosby) at 617:10-618:10.).

The [redacted]. (*Id.*; CPX-0131C (EndyMed Inspection Video) at 0:01.).

The [redacted]. (Tr. (Crosby) at 617:10-618:10; CPX-0128C (Potenza) at 0:03; CPX-0061 (Video, Potenza) at 0:29; CPX-0063 (Potenza Tiger Tip) at 0:30; CX-0164C.0029 (Potenza Manual); CX-0696.0019, 0056 (EndyMed HP Manual); CX-0697C.0023 (EndyMed HP Spec.); CX-0186 (EndyMed Pro Manual); CPX-0067 (Video, Intensif); CPX-0068 (Video, Intensif).).

Jeisys/Cynosure contended through their experts' testimony that their Accused Products do not meet claim 5 by limiting the needle assembly to include only the needles, PCB, and pogo pins—components that they contend are not translucent—and exclude the other components that move as part of the needle assembly within the needle module. (RPBr. at 128; RRBr. at 63-66; RDX-0012C.0011; Tr. (Bérubé) at 1226:23-1228:18; RDX-0013C.0020-21; Tr. (Brennan) at 1163:5-1164:6.). To the contrary, Dr. Brennan's and Dr. Bérubé's interpretations of "needle assembly" contradicts the'812 patent specification, which expressly contemplates that the needle assembly includes more than just the needles, PCB, and pogo pins—it includes the other components that form part of that assembly that moves within the needle module. (JX-0005 at 13:31-34 ("As shown in FIGS. 11B and 11C, the needle assembly 924F may include a pin cover

924J, drive arm module 924L, needles 924A, pins 924G with bases 924H, and needle printed circuit board (PCB) 924K."), Fig. 11C; Tr. (Crosby) at 1486:10-1487:1.).

Although EndyMed did not present evidence during the Hearing to dispute the evidence and Serendia's arguments that EndyMed's Accused Products meet the additional limitations of claim 5, EndyMed incorrectly argued in Respondents' Pre-Hearing Brief that the needles are not illuminated by the LED and that Serendia did not point to a translucent portion of the needle assembly. (RPBr. at 127-28.). That is simply incorrect. As depicted above in Figure 32 (CDX-0001C.0067), the needles are illuminated by the LED. (*See also* CPX-0131C (EndyMed Inspection Video) at 0:00-0:05; CPX-0131C (EndyMed Inspection Video) at 0:00-0:05; CX-3150C; CX-3151C; CPX-0067 (Intensif Video) at 0:15-0:30; CPX-0068 (Video, Intensif) at 2:18, 2:22).). Additionally, the [redacted]. (Tr. (Crosby) at 617:10-618:10; CDX-0001C.0067.). Depicted below are annotated still photos from Mr. Crosby's inspection video, CPX-0131C, which [redacted].

[redacted]

(CBr. at 81.).

For the reasons explained, Serendia has proven by a preponderance of evidence that the Accused Products meet the additional limitations recited in claim 5 of the ’812 patent.

7. The Accused Products Practice Claim 12 of the ’812 Patent

a) 12[pre]: “An apparatus for treating dermatological tissue, comprising”

12[a]: “a user holdable device including a proximal end”

12[b1]: “a releasably couplable deployable needle module”

12[b2]: “the releasably couplable deployable needle module mechanically separatably from the user holdable device proximal end and including a needle assembly including a plurality of needles”

12[b3]: “the needle assembly movable within the releasably couplable deployable needle module to extend the plurality of needles from the releasably couplable deployable needle assembly end surface”

12[b4]: “while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end”

Claim 12, from which asserted claim 13 depends, is the apparatus claim corresponding to method claim 1. (Tr. (Crosby) at 619:10-25.). There are no elements in claim 12 that are not also part of claim 1. (CDX-0001.0072.).

Thus, for the same reasons noted above for claim 1, Serendia has proven by a preponderance of evidence that the Accused Products meet all the limitations of claim 12 of the '812 patent. (Tr. (Crosby) at 620:1-11; *see also* Section X.A.2, *supra*.).

8. The Accused Products Practice Claim 13 of the '812 Patent

a) "The apparatus of claim 12, further including a motor coupled to the needle assembly to extend the plurality of needles a desired distance from the releasably couplable deployable needle assembly end surface when the motor is energized with a particular signal."

Claim 13 depends on claim 12, which is the apparatus claim corresponding to method claim 1. (Tr. (Crosby) at 619:10-25.). There are no elements in claim 12 that are not also part of claim 1, and for the same reasons discussed above for claim 1, the Accused Products meet all the limitations of claim 12. (CDX-0001.0072; Tr. (Crosby) at 620:1-11.).

The weight of the evidence demonstrates that the Accused Products each includes a motor coupled to the plurality of extendable needles. (*See* Sections X.A.3.). Moreover, the evidence confirms that the motor causes the needles to extend a desired distance from the needle module end surface when energized with a particular signal. (*See id.*).

In their Pre-Hearing Brief, Respondents again summarily raised the same arguments as for the limitations of claim 11 of the '536 patent: a "releasably couplable deployable needle assembly" and "plurality of extendable needles . . . extendable from a deployable needle assembly end surface." (RPBr. at 130.). For the same reasons noted above in Section X.A.3, Respondents' arguments conflict with the adopted claim construction as well as with the

evidence presented during the Hearing.

For the reasons explained, Serendia has proven by a preponderance of evidence that the Accused Products meet the additional limitation recited in claim 13 of the ’812 patent.

9. The Accused Products Practice Claim 18 of the ’812 Patent

a) “The apparatus of claim 12, wherein one of the at least one electrical contacts includes a pin that is extendable in the same direction as the plurality of needles.”

The Accused Products practice the additional limitation of claim 18 because “one of the at least one electrical contacts includes a pin that is extendable in the same direction as the plurality of needles.” Specifically, the weight of the evidence demonstrates that the Accused Products include [redacted]. (Tr. (Crosby) at 623:23-625:5; CX-0170C.0001 (Potenza Tip-49 Drawing); CX-0716C (Potenza Tips Presentation); CX-3146C (Intensif with EndyMed Pure 2.0); CPX-0131C (EndyMed Inspection Video) at 0:01; CX-0701C (Intensif Pin Drawing); CPX-0035 (Video, Intensif HP); CDX-0001C.0083 (Crosby); CX-3089C-3158C, CX-3257C-3295C, CPX-0124-0133C, CPX-0140C-0147C (Inspection Photos/Videos); CPX-0162-0183 (physical portions of Accused Products).

Respondents did not contest that the DI Products meet this limitation in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 124-25, 131; RRBr. at 63-66.). Thus, any argument they may make on this issue is deemed abandoned, withdrawn, and/or waived under Ground Rules 7.2 and 10.1.

Accordingly, Serendia has proven by a preponderance of evidence that the Accused Products meet the additional limitation recited in claim 18 of the ’812 patent.

B. Technical Prong of Domestic Industry

1. The DI Products Practice Claim 1 of the ’812 Patent

a) 1[pre]: “A method of treating dermatological tissue, comprising”

The DI Products practice “[a] method of treating dermatological tissue.” (Tr. (Crosby) at 583:3-20; CDX-0001C.0017.). Serendia presented unrebutted evidence demonstrating that the DI Products are described as performing this function. (CX-0826C.0002 (Sylfirm X 510(k) Description); CX-0761C.0002 (Sylfirm X Webpage); CX-0830 (Sylfirm X Brochure) at 2; CX-0827C.0002 (Sylfirm X 510(k) Description).).

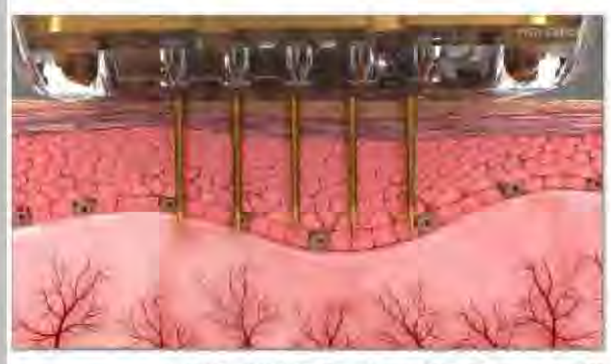
Respondents did not contest that the DI Products meet this limitation in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 133; RRBr. at 67-68.). Thus, any argument they may make on this issue is deemed abandoned, withdrawn, and/or waived under Ground Rules 7.2 and 10.1.

For the foregoing reasons, Serendia has proven by a preponderance of evidence that the DI Products meet the preamble of claim 1 of the ’812 patent.

b) 1[a1]: “placing a user holdable device releasably couplable deployable needle module end surface on or near dermatological tissue to be treated, the user holdable device including a proximal end and the releasably couplable deployable needle module”

The DI Products include a handpiece with a proximal end. The handpiece includes a releasably couplable deployable needle module (depicted in green on the left below), where its end surface is placed on the tissue to be treated.

Figure 34: Crosby Demonstrative Showing the Claimed Releasably Couplable Deployable Needle Module



CPX-0069 (Sylfirm X Video), 0:32

(CDX-0001C.0025.).

As depicted in the photos above in Figure 34 and as Mr. Crosby's inspections confirmed, the weight of the evidence is that the needle module is releasably couplable to the proximal end of the handpiece and is deployable, as the needles extend in operation. (Tr. (Crosby) at 587:24-588:16; CX-0826C.0011 (Sylfirm X 510(k) Description); CPX-0069 (Sylfirm X Video) at 0:32 (above); CX-0760C.0007-10 (above), CX-0759C, CX-2915, CX-2916 (DI Product Photos); CPX-0070 (Sylfirm-X Introduction Video); *see also* CX-3340C, CX-3326C, CX-3330C (Sylfirm X); CX-0823C.0011-12 (Sylfirm X Manual); CX-3384 (Sylfirm X 510(k)); CX-3321C-3350C (Inspection Photos/Videos); CPX-0160-161 (physical portions of DI Products).).

Respondents did not contest that the DI Products meet this limitation in their Pre-Hearing Brief. (RPBr. at 133.). Thus, any argument they may make on this issue is deemed abandoned or withdrawn under Ground Rule 7.2.

For the foregoing reasons, Serendia has proven by a preponderance of evidence that the DI Products meet this limitation of claim 1 of the '812 patent.

c) 1[a2]: "the releasably couplable deployable needle module mechanically separatably from the user holdable device proximal end and including a needle assembly including a plurality of needles"

The needle module in the DI Products includes a needle assembly (as depicted above in blue in Figure 34 (CDX-0001C.0025)) with a plurality of needles. (CX-0826C.0011 (Sylfirm X 510(k) Description); CX-0760C.0007-10 (DI Photos).). The needle module unrebuttedly also includes mechanical elements that engage with mechanical elements in the proximal end of the handpiece, making it releasably couplable and mechanically separable. (Tr. (Crosby) at 591:25-592:13; CDX-0001C.0031; CX-3340C, CX-3326C, CX-3330C (Sylfirm X); CX-0826C.0011 (Sylfirm X 510(k) Description); CX-0760C.0007-10, CX-2915, CX-2916 (DI Photos); CX-0830 (Sylfirm X Brochure); CPX-0069 (Sylfirm X Video) at 0:32; CX-0823C.0011-12 (Sylfirm X Manual); CX-3384 (Sylfirm X 510(k)); *see also* CX-3321C-3350C (Inspection Photos/Videos); CPX-0160-161 (physical portions of DI Products).).

Respondents did not contest that the DI Products meet this limitation in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 133; RRBr. at 67-68.). Thus, any argument they may make on this issue is deemed abandoned, withdrawn, and/or waived under Ground Rules 7.2 and 10.1.

For the reasons discussed above, Serendia has proven by a preponderance of evidence that the DI Products meet this limitation of claim 1 of the '812 patent.

d) 1[a3]: "the needle assembly movable within the releasably couplable deployable needle module to extend the plurality of needles from the releasably couplable deployable needle assembly end surface while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end

The needle assembly moves within the needle module to extend the needles from the

needle assembly end surface, as depicted in Figure 35, in green in the photographs below each other on the right.

Figure 35: Crosby Demonstrative Illustrating Movable Needle Assembly



(CDX-0001C.0038; *see also* CPX-0152C (Sylfirm X Inspection Video) at 0:00-0:05; CX-3329C, CX-3330C (Sylfirm X); Tr. (Crosby) at 595:12-596:4.).

Referring to his demonstrative, as replicated in Figure 36, below, Mr. Crosby explained that the needle assembly includes pogo pins (depicted in gold below in the picture on the far left), which are electrical contacts that maintain electrical contact while the needle assembly moves within the needle module. (Tr. (Crosby) at 599:25-601:18.).

Figure 36: Crosby Demonstrative Illustrating Movable Needle Assembly



(CDX-0001C.0041; *see also* CX-0826C.0011 (Sylfirm X 510(k) Description); CX-0760C.0007-11 (DI Photos); CX-0759C.0002, 0004, CX-0760C.0006, 0011, CX-2915, CX-2916 (DI Photos); CX-0823C.0011-13, 0023 (Sylfirm X Manual); CPX-0069 (Sylfirm X Video) at 0:05-0:11; CX-3384 (Sylfirm X 510(k)); CDX-0001C.0038; CX-3321C-3350C (Inspection Photos/Videos); CPX-0160-161 (physical portions of DI Products).).

Respondents did not specifically contest that the DI Products meet this limitation in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 133; RRBr. at 67-68.). Thus, any argument they may make on this issue is deemed abandoned, withdrawn, and/or waived under Ground Rules 7.2 and 10.1.

For the reasons explained, Serendia has proven by a preponderance of evidence that the DI Products meet this limitation of claim 1 of the ’812 patent.

e) 1[b]: “communicating electrical signals from the user holdable device proximal end to the needle assembly via the electrical contacts”

The DI Products communicate RF, an electrical signal, from the proximal end to the needles of the needle assembly through electrical contacts so treatment can be delivered. (Tr. (Crosby) at 604:9-23; CDX-0001C.0045; CPX-0069 (Sylfirm X Video) at 0:11; CX-0823C.0004, 0016, 0017, 0025-27 (Sylfirm X Manual); CX-0830.0002, 0006, 0007 (Sylfirm X

Brochure); *see also* CX-3321C-3350C (Inspection Photos/Videos); CPX-0160-161 (physical portions of DI Products).).

Respondents did not contest that the DI Products meet this limitation in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 133; RRBr. at 67-68.). Thus, any argument they may make on this issue is deemed abandoned, withdrawn, and/or waived under Ground Rules 7.2 and 10.1.

Accordingly, Serendia has proven by a preponderance of evidence that the DI Products meet this limitation of claim 1 of the ’812 patent.

2. The DI Products Practice Claim 2 of the ’812 Patent

a) “The method of claim 1, further comprising energizing a motor coupled to the needle assembly to cause the plurality of the needles to extend a desired distance from the releasably couplable deployable needle module end surface.”

The DI Products include a motor coupled to the plurality of extendable needles. (*See* Section X.B.1, *supra*.). Serendia presented unequivocal, unrebutted evidence that the motor causes the needles to extend a desired distance from the needle module end surface. (Tr. (Crosby) at 609:15-611:7, 661:10-662:20; CDX-0001C.0053-54; CX-3326C, CX-3329C, CX-3330C, CX-3340C (Sylfirm X); CX-0759C.0002-4, CX-0760C.0002 (DI Photos); CX-0823C.0016 (Sylfirm X Manual); CX-0826C.0007, 0015, 0016 (Sylfirm X 510(k) Description); CX-0829C.0003 (Sylfirm X Circuit Drawing); CX-3384 (Sylfirm X 510(k)); *see also* CX-3321C-3350C (Inspection Photos/Videos); CPX-0160-161 (physical portions of DI Products).).

Respondents did not contest that the DI Products meet this limitation in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 133; RRBr. at 67-68.). Thus, any argument they may make on this issue is deemed abandoned, withdrawn, and/or waived under Ground

Rules 7.2 and 10.1.

For the foregoing reasons, Serendia has proven by a preponderance of evidence that the DI Products meet the additional limitation recited in claim 2 of the ’812 patent.

3. The DI Products Practice Claim 3 of the ’812 Patent

a) “The method of claim 2, further comprising energizing the plurality of needles via a signal generator electrically coupled to the user holdable device proximal end.”

The needles in the DI Products are energized via an RF generator electrically coupled to the user holdable device proximal end. (Tr. (Crosby) at 611:17-612:13; CDX-0001C.0057; CPX-0069 (Sylfirm X Video) at 0:11; CX-3321C-3350C (Inspection Photos/Videos); CPX-0160-161 (physical portions of DI Products).).

Respondents did not contest that the DI Products meet this limitation in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 133; RRBr. at 67-68.). Thus, any argument they may make on this issue is deemed abandoned, withdrawn, and/or waived under Ground Rules 7.2 and 10.1.

For these reasons, Serendia has proven by a preponderance of evidence that the DI Products meet the additional limitation recited in claim 3 of the ’812 patent.

4. The DI Products Practice Claim 4 of the ’812 Patent

a) “The method of claim 3, wherein the user holdable device proximal end further includes at least one embedded LED therein and further including energizing the at least one embedded LED so the at least one embedded LED illuminates the releasably couplable deployable needle module.”

The proximal end of the DI Products includes at least one embedded LED that, when energized, illuminates the needle module. (Tr. (Crosby) at 614:6-22; CDX-0001C.0062; CX-3326C, CX-3330C (Sylfirm X); CPX-0081C (Sylfirm X Video) at 3:08-3:14; CX-0826C.0015-

16 (Sylfirm X 510(k) Description); CX-0759C.0002, 0004, CX-0760C.0007-10 (DI Photos); CX-0823C.0027 (Sylfirm X Manual); CX-0829C.0002-3 (Sylfirm X Circuit Drawing); CX-3384 (Sylfirm X 510(k)); CX-3321C-3350C (Inspection Photos/Videos); CPX-0160-161 (physical portions of DI Products).).

Respondents did not contest that the DI Products meet this limitation in either their Pre-Hearing or Post-Hearing Reply Briefs. (RPBr. at 133; RRBr. at 67-68.). Thus, any argument they may make on this issue is deemed abandoned, withdrawn, and/or waived under Ground Rules 7.2 and 10.1.

For the foregoing reasons, Serendia has proven by a preponderance of evidence that the DI Products meet the additional limitation recited in claim 4 of the ’812 patent.

5. The DI Products Practice Claim 5 of the ’812 Patent

a) “The method of claim 4, wherein the needle assembly includes a translucent section and further including energizing the least one embedded LED to illuminate the plurality of needles via the needle assembly translucent section.”

The needle assembly of the DI Products includes a translucent section, and the LED in the proximal end of the handpiece illuminates the needles via that translucent section. (Tr. (Crosby) at 618:11-619:9; CDX-0001C.0068; CX-3330C (Sylfirm X); CX-0826C.0011 (Sylfirm X 510(k) Description); CX-0759C.0002, 0004, CX-0760C.0007-11 (DI Photos); CX-0823C.0027 (Sylfirm X Manual); CX-0829C.0002, 0003 (Sylfirm X Circuit Drawing); CX-3384 (Sylfirm X 510(k)); CX-3321C-3350C (Inspection Photos/Videos); CPX-0160-161 (physical portions of DI Products).).

In their Pre-Hearing Brief, Respondents made the same arguments raised for claim 11 of the ’536 patent. (RPBr. at 133 (citing *id.* at Section VI.B.2).). They fail for the reasons

discussed above in Section VIII.C.1.

Accordingly, Serendia has proven by a preponderance of evidence that the DI Products meet the additional limitation recited in claim 5 of the ’812 patent.

6. The DI Products Practice Claim 12 of the ’812 Patent

a) 12[pre]: “An apparatus for treating dermatological tissue, comprising”

12[a]: “a user holdable device including a proximal end”

12[b1]: “a releasably couplable deployable needle module”

12[b2]: “the releasably couplable deployable needle module mechanically separatably from the user holdable device proximal end and including a needle assembly including a plurality of needles”

12[b3]: “the needle assembly movable within the releasably couplable deployable needle module to extend the plurality of needles from the releasably couplable deployable needle assembly end surface”

12[b4]: “while at least one electrical contact of the needle assembly remains electrically coupled to at least one electrical contact of the user holdable device proximal end”

Claim 12, from which asserted claim 13 depends, is the apparatus claim corresponding to method claim 1, addressed above in Section X.B.1. (Tr. (Crosby) at 619:10-620:11.). There are no elements in claim 12 that are not also part of claim 1. (CDX-0001.0072.).

Thus, for the same reasons discussed in Section X.B.1, Serendia has proven by a preponderance of evidence that the DI Products meet claim 12 of the ’812 patent. (Tr. (Crosby) at 620:1-10.).

7. The DI Products Practice Claim 13 of the ’812 Patent

a) “The apparatus of claim 12, further including a motor coupled to the needle assembly to extend the plurality of needles a desired distance from the releasably couplable deployable needle assembly end surface when the motor is energized with a particular signal.”

The DI Products meet the additional limitation of claim 13 because they include a motor coupled to the plurality of extendable needles and energize that motor “with a particular signal” to extend the needles a desired distance from the needle module end surface. (Tr. (Crosby) at 620:21-621:12, 622:25-623:12; CDX-0001C.0075, 0079; CX-0826C.0015-16 (Sylfirm X 510(k) Description); CX 0759C, CX 0760C (DI Product Photos 2); CX-0823C (Sylfirm X Manual); CX 0826C (Sylfirm X 510(k) Device Description); CPX-0069 (Video, Sylfirm X); *see also* Section X.B.6.).

In their Pre-Hearing Brief, Respondents relied on the same arguments they presented for claim 5. (RPBr. at 133.). For the reasons discussed above, the arguments are unpersuasive and not supported by the weight of the evidence.

Accordingly, Serendia has proven by a preponderance of evidence that the DI Products meet the additional limitation recited in claim 13 of the ’812 patent.

8. The DI Products Practice Claim 18 of the ’812 Patent

a) “The apparatus of claim 12, wherein one of the at least one electrical contacts includes a pin that is extendable in the same direction as the plurality of needles.”

The DI Products practice the additional limitation of claim 18 because they include pogo pins extendable in the same direction as the plurality of needles. (Tr. (Crosby) at 625:6-626:4; CDX-0001C.0084; CX-3340C (Sylfirm X); CX-0826C.0011 (Sylfirm X 510(k) Description); CX-0759C.0004, CX-0760C.0007-11 (DI Photos); CX-0823C.0012 (Sylfirm X Manual); CX-

0826C.0006 (Sylfirm X 510(k) Description); CX-2918.0001 (Photo, Sylfirm X tip); CX-2919.0001 (Photo, Sylfirm X tip); CX-3384 (Sylfirm X 510(k)); CX-3321C-3350C (Inspection Photos/Videos); CPX-0160-161 (physical portions of DI Products).).

In their Pre-Hearing Brief, Respondents relied on the same arguments they presented for claim 5. (RPBr. at 133.). For the reasons discussed above, the arguments are unpersuasive and not supported by the evidence.

For these reasons, Serendia has proven by a preponderance of evidence that the DI Products meet the additional limitation recited in claim 18 of the '812 patent.

C. Invalidity

1. Scope of the Prior Art

Respondents argued that claims 5, 13, and 18 of the '812 patent are rendered obvious over Mehta in view of the knowledge of a person of ordinary skill in the art.[77] (RPBr. at 134-40; RBr. at 82.). For claim 5 only, Respondents contended that Mehta in view of the knowledge of a person of ordinary skill in the art and in further view of WO 2010/016848 ("Na '848") renders the claim obvious. (RPBr. at 134-40; RBr. at 82.). For the reasons discussed below, these prior art references do not render obvious claims 5, 13, and 18 of the '812 patent.

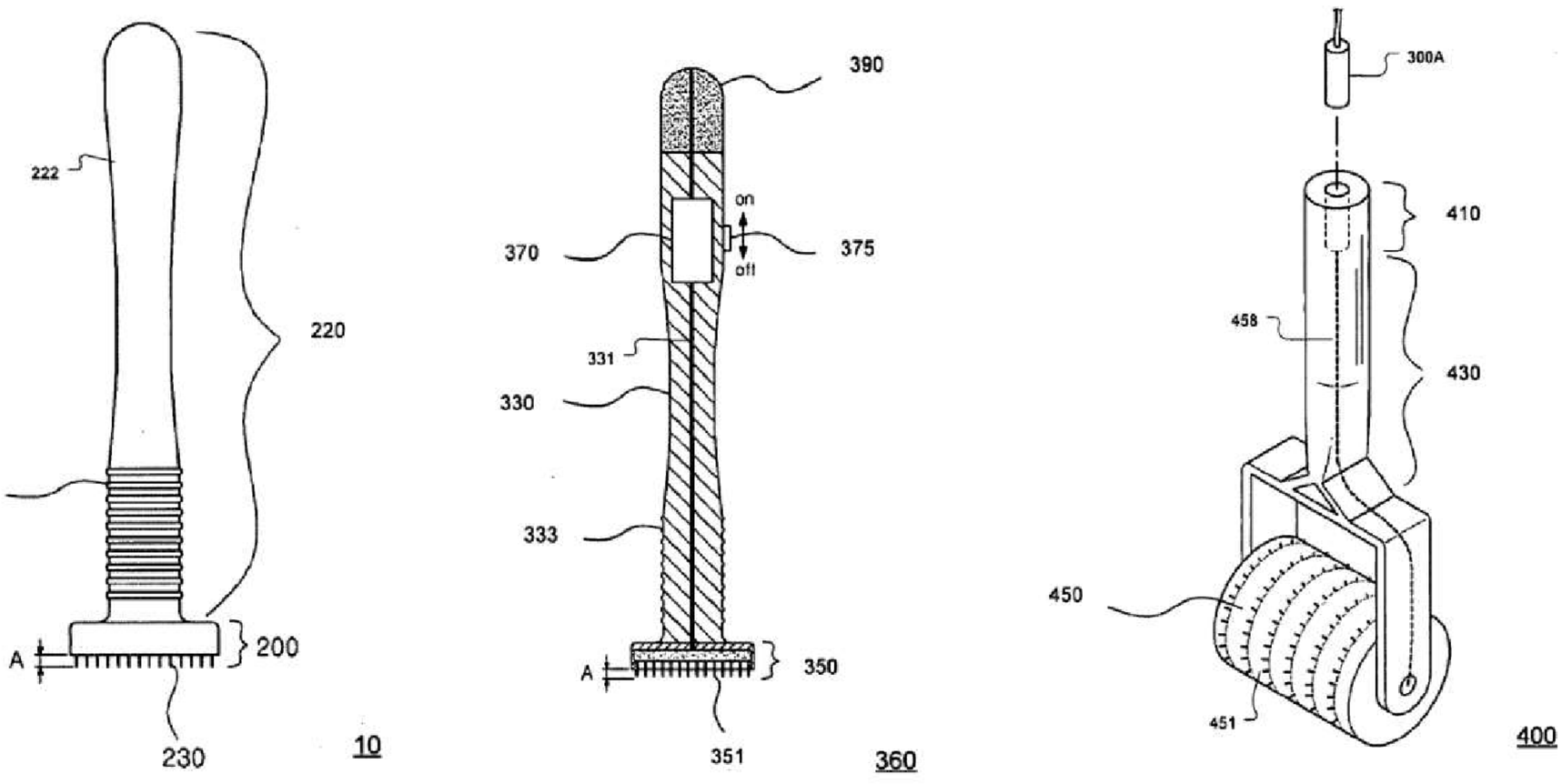
a) Na '848 (RX-1814)

Na '848 is directed towards an acupuncture-type apparatus with either a plate or roller with pins at the end of a handle. (RX-1814 at ¶¶ 22-38, Figs. 1A-4C; *see also* Tr. (Crosby) at 1512:11-1513:14; CDX-0043C.0038-40, 0042.). The figures below in Figure 37 depict the embodiments in Na '848.

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[77] Asserted claim 5 depends from claims 1-4; asserted claims 13 and 18 depend from claim 12. Claims 1-4 and 12 are not at issued in this Investigation.

Figure 37: Figures of Na ’848 Embodiments



(RX-1814 at Figs. 1B (left), 2C (middle), 3A (right).).

The needles in Na ’848 have a fixed length and do not extend. (RX-1814 at ¶¶ 26, 33, Figs. 1A-4C; *see also* Tr. (Crosby) at 1513:10-14; CDX-0043C.0040.). Na ’848 does not disclose RF or supplying RF to needles. (Tr. (Woloszko) at 1046:5-10.). Na ’848 also does not disclose longitudinal movement of the needles to penetrate skin. (*Id.* at 1046:16-22.). Na ’848 also does not have a needle assembly. (*Id.* at 1046:23-1047:2.). Although Na ’848 discloses that the plate or roller can include embedded LEDs, the LEDs are not in the handle. (RX-1814 at ¶¶ 34, 38, Figs. 1A-4C; *see also* Tr. (Crosby) at 1514:5-17; CDX-0043C.0042.).

2. The Prior Art References Do Not Render Obvious the Asserted Claims of the '812 Patent[78]

a) Mehta in View of the Knowledge of a Person of Ordinary Skill in the Art (Claims 5, 13, and 18)

i. Respondents Improperly Relied on Multiple Embodiments Disclosed in Mehta

Like the '536 and '774 patents, Respondents relied on multiple embodiments in an attempt to demonstrate that Mehta discloses all the limitations of the asserted claims of the '812 patent. For the same reasons discussed above in Section VIII.D.4(a) with respect to the '536 patent, Respondents failed to explain why one of ordinary skill would mix and match the embodiments of Mehta as they proposed. *In re Stepan Co.*, 868 F.3d at 1346 n.1. (*See also* Tr. (Crosby) at 1499:23-1500:11.).

ii. Mehta Does Not Disclose the Desired Distance Limitation

Like the '536 and '774 patents, claims 2 and 13 of the '812 patent require needles that extend "a desired distance" from an "end surface." (JX-0005 at cls. 2, 13.). As explained in Sections VIII.D.3 and VIII.D.4 above with respect to the '536 patent, Mehta does not disclose needles that extend a "desired distance" from any surface. Respondents did not point to how the knowledge of a skilled artisan would fill the gaps. (RBr. at 85.). Neither did Dr. Woloszko, because he relied on his same analysis for claim 11 of the '536 patent. (Tr. (Woloszko) at 965:11-966:23.). Respondents' arguments fail for the same reasons discussed above in Section VIII.D.4.

iii. Mehta Does Not Disclose the Embedded LED Limitation

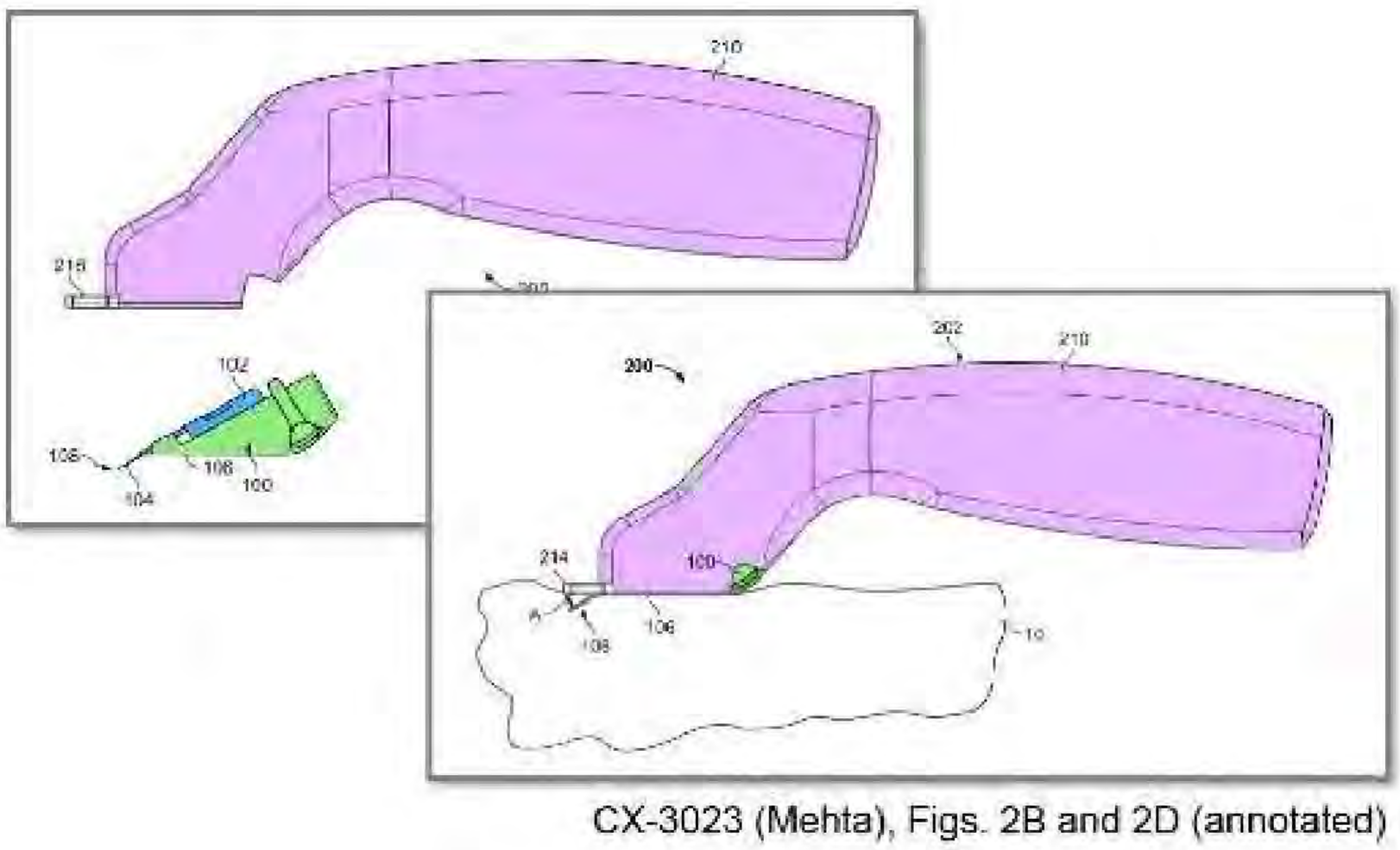
Respondents identified Mehta's electrode assembly 102 as the claimed "needle

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[78] *See* n.54, *supra* (regarding institution of IPRs).

assembly." (Tr. (Woloszko) at 939:6-940:16; RDX-0010C.0108; RBr. at 64, 66.). As depicted below in the annotated Figures of Mehta, Mehta discloses that electrode assembly 102 (in blue) is within a removable cartridge 100 (in green), both of which are inserted into the device body 210 (purple).

Figure 38: Annotated Figures 2B and 2D of Mehta



CX-3023 (Mehta), Figs. 2B and 2D (annotated)

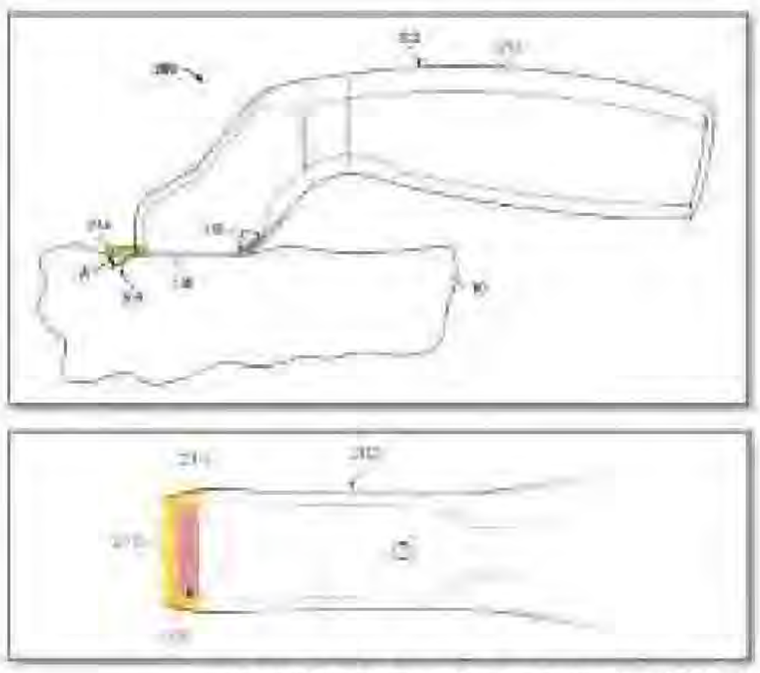
(CDX-0043C.0036 (citing RX-0307 at Figs. 2B and 2D (annotated)).).

As Mr. Crosby explained credibly, Mehta does not describe the electrode assembly 102 or any portion of the removable cartridge 100 as transparent or translucent. (Tr. (Crosby) at 1508:24-1509:12; CDX-0043C.0033.). Rather, the only components Mehta describes as possibly transparent to allow for visualization of the needles are stabilization plate 214 (or cooling surface) and feature 216 (a window or opening). (RX-0307 at 4:19-34, 22:7-10, 13:20-23.).

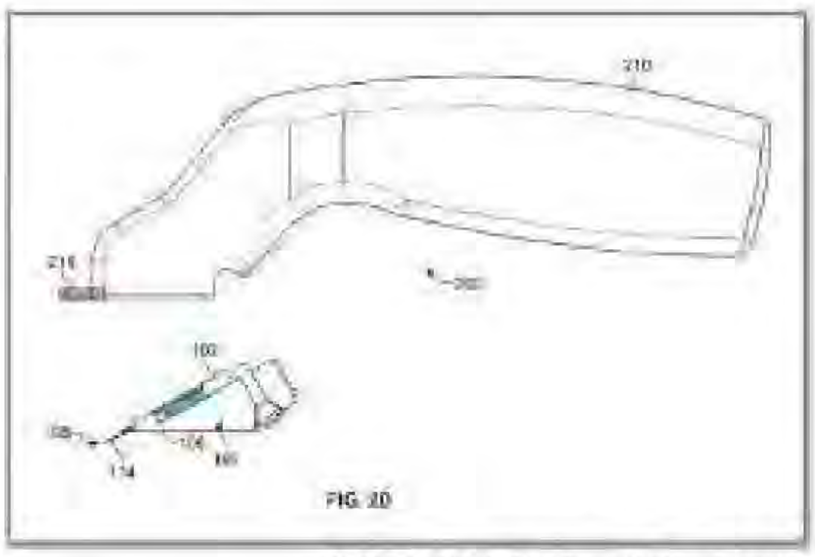
As reflected below in annotated Figures 2B, 2C, and 2D of Mehta, i.e., in Figure 39,

neither the stabilization plate 214 (in yellow) nor feature 216 (in pink) are part of (or exposed to) the electrode assembly 102 (in blue); instead, they are part of device body 210 and separated from the electrode assembly by the device body. (Tr. (Crosby) at 1509:13-1510:18 ("Q. . . . Are the plate 214 or feature 216 part of what Dr. Woloszko relies on for the needle assembly? A. They are not. Q. How do we know that? A. Well, Mehta tells us that. The cartridge and the needle assembly Dr. Woloszko relies on to call the needle assembly is 102 is completely separate from the feature 216 with the stabilization 214, which is attached to the body, not to the cartridge or needle assembly.").).

Figure 39: Annotated Figures 2B-2D of Mehta



CX-3023 (Mehta), Figs. 2B, 2C (annotated)



CX-3023 (Mehta), Figs. 2D (annotated)

(CDX-0043C.0034-35 (citing RX-0307 at Figs. 2B-2D (annotated).).

Even if electrode assembly 102 had a translucent section, Mehta does not disclose an LED illuminating a plurality of needles via any portion of the electrode assembly.

Respondents contended that the LED in Mehta would be around the portion of the device body near feature 216. (RBr. at 86; Tr. (Woloszko) at 968:5-17, 1043:25-1044:12; RDX-0010C.0140).). Mr. Crosby provided persuasive, credible testimony that an LED in that location would not illuminate a plurality of needles via the electrode assembly because the electrode

assembly is encased in the cartridge within device body.

> Q. . . . Would that LED illuminate a plurality of needles via any kind of translucent section in Mehta?
>
> A. No, I don't see how it could.
>
> Q. Why not?
>
> A. Well, the electrode assembly 102, which is the needle assembly, according to Dr. Woloszko, is encased within a cartridge 100, which is the green part, and that's within the device body 210. So any LED in the region of element 216 could not get to the needle assembly even if it had a transparent section and thereby illuminate the needles. There is no light path for that to go.

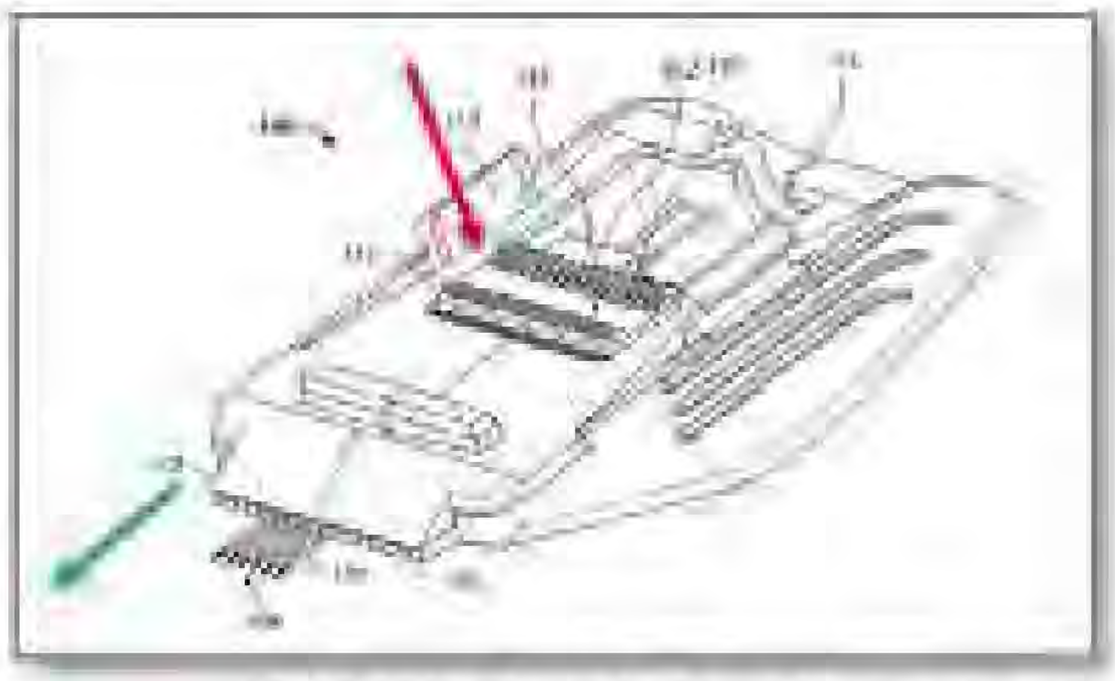
(Tr. (Crosby) at 1510:19-1511:15; CDX-0043C.0036.).

Thus, Mehta fails to disclose any light path from an LED around the region 216 in the device body via the electrode assembly to illuminate the needles.

iv. Mehta Does Not Disclose the Electrical Contacts Limitation

Respondents mapped the claimed electrical contact that includes a pin to Mehta's connection portion 116. (RBr. at 89.). However, as depicted below and as Mr. Crosby explained, the movement of connection portion 116 (in red) is perpendicular to the movement of the probes 104 (in green), and not "in the same direction," as claimed.

Figure 40: Annotated Figure 4A of Mehta



CX-3023 (Mehta), Fig. 4A (annotated)

(CDX-0043C.0030 (citing RX-0307 at Fig. 4A (annotated); Tr. (Crosby), 1507:10-1508:3; *see also* RX-0307 at 16:12-18.).

Respondents relied on movement of the printed circuit board, which includes connection portion 116, when probes 104 extend. (RBr. at 89-91; Tr. (Woloszko) at 976:4-20; RDX-0010C.0150.). This fails for two reasons.

First, claim 18 does not recite that the pin ***moves*** in the same direction as the needles, but rather that it ***extends*** in the same direction as the needles. (JX-0005 at cl. 18; *see also* Tr. (Crosby) at 1508:4-16; CDX-0043C.0031.). That is not the case in Mehta.

Second, in their Initial Post-Hearing Brief, Respondents presented a new claim construction argument, in which they attempted to import portions from the construction of the "needle assembly end surface" term into this limitation to argue that "extend" is the same as "move." (RBr. at 90.). That argument is deemed waived for failing to raise it during the claim construction proceedings under Ground Rule 1.14.1 and deemed abandoned or withdrawn because Respondents failed to disclose it in their Pre-Hearing Briefing under Ground Rule 7.2.

Thus, Mehta fails to disclose a pin that is extendable in the same direction as the plurality

of needles.

v. No Motivation to Combine

A person of ordinary skill in the art would not have had a reasonable expectation of success or been motivated to modify Mehta or combine its various embodiments to arrive at the claimed invention. Respondents did not provide adequate reasoning or evidentiary support for their assertion that one of ordinary skill would use his or her knowledge to fill in the gap of the missing limitations above. (RBr. at 88, 91.).

For the "desired distance" limitation, as discussed above in Sections VIII.D.4, Respondents did not prove clearly and convincingly that there would have been a motivation to modify Mehta.

For the LED and pin extendable in the same direction as the needles limitations, Respondents relied on the same alleged motivations to modify Mehta as they did for the "desired distance" limitation. They again argued that the differences between Mehta and the claims are minor; that the art is basic mechanical design and highly predictable; and that the claimed implementation is obvious and easy to optimize. (RBr. at 88, 91.). However, other than Dr. Woloszko's conclusory opinions, Respondents did not provide substantive evidence to support their arguments.

As explained above, Dr. Woloszko's opinions on motivations are deficient because they are generic and conclusory. (Tr. (Woloszko) at 976:21-977:10; RDX-0010C.0118, 0128, 0151; *see also* Tr. (Crosby) at 1511:16-1512:10, 1512:4-10; CDX-0043C.0037.). *See ActiveVideo*, 694 F.3d at 1328.

Moreover, Mehta intrinsically discloses mechanisms to observe proper needle placement, including virtual depiction 350 and a window between the stabilization plate and the tissue

engaging surface. (*See* Section VIII.D.2, *supra*; Tr. (Crosby) at 1516:10-22; CDX-0043C.0044.). Thus, there would be no motivation to modify Mehta to include a translucent section in the needle assembly, much less to illuminate the needles via any such translucent section.

b) Mehta in View of the Knowledge of a Person of Ordinary Skill in the Art and Further in View of Na '848 (Claim 5)[79]

i. Respondents Improperly Relied on Multiple Embodiments Disclosed in Mehta

Respondents again rely on multiple embodiments in Mehta without explanation, which as explained above in Section X.C.2(a)(i), fails to meet their burden. (Tr. (Crosby) at 1499:23-1500:11.).

ii. Mehta Does Not Disclose the Desired Distance Limitation

Mehta does not disclose the "desired distance" limitation as depicted in VIII.D.4(a). Again, Respondents failed to point to knowledge of a person of ordinary skill in the art or Na '848 to fill the gaps. (RBr. at 91-93.). Dr. Woloszko relied on his analysis of Mehta for claim 11 of the '536 patent for this limitation. (Tr. (Woloszko) at 965:11-966:23.). For the same reasons discussed above in Section VIII.D.4(a), his analysis is not supported by the evidence.

iii. Mehta Does Not Disclose the Embedded LED Limitation

As explained above in Section X.C.2(a)(iii), Mehta does not disclose this limitation. The deficiency is not cured by the disclosures of Na '848. Although Na '848 discloses LEDs on plate or roller (RX-1814 at ¶¶ 34, 38, Figs. 1A-4C), those LEDs are not in the handle (*id.* at ¶¶ 34, 38, Figs. 1A-4C; *see also* Tr. (Crosby) at 1514:5-17; CDX-0043C.0042).). Therefore, as Mr. Crosby

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[79] Respondents relied on the combination of Mehta and Na '848 solely for the LED limitations in claim 5 and claim 4, on which claim 5 depends. (RBr. at 91-93.).

opined, Na '848 does not disclose an LED embedded in the proximal end of the user holdable device as the claims require. (Tr. (Crosby) at 1514:13-17; CDX-0043C.0042 (Crosby).)

Additionally, although Na '848 explains that certain materials in pin sections 250, 353 can be translucent, it does not disclose a needle assembly at all. (CX-1096 (Na '848) at ¶ 35.). As Respondents' expert, Dr. Woloszko, acknowledged, Na '848 only includes a needle module. (Tr. (Woloszko), 1046:23-1047:2 ("[Na '848] does not have a needle assembly, but it would have a needle module").). However, claim 5 requires that the needle assembly include a translucent section. (JX-0005 at cl. 5.). Dr. Woloszko's testimony that Na '848 meets this portion of the claim is inconsistent with his testimony during cross-examination. Moreover, that the Family Two Patents include some of the same figures as Na '848's acupuncture-type apparatus does not support Respondents' invalidity arguments (RBr. at 92) because the claims of the Family Two Patents are directed to a different invention than Na '848. (Tr (Crosby), 1512:21-24.).

iv. No Motivation to Combine

One of ordinary skill in the art would not have had a reasonable expectation of success or been motivated to modify Mehta or to combine Mehta with Na '848 to arrive at the claimed invention.[80] Respondents failed to provide adequate reasoning or evidentiary support for their assertion that a person of ordinary skill would use his or her knowledge to fill in the gap of the missing limitations. (RBr. at 91-93.). For the "desired distance" limitation, as discussed in Section X.C.2(a), there is no motivation to modify Mehta. For the LED and needle assembly translucent limitation, Respondents relied on the same alleged motivation to modify Mehta for

[80] Respondents did not rely on Na '848 for the desired distance limitation, but only for limitations introduced in claims 4 and 5. (RBr. at 92.).

the "desired distance" limitation as they did for the combination of Mehta and Na '848. (RBr. at 93.).

For the same reasons discussed above in Section X.C.2(a), Dr. Woloszko opinions are conclusory and bear no explicit or specific relationship to the claimed limitations. (Tr. (Woloszko), 977:11-978:2; Tr. (Crosby), 1512:4-10.). Conclusory statements are insufficient for Respondents to meet their burden by clear and convincing evidence. *ActiveVideo*, 694 F.3d at 1328.

There would be no motivation to modify Mehta or combine it with Na '848 to include the claimed LED and needle assembly translucent sections. As discussed above in Section VIII.D.2, Mehta discloses mechanisms to observe proper needle placement, including virtual depiction 350 and a window located between the stabilization plate and the tissue engaging surface. (Tr. (Crosby) at 1516:10-22; CDX-0043C.0044.). As noted above, Na '848 does not disclose an LED in a handpiece (proximal end) or a needle assembly, which further removes a motivation to modify Mehta to include such features. (Tr. (Crosby) at 151:12-1516:22; CDX- 0043C.0044.). Even if the electrode assembly in Mehta were translucent (it is not), a person of ordinary skill in the art would not combine Mehta and Na '848 because the LED is encased within other components, that is, the cartridge and the device body. (*See* Section X.C.2(a), *supra*.). No light from an LED would travel through a translucent section of the needle assembly to illuminate the needles, as the claims require. (*See id.*).

XI. DOMESTIC INDUSTRY REQUIREMENT: ECONOMIC PRONG

A. Legal Standard

The Commission may only find a violation of Section 337 "if an industry in the United States relating to the articles protected by the patent . . . exists or is in the process of being

established." 19 U.S.C. § 1337(a)(2) (emphases added). Typically, a complainant must prove that a domestic industry existed at the time the complaint was filed. *See Motiva LLC v. Int'l Trade Comm'n*, 716 F.3d 596, 601 n.6 (Fed. Cir. 2013).

The domestic industry requirement consists of a "technical prong" and an "economic prong." *See, e.g.*, *Certain Elec. Devices, Including Wireless Commc'n Devices, Portable Music & Data Processing Devices, & Tablet Computs.*, Inv. No. 337-TA-794, Order No. 88, 2012 WL 2484219, at *3 (June 6, 2012); *Certain Unified Commc'ns Sys., Prods. Used with Such Sys., and Components Thereof*, Inv. No. 337-TA-598, Order No. 9 at 2 (Sept. 5, 2007) ("*Communications Systems*"). A complainant satisfies the "technical prong" of the domestic industry requirement when it proves that its activities relate to an article "protected by the patent." *See Communications Systems*, Order No. 9 at 2. A complainant satisfies the "economic prong" of the domestic industry requirement when it demonstrates that the economic activities set forth in subsections (A), (B), and/or (C) of Section 337(a)(3) have taken place or are taking place with respect to the protected articles. *See id.*

Subsection 337(a)(3) states that:

> (3) For purposes of paragraph (2), and industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned –
>
> (A) significant investment in plant and equipment;
> (B) significant employment of labor, or capital; or
> (C) substantial investment in its exploitation, including engineering, research and development, or licensing.

19 U.S.C. § 1337(a)(3).

Because the criteria are listed in the disjunctive, satisfaction of any one of them will be sufficient to meet the economic prong of the domestic industry requirement. *Certain Integrated*

Circuits, Chipsets and Prods. Containing Same, Inv. No. 337-TA-428, Order No. 10, Initial Determination (May 4, 2000) ("*Integrated Circuits*") (unreviewed). Establishment of the "economic prong" is not dependent on any "minimum monetary expenditure" and there is no need for a complainant "to define the industry itself in absolute mathematical terms." *Certain Stringed Musical Instruments and Components Thereof*, Inv. No. 337-TA-586, Comm'n Op. at 25-26 (May 16, 2008) ("*Stringed Instruments*"). However, a complainant must substantiate the nature and the significance of its activities with respect to the articles protected by the patent at issue. *Certain Printing and Imaging Devices and Components Thereof*, Inv. No. 337-TA-690, Comm'n Op. at 30 (Feb. 17, 2011) ("*Imaging Devices*").

The Commission has interpreted Sections 337(a)(3)(A) and (B) to concern "investments in plant and equipment and labor and capital with respect to the ***articles*** protected by the patent." *Certain Ground Fault Circuit Interrupters and Prods. Containing Same,* Inv. No. 337-TA-739, 2012 WL 2394435, at *50, Comm'n Op. at 78 (June 8, 2012) ("*Circuit Interrupters*") (emphasis in original) (quoting 19 U.S.C. §§ 1337(a)(3)(A), (B)).

When a complainant proceeds under Section 337(a)(3)(C), it is not sufficient for the "substantial investment" under subsection (C) to merely relate to articles protected by the asserted patents. Rather, "the complainant must establish that there is a nexus between the claimed investment and asserted patent regardless of whether the domestic- industry showing is based on licensing, engineering, research and development." *Certain Integrated Circuit Chips & Prods. Containing*, Inv. No. 337-TA-845, Final Initial Determination, 2013 WL 3463385, at *14 (June 7, 2013).

In addition, the Commission has definitively stated that investments in plant and equipment or labor and capital that relate to engineering and research and development ("R&D")

(that are expressly identified under subsection (C)), are properly considered under subsections (A) and (B):

> The statutory text of section 337 does not limit sections 337(a)(3)(A) and (B) to investments related to manufacturing or any other type of industry. It only requires that the domestic investments in plant and equipment, and employment of labor or capital be "with respect to the articles protected by the patent." 19 U.S.C. § 1337(a)(3). Moreover, even though subsection (C) expressly identifies "engineering" and "research and development" as exemplary investments in the "exploitation" of the patent, that language does not unambiguously narrow subsections (A) and (B) to exclude those same types of investments.

Certain Solid State Storage Drives, Stacked Elecs. Components, and Prods. Containing Same, Inv. No. 337-TA-1097, Comm'n Op. at 8 (June 29, 2018) ("*Storage Drives*"); *see also, e.g.*, *Certain Marine Sonar Imaging Devices, Including Downscan and Sidescan Devices, Prods. Containing the Same, and Components Thereof*, Inv. No. 337-TA-921, Comm'n Op. at 57-64 (Jan. 6, 2016) ("*Sonar Imaging Devices*").

There is no mathematical threshold test or a "rigid formula" for determining whether a domestic industry exists. *Certain Male Prophylactic Devices, Inc.*, Inv. No. 337-TA-292, Comm'n Op. at 39, USITC Pub. 2390 (June 1991) ("*Male Prophylactic Devices*"). However, to determine whether investments are "significant" or "substantial," the actual amounts of a complainant's investments or a quantitative analysis must be performed. *Lelo Inc. v. Int'l Trade Comm'n*, 786 F.3d 879, 883-84 (Fed. Cir. 2015). Even after *Lelo*, which requires some quantification of a complainant's investments, there is still no bright line as to a threshold amount that might satisfy an economic industry requirement.

It is the complainant's burden to prove by a preponderance of evidence that each prong of the domestic industry requirement is satisfied. *Certain Prods. Containing Interactive Program Guide and Parental Control Tech.*, Inv. No. 337-TA-845, Final Initial Determination, 2013 WL 3463385, at *14 (June 7, 2013.). Moreover, the Commission makes its determination by "an examination of the facts in each investigation, the article of commerce, and the realities of the

marketplace." *Male Prophylactic Devices*, Comm'n Op. at 39 (quoting *Certain Double Sided-Floppy Disk Drives and Components Thereof*, Inv. No. 337-TA-215, Comm'n Op. at 17, USITC Pub. 1859 (May 1986)).

B. Benev's Domestic Industry

1. Overview of the Sylfirm X DI Products

Serendia's DI Products ("DI Products" or "Sylfirm X"), which entail the Sylfirm X microneedling device and its handpieces and microneedle tip attachments, are manufactured in Korea by one of Serendia's licensees, ViOL. (CX-0823C.0004 (Sylfirm X User Manual) (identifying "Manufacturer – VIOL Co., Ltd.," and "Country of Origin – South Korea"). ViOL, the original assignee of the Asserted Patents from assignor, Dr. Na, was founded in 2009 by Dr. Na. (Tr. (Na) at 75:15-20; CX-0766, CX-0769-0771 (assignment records).). Benev's CFO, Mr. Dan Park,[81] testified that Benev is "ViOL's business partner as well as a distributor for Sylfirm X in the United States," [redacted]. (Tr. (Park) at 445:3-5; CX-0763C [redacted]; *see also* CX-0918 (press release announcing Benev as the exclusive distributor of Sylfirm X); RX-2551C (July 26, 2023 Na Dep. Tr.) at 378:15-379:1 [redacted].).

[81] At the time he testified during the Hearing on November 2, 2023, Mr. Dan Park was Benev's Chief Financial Officer. (CPSt. at 2-3.). Serendia identified Mr. Park as a fact witness to "testify generally as to Benev's business operations in the United States, including business operations relating to the Domestic Industry Product, investments pertaining to its domestic industry, including its facilities and domestic operations in the United States." (*Id.* at 3.).

ViOL's CEO, Mr. Sang Jin Lee,[82] testified that [redacted]. (RX-2566C (Lee Dep. Tr.) at 179:13-180:4.). Dr. Na explained that [redacted] (RX-2551C (July 26, 2023 Na Dep. Tr.) at 379:2-380:22.).

Benev is a U.S. company that "sell[s] medical aesthetics products, including medical devices, such as Sylfirm X[.]" (Tr. (Park) at 444:21-24; *see also* CX-0895.0003.). Mr. Park testified that [redacted] (Tr. (Park) at 447:10-20.). He confirmed that Benev operates an approximately 13,000 sq. ft. facility in Mission Viejo, CA, and does not have any facilities outside of the U.S. (*See id.* at 443:18-444:4.). Mr. Park explained that Benev works with several domestic contractors who also work with Sylfirm X, including [redacted] (*Id.* at 447:21-448:18, 456:18-25, 461:24-462:1, 470:10-15; CX-0664C [redacted].).

[82] At the time of his deposition on July 19, 2023, Mr. Sang Jin Lee was ViOL's Chief Executive Officer. (RX-2566C (Lee Dep. Tr.) at 28:7-10; *see also* CPSt. at 3.). Serendia identified Mr. Lee as a fact witness to "testify generally regarding the Domestic Industry Product and ViOL's business operations, including business operations relating to the Domestic Industry Product, and including ViOL's expenses pertaining to the Domestic Industry Product." (*Id.*).

2. Benev Is a Licensee of the Asserted Patents

On [redacted] [83] ViOL later [redacted]. (CX-0762C (PAA) at §§ 2(a)-(b); Tr. (Na) at 89:11-20.).[84] The certified assignments reflect ViOL's transfer of the pertinent patents to Serendia. (CX-0766 ('836 patent assignment); CX-0769 ('536 patent assignment); CX-0770 ('774 patent assignment); CX-0771 ('812 patent assignment).). [redacted]. (CX-0762C (PAA) at § 2(c).). Accordingly, as [redacted]. *Genetic Implant Sys., Inc. v. Core-Vent Corp.*, 123 F.3d 1455, 1458–59 (Fed. Cir. 1997) ("The appointment of a distributor to sell a product covered by a patent is analogous to a grant of a patent license . . . [and] conveys an implied license to the distributor."). This is consistent with the Benev's CFO's that [redacted] (Tr. (Park) at 446:15-17; *see also* Tr. (Na) at 88:12-24 (same).).

Commission precedent allows articles that are impliedly licensed to be relied upon for the domestic industry requirement. *See Certain Magnetic Tape Cartridges and Components*

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[83] Benev subsequently [redacted] (Tr. (Park) at 446:21-447:11 (discussing CX-0765C).). Whether Serendia may rely upon Benev's qualifying investments since the date of the [redacted] as opposed to the date of the [redacted] does not impact whether Benev's qualifying investments are significant.

[84] The assignment to Serendia included the [redacted] (CX-0762C (PAA) at §§ 1(a), 2(a).).

Thereof, Inv. No. 337-TA-1058, Comm'n Op. at 41-42 (Mar. 25, 2019) ("*Magnetic Tape Cartridges*"); *Certain Multi-Stage Fuel Vapor Canister Sys. and Activated Carbon Components Thereof*, Inv. No. 337-TA-1140, ID at 116-17 (Jan. 28, 2020) (finding that the complainant could rely on third party for the domestic industry requirement based on implied licenses); *see also Certain Multi-Stage Fuel Vapor Canister Sys.*, Inv. No. 337-TA-1140, Order No. 16 at 3 (Aug. 13, 2019) ("The fact that *Magnetic Tape Cartridges* involved an express, written license, whereas here the claimed license is implied, does not negate the fact that both are a form of authorization; and an overarching principle of section 337 domestic industry is the identification of articles which practice or embody the claims of an asserted patent under authorization from the patent owner."). Here, as Serendia argued. and as Staff agreed, the documents and testimony demonstrate that Benev was authorized to use the Asserted Patents and thus, its investments appropriately can be credited in a domestic industry analysis. (CBr. at 93; SBr. at 137-38.).

Moreover, on [redacted]. (CX-0765C [redacted].). Respondents' assertion that there was no implied license because Benev later entered an express license is unsupported by law, contrary to the evidence, and ignores the realities of the marketplace. (Tr. (Park) at 447:5-11 (testifying that [redacted].).

Additionally, Respondents argued that the [redacted] (CX-3031C) of the [redacted] (CX-3028C [redacted]. (RRBr. at 74-75.). As Serendia has argued correctly, Respondents' argument is

not supported by the evidence. (CBr. at 93.). When the [redacted]. (CX-3028C [redacted]. In the [redacted]. (CX-0765C [redacted]. The [redacted] does not identify the [redacted] as being terminated/rescinded.

Moreover, as Respondents have acknowledged, [redacted] Respondents' Motion to Terminate (Motion Docket No. 1356-017) at 23.). Serendia's and SynKloud's termination rights are limited to terminating [redacted]. (CX-0765C [redacted]; Respondents' Motion to Terminate (Motion Docket No. 1356-017) at 1.). Thus, the [redacted] remains in force, notwithstanding the status of the [redacted]. Respondents have not cited to legal authority for their assertion that [redacted]. Furthermore, Respondents' allegation that [redacted], conflicts with the plain language of the [redacted].

Additionally, Respondents contended that Benev, [redacted], was not impliedly licensed to the Asserted Patents because ViOL did not have the ability to enter into the [redacted]. (RRBr. at 71-72.). Specifically, relying on the [redacted] (CX-2862C [redacted]), Respondents asserted that as of [redacted] Serendia, not ViOL, held the

"exclusive" right to distribute products practicing the Asserted Patents in the U.S. (*Id.* at 72.). As Staff pointed out, Respondents' contention is incorrect and overlooks the fact that Serendia and ViOL authorized Benev's activities with respect to the Sylfirm X. (SRBr. at 24.).

First, Serendia relied only on Benev's domestic investments/activities beginning in 2021. (*See, e.g.*, CBr. at 114; *see also* CDX-0003C.0048 (Thomas demonstrative reflecting labor and capital DI investments during 2021-2023).). The evidence also indicates that Benev did not begin its exclusive distribution of the Sylfirm X until 2021. (*See, e.g.*, CX-0918.0001 (Benev News Release) (announcing on April 21, 2021, that Benev was "launching the Sylfirm X in the U.S. as the exclusive distributor"); Tr. (Thomas) at 1556:19-22 (testifying that the Sylfirm X was first commercially available in the United States in 2021).). Thus, even if Benev did not have rights to distribute the Sylfirm X until after the [redacted], the effective date of the PAA (CX-0762C), as Respondents contended, that two-month gap in 2020 is irrelevant for purposes of the alleged domestic industry. In the PAA, ViOL and Serendia agreed that the [redacted]. (*See* CX-0762C.0001 [redacted].).

The evidence demonstrates that Benev's exclusive distribution of the Sylfirm X (which began in 2021) was understood impliedly to authorize Benev to use the Asserted Patents. (*See* Tr. (Park) at 446:8-17 (testifying that [redacted].). Serendia, the patent owner and entity that possessed the exclusive distribution rights before Benev, agreed that Benev's exclusive distribution of the Sylfirm X gave Benev [redacted]

(Tr. (Na) at 88:12-24; *see Wang Lab'ys, Inc. v. Mitsubishi Elecs. Am., Inc.*, 103 F.3d 1571, 1580 (Fed. Cir. 1997) ("In patent law, an implied license merely signifies a patentee's waiver of the statutory right to exclude others from making, using, or selling the patented invention."). Thus, the course of conduct between Benev, Serendia, and ViOL supports a finding that Benev was impliedly licensed to the Asserted Patents through its exclusive distribution activities during the relevant period. *See id.* at 1580-82 (Fed. Cir. 1997) (finding that an implied license may arise by conduct or acquiescence, and holding that the "entire course of conduct between the parties . . . led Mitsubishi to infer consent to manufacture and sell the patented products . . . [and thus] properly inferred consent to its use of the invention of Wang's patents."); *Certain Magnetic Tape Cartridges and Components Thereof*, Inv. No. 337-TA-1058, Comm'n Op. at 41-42 (Apr. 9, 2019) (holding that complainant could rely on third party products for purposes of the domestic industry requirement based on "post-litigation correspondence and hearing testimony regarding the understanding of the contracting parties during the time period since the execution of [the agreement at issue.]");[85] *Certain Integrated Repeaters, Switches, Transceivers, and Prods. Containing Same*, Inv. No. 337-TA-435, ID at 177, 190-91 (July 19, 2001) (finding that the select, identified customers of the DI products had implied licenses for purposes of the domestic industry requirement) (not reviewed).

Respondents' additional argument, i.e., that recognizing that Benev had an implied licensee through its exclusive distributorship of the Sylfirm X "would dramatically expand the

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[85] As Staff correctly pointed out, Respondents' attempt to distinguish *Magnetic Tape Cartridges* misses the mark. (SRBr. at 25 n.17 (quoting *Certain Multi-Stage Fuel Vapor Canister Sys. & Activated Carbon Components Thereof*, Inv. No. 337-TA-1140, Order No. 16 at 3 (July 1, 2019) (emphasis added) ("The fact that *Magnetic Tape Cartridges* involved an express, written license, whereas here the claimed license is implied, does not negate the fact ***that both are a form of authorization; and an overarching principle of section 337 domestic industry is the identification of articles which practice or embody the claims of an asserted patent under authorization from the patent owner***.").).

universe of parties whose investments and activities are creditable towards a domestic industry," misstates the facts in this Investigation. (RRBr. at 74.). Benev is not a "mere reseller" or a "user," akin to a retailer like Best Buy or Target, Respondents have alleged. (*Id.* at 73-74.). It is undisputed that Benev has been the business partner and sole distributor of the Sylfirm X since 2021. As discussed in detail below in Section XI.B.3, Benev undertook far more activities pertaining to that product than a mere reseller or user could or would. Benev's activities have included research and trials of products, pursuit of additional FDA clearances, and product improvement/development. Thus, Respondents' equation of Benev to a "mere reseller" or "user" is without merit. Respondents' assertion that Benev's implied license would expand the type of entities that can be relied upon for purposes of the domestic industry requirement is unpersuasive.

Respondents' unsupported and conclusory "exhaustion" argument also fails. In just one sentence, Respondents contend that "the patent rights in Sylfirm X exhausted with each sale to Benev." (RPBr. at 167; RRBr. at 73.).

First, Respondents' allegation is conclusory and therefore deemed waived under Ground Rules 7.2 and 10.1. (G.R. 7.2, 10.1; *see also* Order No. 46 at 2 ("conclusory statements are insufficient to preserve an argument").). Second, even if the argument were to be considered on its merits, Respondents are incorrect. As Serendia correctly pointed out, patent exhaustion involves patent rights related to post-sale use, not to patent rights conferred through licensing. *See, e.g.*, *Impression Prods., Inc. v. Lexmark Int'l, Inc.*, 581 U.S. 360, 375-76 (2017) (patent exhaustion is about "passing title to a product" while a license is about "changing the contours of the patentee's monopoly"); *Helferich Pat. Licensing, LLC v. New York Times Co.*, 778 F.3d 1293, 1301 (Fed. Cir. 2015) ("Patent exhaustion . . . eliminates the legal restrictions on what

authorized acquirers 'can do with an article embodying or containing an invention' whose initial sale (or comparable transfer) the patentee authorized."). Accordingly, patent exhaustion is irrelevant to the rights conveyed in Benev License.

3. Benev's Domestic Industry Activities Demonstrate It Is More Than a "Mere Importer"

Serendia demonstrated that Benev, Serendia's domestic industry licensee, has significant employment of labor and capital in the DI Products in the U.S. Benev's investments in the following activities related to the Sylfirm X inlcude: (i) FDA clinical research and trials; (ii) research and development ("R&D") (via product improvement); (iii) post-sale customer training and education; (iv) development of patient care protocols; (v) warranty/repair services; and (vi) installation and delivery.

As Serendia noted, each of those activities has been determined to be a qualifying domestic industry activity. *See, e.g.*, *Certain Strontium-Rubidium Radioisotope Infusion Sys.*, Inv. No. 337-TA-1110, ID at 140-142 (Aug. 1, 2019) (FDA-related expenses); *Certain Bone Cements*, No. 337-TA-1153, Comm'n Op. at 25 (Jan. 25, 2021) (warranty, service, repair, and packaging activities); *Certain Child Carriers*, No. 337-TA-1154, ID at 195 (Mar. 10, 2020) (customer service and support and product training); *Certain Sleep-Disordered Breathing Treatment Sys.*, Inv. No. 337-TA-890, ID at 168 (Sept. 16, 2014) (clinical education to train medical providers); *Certain Airtight Cast-Iron Stoves*, Inv. No. 337-TA-69, Comm'n Op. at 11 (Jan. 1981) (repair, testing, installation activities); *Certain Video Displays*, Inv. No. 337-TA-687, Order No. 20 (ID), 2010 WL 2306671, at *5 (May 20, 2010) (customer support, repairs). Staff agreed that Benev's qualifying activities and investments establish that Benev is more than a mere importer. (SPBr. at 159; SBr. at 138.).

As Mr. Park testified, "other than the actual manufacturing of Sylfirm X, we [Benev] do [redacted] (Tr. (Park), 482:24-483:2.). Each of Benev's qualifying DI activities, listed above in (i)-(vi), are described in more detail below.

a) FDA Clinical Research and Clinical Trials

With respect to FDA research and clinical trials for the Sylfirm X, Mr. Park made clear that [redacted]. (Tr. (Park) at 452:19-453:4; *see also* Tr. (Na) at 92:18-93:5, 94:2-7 (describing Benev's involvement in [redacted] studies, FDA approval, academic seminars, training, and product improvement as well as Dr. Na's Sylfirm X-related consulting work for Benev); RX-2544C (Park Dep. Tr.) at 95:18-24 (testifying that Benev also "contribute[s] a significant amount of time, resources, [] energy, cash to engage in the R&D activities, the clinical trials, specifically in relation to Sylfirm X").). In its Initial Post-Hearing Brief, Serendia stated that "Benev is currently involved in [redacted] clinical trials to [redacted] for the Sylfirm X." (CBr. at 96 (citing CPX-0109C (Benev clinical study summary); CX-1101C).). Dr. Na confirmed that the effort to obtain [redacted] originated with Benev. (Tr. (Na) at 149:15-150:5.).

Mr. Park explained that ongoing product trials are supported by Benev's expenditures in labor and capital (including R&D equipment), made through the activities of Benev's: MAB and KOL consultants; with the assistance of Dr. Na; with the assistance of Benev personnel who support the studies involved; and with the help of Benev's consultants who have worked on studies. (Tr. (Park) at 453:21-455:19.). Serendia's evidence supports findings that: Benev's MAB/KOLs have participated in clinical trials; have [redacted], have

published their results; have provided before-and-after pictures; have given presentations on their research; and have assisted with clinical implementations. (CX-0360C.0007 (MAB Agmt.); CPX-0109C; CX-0652C, CX-0504C, and CX-0503C (MAB Agmts.); CX-1099C, CX-1100C, CX-1101C, CX-2539C, CX-2545C, and CX-2552C (clinical trial files).). Documentary and testimonial evidence also reflect that Dr. Na has participated in the required FDA clinical trials of the DI Products. (CPX-0109C; RX-2551C (July 26, 2023, Na Dep. Tr) at 367:16-371:17; Tr. (Park) at 454:18-25.). Mr. Park testified that Benev's CEO, CFO, and the customer support team have supported clinical trials by collaborating with the MABs/KOLs, working directly with the teams running the clinical trials, and [redacted]. (Tr. (Park) at 453:25-455:14; *see also* CX-0464C, CX-0465C, CX-0467C, CX-0469C, and CX-1015C [redacted].).

In addition to its labor investments, Serendia presented evidence that [redacted] (CPX-0016C [redacted].). Moreover, Serendia provided evidence that [redacted]. (Tr. (Park) at 456:20-457:8; CX-0478C to CX-0496C, CX-0498C to CX-0502C, and CX-1010C ([redacted] thereof); CPX-0109C.).

Additionally, invoices also reflect that [redacted]. (CX-0464C, CX-0465C, CX-0467C, CX-0469C, and CX-1015C [redacted]; CX-0877.). Mr. Park explained that [redacted]. (Tr. (Park) at 455:15-19.).

b) R&D (via Product Improvement)

As Mr. Park testified, Benev has engaged in Sylfirm X product improvement through its MABs/KOLs, its personnel, Dr. Na, and [redacted] as discussed above. (Tr. (Park) at 457:16-460:10.). Testimonial and documentary evidence demonstrate unrefutedly that Benev's MABs/KOLs also made additional improvements to the product that are significant, including the [redacted]. (Tr. (Park) at 458:14-460:4; RX-2551C (July 26, 2023, Na Dep. Tr.) at 389:5-15; RX-2549C (Aug. 9, 2023, Na Dep. Tr.) at 76:12-79:16; CX-2901C, CX-2902C, and CX-0667C [redacted]; CX-0459C [redacted].).

For example, Dr. Na testified that Benev's CEO developed improvements, as his "idea was that if [redacted] (RX-2551C (July 26, 2023, Na Dep. Tr.) at 396:2-397:3; *see also* Tr. (Park) at 458:24-459:4.). Additionally, Mr. Park testified that Benev's MABs/KOLs and personnel monitored for additional product improvements. They consulted with doctors and others in the field about potential product improvements. (Tr. (Park) at 460:5-14; *see also* Tr. (Thomas Vander Veen)[86] at 1406:17-21 (***Respondents'*** economic expert agreeing that monitoring for product

[86] When he testified during the Hearing on December 12, 2023, Dr. Thomas Vander Veen was a Managing Director at Epsilon Economics. (RPSt. at 2.). Respondents identified Dr. Vander Veen as an expert to testify about "the economic prong of Serendia's claimed domestic industry and the appropriate bond during any 60-day Presidential Review Period." (*Id.* at 3.). He was accepted without objection as an expert on the subject matter for which he was called to testify.

improvements could qualify as a domestic industry activity).). Notably, part of the MABs/KOLs' express scope of work was to [redacted] (CX-0360C.0007 (MAB Agmt.).

c) Post-Sale Customer Training and Education

Mr. Park explained that Benev provides post-sale customer training on how to use the Sylfirm X device through its MABs/KOLs, Dr. Na, Independent Sales Reps ("ISRs"), contractor nurse trainers, and its own personnel who supported the training. (Tr. (Park) at 460:16-463:14.). Mr. Park also testified that Benev worked with the Clearskin Institute to train its trainers. (*Id.* at 463:15-21.).

Additionally, relying on documentary evidence, Mr. Park also testified that Benev's MABs/KOLs provide training to trainers, customers, and participated in education lectures, including at the X-Class Aesthetic Elite Summit, which is limited only to existing Benev customers. (*Id.* at 461:25-462:5, 464:4-465:2; CX-0895 (X-class announcement); CPX-0104C (X-class expenses); CX-1005C-CX-1008C (Thomas Schedules).). Mr. Park also confirmed, along with Dr. Na, that Dr. Na has developed protocols for training programs, and has provided workshops and training sessions directly to customers. (Tr. (Park) at 462:6-10; RX-2551C (July 26, 2023, Na Dep. Tr.) at 370:7-374:18; CX-0664C (Benev Na Agmt.).). Benev's ISRs also provided post-sale training to customers. (CPX-0108C (ISR comp.); *see also* Tr. (Park) at 462:11-17.).

In addition, Mr. Park testified that Benev worked and continues to work with contractor nurses to provide onsite training of the operation of the Sylfirm X to customers. (Tr. (Park) at 462:18-25; CX-1018C and CX-1019C (Thomas Schedules) (identifying, for example, Jungah ("Sarah") Oh, RN; Shawn Lea Carter, RN; Daniel Lee, RN; Jin Woo, RN; and Trong Bae