

Paper No. ____

Filed on behalf of MT. Derm GMBH

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BOMTECH ELECTRONICS, CO. LTD.
Petitioner

v.

MT. DERM GMBH
Patent Owner

Case IPR2014-00138
U.S. Patent No. 6,505,530

**MT. DERM GMBH'S PRELIMINARY RESPONSE TO PETITION FOR
INTER PARTES REVIEW UNDER 37 C.F.R. § 42.107**

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Pursuant to 35 U.S.C. § 313 and 37 C.F.R. § 42.107, Patent Owner MT. Derm GmbH (“Mt. Derm”) submits the following Preliminary Response to Bomtech Electronics Co., Ltd.’s Petition for *inter partes* review of U.S. Patent 6,505,530 (the ’530 patent”). This filing is timely under 35 U.S.C. § 313 and 37 C.F.R. §42.107(b), as it is filed within three months of the November 19, 2013, mailing date of the Notice granting the Petition a filing date of November 11, 2013 (Paper No. 4). Further, this Preliminary Response is within the page limit set by 37 C.F.R. §§ 42.107(a) and 42.24.

I. INTRODUCTION AND SUMMARY OF ARGUMENT

The present *inter partes* review (IPR) should not be instituted because there is not a reasonable likelihood that any of claims 1-20 of the ’530 patent will be found unpatentable based on the references submitted by petitioner.

The Petition incorrectly argues that claims 10-18 are not entitled to the priority date of the original German priority document, positing that a single claim limitation, “sealing means” has no support therein. The USPTO has already found adequate support for the claims in issuing the ’530 patent. Petitioner’s argument to the contrary should be rejected.

All of the anticipation challenges proposed in the Petition are deficient for failing to set forth each and every feature arranged as recited by the respective claims of the ’530 Patent, including the “means for allowing simultaneous removal

of the entire disposable module from the basic module”, the “bearing element” and the “simultaneously removing the entire disposable module from the basic module directly following an application of ink using the ink application device” limitations. For at least these reasons, the petition does not establish a *prima facie* case of anticipation.

Further, the petitioner has urged eight alternative grounds alleging obviousness of claims 1-11 and 13-20 of the ‘530 Patent over various overlapping combinations of references, but in most every case has failed to explain (1) whether the embodiments are *capable* of being combined, (2) how such substitution/combination could be made, (3) how the resulting apparatus would be configured, (4) whether any the combination would yield predictable results, or (5) whether one of ordinary skill in the art would have been motivated to combine the references. Furthermore, with respect to several of the obviousness grounds based on combinations of references, the petition fails to identify: (1) which elements are being combined or substituted, and (2) the specific prior art disclosures purportedly showing recited claim features. Petition has not established a *prima facie* case of obviousness under 35 U.S.C. §103 based on any of the asserted combinations of references.

In addition, the Petition sets forth redundant rejections based on anticipation (three references) and obviousness (at least eight combinations of eight references) but does not undertake the rigor of explaining the basis for each proposed ground of unpatentability, instead relying on a generalized discussion of the references and conclusory and unsupported assertions in declaration testimony concerning claim elements. The declaration of an expert who does not disclose the bases for his opinions is entitled to no weight. 37 C.F.R. § 42.65(a).

Accordingly, the present petition should not be granted.

II. BACKGROUND OF THE '530 PATENT

The claims of the '530 patent define the invention at issue. The present petition is directed to claims 1-20 of the '530 patent. Of these, claims 1, 10, and 19 are independent claims and are reproduced below:

Claim 1: An ink application device for tattooing or for making permanent make-up, comprising: a basic module having a handle and an integrated needle drive; and a disposable module including an outer housing substantially surrounding a needle which is supported at one end of the disposable module by a needle nozzle and which is supported at another end of the disposable module by a portion that can contact the integrated needle drive, the needle being movable relative to the outer housing, and an ink receiving portion disposed around the

needle, and means for allowing simultaneous removal of the entire disposable module from the basic module.

Claim 10: An ink application device for tattooing or for making permanent make-up, comprising: a basic module having a handle and an integrated needle drive; and a disposable module having a housing that includes a needle disposed therein, an ink receiving portion around the needle disposed inside the housing, a needle nozzle disposed on one end of the disposable module, another end of the disposable module having a portion that is connectable to the integrated needle drive and a bearing element disposed inside the housing and supporting the needle in the housing so that the needle, the ink receiving portion, the bearing element and the housing form a unit that is detachable from the basic module, and sealing means disposed between the ink receiving portion and the basic module for preventing liquids from reaching the basic module; whereby components of the device that could be infected by the bodily fluids of a user are integrated into the disposable module.

Claim 19: A method of using an ink application device for tattooing or for making permanent make-up, comprising the steps of: providing a basic module having a handle and an integrated needle drive; providing a disposable module including an outer housing substantially surrounding a needle which is supported at one end of the disposable module by a needle nozzle and which is supported at another end of the disposable module by a portion that can contact the integrated needle drive, an ink

receiving portion disposed around the needle, applying ink to a surface; and simultaneously removing the entire disposable module from the basic module directly following an application of ink using the ink application device.

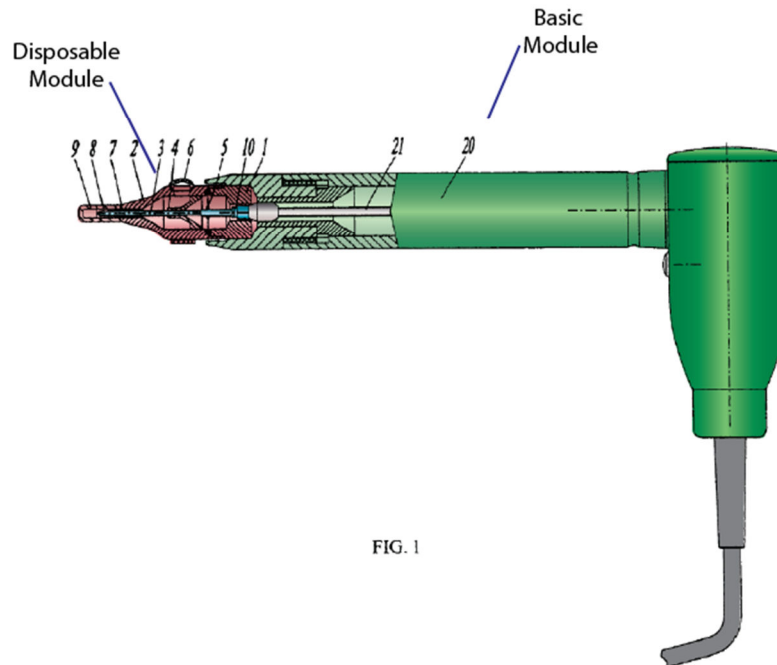
The disclosure of the '530 patent is directed to a unique disposable needle cartridge design for an ink application device, such as the type used for tattooing or applying permanent makeup. ('530 patent, Abstract).

The practice of tattooing and applying permanent makeup involves an operator using a machine with a reciprocating needle that repeatedly pierces the customer's skin to apply ink to the treated area. As a result of the needle piercing the skin in this process, bodily fluids from the customer, including blood or blood serum, can be transmitted from the customer's skin to the needle of the tattoo machine as well as other parts of the tattoo machine that come into contact with the needle and/or the customer's skin. ('530 patent at col. 1, ll. 18-37).

The '530 patent discloses a modular ink application device design in which a basic module comprises reusable components of the device, such as the handle and the components that drive the needle. In addition, a disposable module is provided that is removably attached to the basic module. The disposable module contains the components of the ink application device that are capable of being infected by bodily fluids during a tattoo procedure. After

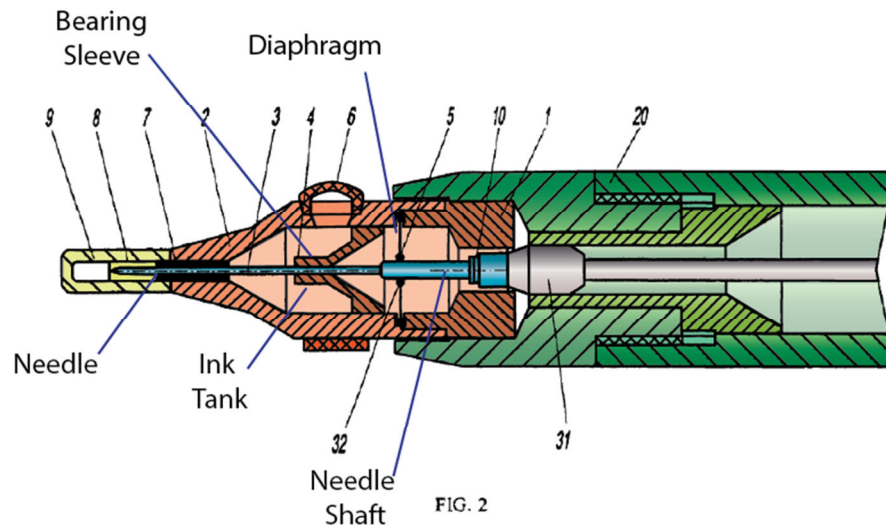
use, the contaminated disposable module is simply removed and discarded. Then, a new disposable module is attached to the basic module, ensuring the sterility of the device and ink for each customer. ('530 patent at col. 2, ll. 11-58). This modular design also improves the efficiency of the preparing the ink application device for a new procedure, as compared to prior approaches requiring extensive disassembly and cleaning of individual components, by providing for a simple removal of the used needle cartridge and replacement with a new, sterile cartridge.

The '530 patent describes an embodiment of such an ink application device with reference to Figure 1. The structure includes a basic module, which is described as a "conventional handle," and a detachable disposable module that is attached to the basic module. The basic module includes the components for driving the needle, such as an electric motor together with mechanical linkage to convert the rotary motion of the motor into reciprocal motion for driving a needle. Figure 1 shows a portion of this drive structure as element 21, which is a rod that contacts the needle shaft of the disposable module when it is inserted. ('530 Patent at col. 3, ll. 43-48).



Details of the design of the disposable module are shown in Figure 2 of the '530 patent. The disposable module structure includes a housing with a rear housing part 1 and a front housing part 2. Within the housing, a needle 3 is supported by a sealing and bearing element 4 and by bearing sleeve 7. The bearing sleeve is structured so that reciprocating movement of the needle will transfer ink from within the housing to outside the disposable module for injection into the skin. ('530 patent at col. 3, ll. 49-65).

The interior of the disposable module provides an ink tank 14 (*see also* Figure 3 of the '553 patent), which is closed by a collar 6. ('530 patent at col. 3, ll. 66- to col. 4, l. 3).



Bearing sleeve 4 is dimensioned to provide a tight fit around the needle 3. Behind the bearing, a resilient diaphragm 5 surrounds the needle shaft 13 of the needle. The diaphragm includes a sealing bead or lip 32 that is disposed around the needle shaft. The resilient nature of the diaphragm allows for movement of the needle within a required stroke interval. By virtue of the bearing and diaphragm, leaking of ink towards the back of the disposable module is prevented. ('530 patent at col. 4, ll. 12-25).

III. THE '530 PATENT IS ENTITLED TO THE PRIORITY DATE OF THE GERMAN PRIORITY DOCUMENT FOR ALL CLAIMS

The '530 patent was filed as a continuation of U.S. Patent Application No. 09/671,650, filed on September 28, 2000 (which was issued as U.S. Patent No. 6,345,553 ("the '553 Patent")) and both the '530 patent and the '553 patent claim priority to German Patent Application No. DE 299 19 199 U1 ("DE '199"), filed on October 22, 1999.

Petitioner argues that claims 10-18 of the '530 patent are not entitled to claim foreign priority under 35 U.S.C. §119 to German Patent Application No. DE 299 19 199 U1 or to claim priority under 35 U.S.C. §120 to the '553 Patent. (Petition pp. 7-8). Specifically, petitioner argues that the claimed term “sealing means” was not described in the original specifications of the '530 Patent, the '553 Patent and DE '199. (Petition p. 8).

However, in all of the original specifications of the '530 Patent, the '553 Patent and DE '199, a diaphragm 5 was disclosed in several different embodiments with several different structural aspects (See Figs. 1-6). On page 6, lines 10-18 of the '530 patent application, the specification states “[a] sealing diaphragm provided, according to the preferred embodiments, between the basic and disposable module ensures that no ink leaks from the ink tank of the disposable module and enters the basic module. This ensures that the reusable basic module is not exposed to bodily fluids and can be reused without having to be sterilized. In addition, the diaphragm also prevents the penetration of impurities, germs or bacteria which may adhere to the basic module, into the sterile disposable module.” (Exh. 1015, p. 6, ll. 10-18 of the specification)(emphasis added).

Further, on page 12, lines 4-7 of the '530 patent application it states “[i]n the embodiment of FIG. 5, the disposable module is sealed in a direction of the basic

module by a closed diaphragm 5.” (Exh. 1015, p. 12, ll. 4-7 of the specification) (emphasis added).

As stated in the Manual of Patent Examining Procedure (“MPEP”) in Section 2163, Part II. A. 3(b): “To comply with the written description requirement of 35 U.S.C. 112, ¶ 1, or to be entitled to an earlier priority date or filing date under 35 U.S.C. 119, 120, or 365(c), each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure.”

The diaphragms illustrated in the figures and which seal as described in the all of the original specifications of the ’530 Patent, the ’553 Patent and DE ’199 provide clear and express support for the claimed “sealing means.”

Moreover, the USPTO has already considered the claim term “sealing means” before allowing the ’530 patent claims. An Examiner Interview Summary Record reflecting an interview date of August 7, 2002 states: “[i]n claim 10, a sealing means would appear to read out prior art...” (Ex. 1015, Interview Summary dated August 7, 2002). Following the interview, applicant amended Claim 10 to recite a “sealing means disposed between the ink receiving portion and the basic module for preventing liquids from reaching the basic module.” (Ex. 1015, Amendment dated Sep. 9, 2002, page 9). In his remarks, applicant stated that “[s]ealing can be done with a number of structural elements including a material composition that causes the sealing rather than a separate element.” *Id.* at

9. Had the examiner considered the addition of “sealing means” as new matter, he would not have indicated at the interview that the term was acceptable, and would have further rejected amended claim 10 under § 112 for lack of adequate written description support. The USPTO thus considered the term “sealing means” both at the August 7, 2002, interview, and again when reviewing the September 9, 2002 amendment. At no time did the USPTO reject amended claim 10 or otherwise indicate that the term “sealing means” was unsupported, as petitioner now suggests.

The claimed term “sealing means” is a means-plus-function term, and under the plain language of 35 U.S.C. § 112, its scope is governed by the corresponding structures disclosed in the specification and equivalents thereof. The USPTO has presumptively accepted that “sealing means” is adequately supported based on the disclosure and the drawings presented in the applications. Petitioner raises no new arguments as to why the USPTO was incorrect.

Thus, the “sealing means” in claims 10-18 is expressly supported by the disclosure of a “sealing diaphragm” as described in the original specifications and Figures showing the same, and as such, is not new matter in the ’530 Patent claims.

The ’530 Patent is entitled to claim priority to the filing dates of both the ’553 patent and DE ’199.

IV. PETITION RELIES ON A DEFECTIVE CLAIM CONSTRUCTION

In conducting its review, the Board interprets claim terms using the “broadest reasonable construction in light of the specification of the patent in which it appears.” 37 C.F.R. § 42.100(b).

The petition relies on an erroneous construction of the term “diaphragm” in claims 9 and 18 intended to improperly define the scope of that term. Purporting to apply the broadest reasonable interpretation standard, petitioner contends that the proper construction of “diaphragm” is a “resilient structure ensuring substantially no ink leakage from the ink tank of the disposable module.” (Petition p. 16). Petitioner’s proposed construction should be disregarded for several reasons.

First, petitioner has sidestepped any proposed plain and ordinary meaning of the term “diaphragm” and has - without evidentiary support - proposed that a “*diaphragm*” is a “resilient *structure*.” (Petition pp. 12-13). Yet the portions of this specification petitioner relies on do not use the term “structure” or any similar term. For example, petitioner relies on a passage from the Summary of the Invention section disclosing the location of the diaphragm (between the basic and disposable module) and two of its functions (preventing ink leaks into the basic module and preventing the penetration of impurities into the disposable module). (Petition pp. 16-17). Petitioner also relies on a portion of the Detailed Description

section disclosing the configuration of the diaphragm in an embodiment relative to its surrounding structures. (Petition p. 17). Without any further support, petitioner concludes that one of ordinary skill in the art would understand the proper scope of “diaphragm” would not be limited by the Summary or Detailed Description sections . (Petition pp. 17-18).

Second, petitioner relies on a construction of “diaphragm” that is defined only in terms of its function, not any aspect of its structure. Petitioner has not offered an explanation why its proposed construction includes no structural features.

Third, the claims of U.S. Patent No. 6,345,553 (the ‘553 patent”)(the parent of the ‘530 patent) recite a “resilient diaphragm.” In co-pending IPR2014-00137 (directed to the ‘553 patent), petitioner Bomtech has proposed that “resilient diaphragm,” be construed identically to the “diaphragm” claimed herein. *Bomtech Electronics, Co. Ltd. v. Medium-Tech Medizingeräte GmbH*, IPR2014-00137 * at 12 (PTAB, Nov. 11, 2013). Petitioner has offered no factual basis for its proposed inconsistent constructions, which are confusing at best, and inspired by its present invalidity challenges at worst.

Next, petitioner goes beyond the specification as required under 37 C.F.R. § 42.100(b), and relies on extrinsic evidence including proceedings before the International Trade Commission in *In re Certain Ink Application Devices and*

Components Thereof And Methods of Using the Same, Investigation No. 337-TA-832, and the '530 prosecution history, neither of which is appropriate here.

Glaringly, petitioner relies on the *Markman* hearing and related litigation positions from Patent Owner's recent ITC case to support its claim construction here (Petition pp. 18-20), but disclaims its presently proposed construction for future litigation:

Petitioner's proposed claim construction below is offered only to comply with 37 C.F.R. § 42.100(b) and for the sole purpose of this Petition, and thus, do not necessarily reflect appropriate claim constructions to be used in litigation and other proceedings where a different claim construction standard applies.

(Petition p. 14). Patent owner acknowledges different claim construction standards exist in different jurisdictions, but disagrees that the "broadest reasonable construction in light of the specification" standard under 37 C.F.R. § 42.100(b) permits consideration of extrinsic evidence or the other evidence petitioner uses here.

There is a "heavy presumption" that a claim term carries its ordinary and customary meaning, *i.e.*, the meaning the term would have to a person of ordinary skill in the art. *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002). For such terms, no construction is required. *See Biotec Biologische*

Naturverpackungen GmbH & Co. KG v. Biocorp, Inc., 249 F.3d 1341, 1349 (Fed. Cir. 2001) (finding no error in non-construction of “melting”); *Mentor H/S, Inc. v. Med. Device Alliance, Inc.*, 244 F.3d 1365, 1380 (Fed. Cir. 2001) (finding no error in court’s refusal to construe “irrigating” and “frictional heat”). Further, claims interpreted under the broadest reasonable interpretation standard are done so “consistent with the specification, and ... claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art.” *In re NTP, Inc.*, 654 F.3d 1268, 1274 (Fed. Cir. 2011) (quoting *In re Am. Acad. Of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004)).

Petitioner has pointed to nothing in the specification that supports departing from the plain and ordinary meaning of “diaphragm,” and has provided no explanation as to how the purported extrinsic evidence from the proceedings before the International Trade Commission justify its construction. Petitioner’s construction, premised on a single functional limitation, is incorrect and should be rejected.

**V. PETITIONER HAS FAILED TO ESTABLISH A REASONABLE
LIKELIHOOD THAT THE PRIOR ART ANTICIPATES THE ’530
PATENT CLAIMS**

**A. Ground 1: Claims 10-18 are not anticipated by DE 299 19
199 U1 to Adler (“Adler”)**

As discussed in Section III, above, the '530 Patent is entitled to claim priority to the filing dates of both the '553 patent and DE '199. Accordingly, the January 20, 2000 publication of the DE '199 application is not prior art to the '530 Patent.

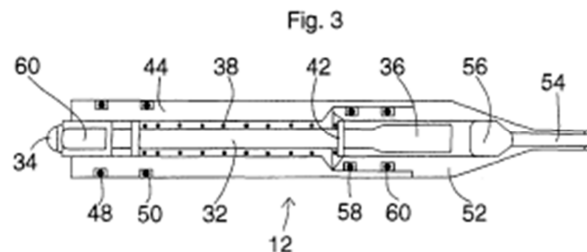
B. Ground 2: Claims 1-3, 7-12, and 16-20 are not anticipated by U.S. Patent No. 6,033,421 to Theiss

The petition fails to establish that Theiss anticipates any of claims 1-3, 7-12, and 16-20 of the '530 Patent. As shown herein, the petition is deficient in failing to identify evidence of any disclosure in Theiss of at least the “disposable module”; the “means for allowing simultaneous removal of the entire disposable module from the basic module,” the “bearing element,” the “simultaneously removing the entire disposable module from the basic module directly following an application of ink using the ink application device,” and the “diaphragm” limitations of claims 9 and 18.

Petitioner has failed to identify any disclosure in Theiss of a “disposable module,” which is required by each of the independent claims 1, 10, and 19. Rather, petitioner has only identified disclosure in Theiss that establishes that Theiss' grip tube 12 is “replaceable,” which is clearly not the same as “disposable.” (Petition p. 25). A claim is anticipated “only if each and every element as set forth in the claim is found, either expressly or inherently described,

in a single prior art reference.” *Verdegaal Brothers, Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 827 (1987). Further, 37 C.F.R. § 42.104(b)(4) requires that the petition must specify where each element of a challenged claims is found in the prior art patents or printed publications. Because the petition fails to identify any disclosure in Theiss of the “disposable module” as claimed in claims 1, 10, and 19, the petition is deficient and the proposed ground based on Theiss should be rejected.

With respect to claims 1 and 19, the petition is deficient for failing to identify the feature of the “means for allowing simultaneous removal of the entire disposable module from the basic module.” The only proffered support for this feature provided by petitioner is the fact that the driven grip tube 12 is “easily insertable” thus “permitting the ready substitution of different needles during use of the device”. (Petition, pp. 26, 33). The grip tube 12 of Theiss is illustrated in the figure below: (Petition p. 26).



But a disclosure that *needles* can be readily substituted is not a disclosure of the “simultaneous removal of the *entire disposable module* from the basic

module.” The disclosure petitioner cites does not support its anticipation challenge, and Theiss does not anticipate claim 1. *See Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369-70 (Fed. Cir. 2008) (anticipation requires more than simply disclosing every element of the challenged claims, it also requires that the anticipatory reference disclose those elements “arranged as in the claim.”).

Claim 10 requires a “bearing element disposed inside the housing” and a “sealing means disposed between the ink receiving portion and the basic module for preventing liquids from reaching the basic module”. For the “bearing element” feature, petitioner identifies the needle connector 36 of Theiss. (Petition pp. 29-30). However, the needle connector does not disclose the claimed bearing element because the needle connector has no bearing ability relative to the needle. This is because the needle is attached to the needle connector 36 by, e.g., soldering. (*See* Theiss, col. 4, ll. 59-60.) Such a direct connection can not act as a bearing surface for the needle.

For the “sealing means disposed between the ink receiving portion and the basic module for preventing liquids from reaching the basic module” feature, petitioner identifies the O-rings of Theiss. (Petition p. 30). However, these structures do not disclose the claimed sealing means because the O-rings are not located “between” the ink tank and the basic module as the claim language

unambiguously requires, but are located on the outer periphery of the grip tube and needle tip.

Further, the O-rings would have no effect on fluid flowing from the pigment reservoir 56 of Theiss to the basic module. Theiss's O-rings cannot satisfy the requirement of “prevent[ing] ink from passing from the ink tank to the basic module,” and petitioner nowhere alleges that they do. The petition fails to identify any disclosure of the O-rings in Theiss preventing fluid flow from the ink tank back to the disposable module, as required by claim 10.

With respect to claims 9 and 18, the petition is deficient for failing to identify the feature of the “a diaphragm disposed between the ink receiving portion and the basic module.” Apart from Petitioner’s erroneous claim construction of the term “diaphragm” as any “resilient structure ensuring substantially no ink leakage from the ink tank of the disposable module,” as discussed above, Petitioner fails to identify support for the claim limitation even under its incorrect interpretation. At best, O-rings 48, 50, 56, and 58 connect grip tube 12 with end cap 24. Figure 3 makes clear that O-rings 48, 50, 56, and 58 do not provide the structure through which the cam follower 34 is connectable to cam face 20.

Moreover, the O-rings of Theiss are disclosed as being located on the outer periphery of the grip tube 12 (at 48 and 50) as well as on the outer periphery of tip section 52 (at 58 and 60). At best, the O-rings of Theiss provide a seal between the

portion of the outer periphery of the grip tube 12 that is inserted into the drive unit, as well as a seal between the portion of tip section 52 that is inserted into the grip tube 12. However, there is no disclosure in Theiss of a portion of the grip tube (which petitioner identifies as the claimed sterilized disposable module) that is connectable to the integrated needle drive *through* the O-rings, and neither petitioner nor its declarant have pointed to any.

For these additional reasons, Theiss does not anticipate claims 9 and 18. *See Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369-70 (Fed. Cir. 2008) (anticipation requires more than simply disclosing every element of the challenged claims, it also requires that the anticipatory reference disclose those elements “arranged as in the claim.”).

With respect to the challenged dependent claims, the Petition fails to establish that Theiss anticipates any of these claims at least because it fails to establish anticipation of the independent claims for the reasons set forth herein. Because petitioner has not “specif[ied] where each element of the claim is found in the prior art patents” or “identif[ied] specific portions of the evidence that support the challenge,” it has not established a reasonable likelihood that any claim is anticipated based on the Theiss reference. 37 C.F.R. §§42.104(b)(4)-(5).

C. Ground 3: Claims 1-3, and 7-20 are not anticipated by TW326643B to Zhan (“Zhan”)¹

Each of claims 1, 10, and 19 require a “disposable module.” The petition, however, fails to identify any evidence that Zhan discloses this element. The petition relies on dye cartridge (10) of Zhan as allegedly disclosing the claimed “disposable module,” but points to no evidence that the dye cartridge (10) is disposable. (Petition pp. 38-41).

Moreover, to be operational, the apparatus of Zhan requires a multi-step assembly that includes:

- (1) attachment of dye cartridge (10) to tattoo machine (30);
- (2) breaking off the enclosure member (15) at the bottom of dye cartridge (10);
- (3) running tattoo needle (42) through the conical guide channel (22) on the flexible sealing element (16);
- (4) ensuring the needle (42) is positioned in the clamping needle holder (40)
- (5) tightly fitting a needle sleeve (44) onto the outside of the intruding tube (11) at the bottom of the dye cartridge; and

¹ Patent Owner cites to the English Translation of Zhan (Ex. 1006) of Petitioners exhibits, but by doing so, does not represent that the translation is correct and accurate.

(6) ensuring that guiding grooves (46) on needle sleeve (44) connect with guiding grooves (26) inside the dye cartridge. (Zhan, p. 6, ll. 3-10). Petitioner has nowhere shown how the multi-step assembly using multiple components as required by Zhan meets the “disposable *module*” requirement of the claims.

Additionally, while Zhan may disclose that the dye cartridge (10) can be “discarded” (Petition p. 39 and Zhan at p. 6, ll. 27-30), the petition fails to identify any disclosure of a “module” as claimed that is discarded. Zhan discusses “disinfection” of the dye cartridge components before reuse (Zhan at p. 6, l. 31 – p. 7, l. 2), but “disinfection” is not the same thing as “sterilized,” and “reuse” is the antithesis of “disposable.”

The Petition further fails to set forth any analysis as to why Zhan anticipates the claimed elements of independent claims 10 and 19 other than saying that the “flexible sealing element 16” corresponds to the “sealing means” of the ’530 patent. (Petition p. 40). While the “sealing means” is claimed in claim 10, there is no analysis or discussion of all of the remaining elements in claims 10 and 19. For example, there is no discussion of the needle nozzle or the bearing element of claim 10. Also, there is absolutely no discussion of any of the method steps of claim 19.

Petitioner argues that the “means for simultaneous removal of the entire disposable module from the basic module” limitation is met by the disclosure of

Zhan that “[b]efore a tattoo or eyebrow operator, attach the dye cartridge 10 to the main body of the tattooing machine 30 by clicking, screwing...”. (Petition p. 39).

Petitioner’s argument fails because ***attachment*** is the antithesis of ***removal***.

Contrary to the petitioner’s argument, the dye cartridge subunit of Zhan is assembled stepwise and removed stepwise. See above. (Zhan, p. 3, ll. 3-30).

Petitioner has cited no disclosure of simultaneous removal.

Petitioner also relies on aspects of multiple embodiments to show anticipation of each of the challenged claims. Figures 1-3 of Zhan are directed to a first embodiment, Figures 4-5 are directed to a second embodiment, and Figures 6-9 are directed to a third embodiment of Zhan's claims. (Zhan at p. 4, l. 25 – p. 5, l. 6). Petitioner relies on Figures 1-7 throughout its table comparing the features of Claim 1 with aspects contained in multiple embodiments of Zhan (Petition p. 38-39), and further relies on, *e.g.*, Figures 3, 4 and 6 (depicting second and third embodiments) in an attempt to meet the "sealing means" limitations of Claim 1: “Each of Figs. 3, 4 and 6 of Zhan above depicts an embodiment of a tattoo machine comprising a basic module 30 (colored GREEN) and a disposable unit 10 (colored YELLOW) containing a “flexible sealing element 16” which corresponds to “sealing means” of the ‘530 Patent” (Petition, p. 40). It is improper to rely on elements found in multiple, alternative embodiments in establishing anticipation of a single claim. “Anticipation requires that a reference disclose “not only all of the

limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim.” *Net MoneyIN v. VeriSign*, 545 F.3d 1359, 1371 (Fed. Cir. 2008) (emphasis added); *Karsten Manufacturing Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001).

The proposed grounds of rejection based on Zhan are deficient at least because they fail to establish that all elements of independent claims 1, 10, and 19 are disclosed by Zhan. 37 C.F.R. §§42.104(b)(4)-(5).

VI. PETITIONER HAS FAILED TO ESTABLISH OBVIOUSNESS BY ANY OF THE ASSERTED REFERENCES

A patent is invalid as obvious if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. 35 U.S.C. § 103(a). In any obviousness analysis, the following “*Graham factors*” must be considered: (1) the scope and content of the prior art; (2) the differences between the prior art and the claimed invention; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966); *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406–407 (2007) (noting that these four factors “continue to define the inquiry that controls”). Although obviousness is a question of law, it is premised on the underlying

factual determinations regarding the four factors noted above. *Graham*, 383 U.S. at 17; *In re Kubin*, 561 F.3d 1351, 1355 (Fed. Cir. 2009).

The Petition asserts that each of claims 1–11 and 12-20 is invalid for obviousness based on combining the teachings of multiple references, including Theiss and Zhan. (Petition pp. 3-4). As discussed below in Section IV, the Petition fails to prioritize the various combinations of these references as to their relative strengths and weaknesses. The Petition also fails to establish a reasonable likelihood of prevailing on obviousness on any of the combinations.

The Theiss and Zhan references each lack disclosures or suggestions of certain claimed features, e.g., “disposable module”, the “means for allowing simultaneous removal of the entire disposable module from the basic module”, the “bearing element”, the “simultaneously removing the entire disposable module from the basic module directly following an application of ink using the ink application device” and “diaphragm,” limitation. *See* Sections V.B-V.C above. As a result and as discussed below, each and every combination including these references is still missing those claim elements, and the petition fails to establish a reasonable likelihood that any of the challenged claims would be obvious based on the asserted combinations.

A. Ground 4: Claims 2, 4-6, 11 and 13-15 are not obvious over Theiss in view of U.S. Patent No. 4,671,227 to Beuchat

Claims 2 and 4-6 depend directly and indirectly from independent claim 1 and petitioner relies upon Theiss as teaching all of the elements of claim 1.

Claims 11 and 13-15 depend directly and indirectly from independent claim 10 and petitioner relies upon Theiss as teaching all of the elements of claim 10. For the reasons set forth above in Section V.B, Theiss does not teach all of the elements of claims 1 and 10, and so petitioner's arguments with respect to claims 2, 4-6, 11 and 13-15 fail to establish a *prima facie* case of obviousness. In addition, petitioner's arguments are necessarily noncompliant with 37 C.F.R. § 104, since petitioner has not "specif[ied] where each element of the claim is found in the prior art patents" or "identif[ied] specific portions of the evidence that support the challenge," 37 C.F.R. §§42.104(b)(4)-(5).

Claims 2 and 11 recite "the ink receiving portion has a volume sufficient for one application of ink." ('530 Patent at col. 5, ll. 39-41 and col 6, ll. 26-28). Beuchat is stated to disclose "a reservoir for use in such controlled dispensing wherein the reservoir contains sufficient pigment to perform the entire procedure without requiring the operator to stop and refill the reservoir with additional (sic) aqueous pigment." (Petition pp. 44 and Beuchat at col. 1, ll. 40-45).

The sum total of petitioner's argument as to the obviousness of claims 2 and 11 based on the combination of references is as follows:

As stated by Beuchat, it is inconvenient and unsanitary to have an ink reservoir that requires “refill” during a tattoo operation, and a person having ordinary skill in the art would have been strongly motivated to have an ink reservoir having a volume sufficient for one application of ink as taught by Beuchat. Therefore, Theiss in view of Beuchat renders obvious claims 2 and 11.

(Petition p. 44). Yet petitioner nowhere identifies *which* element in Beuchart is being substituted into which embodiment or apparatus of Theiss. Nor is there any explanation of (1) whether the embodiments are *capable* of being combined, (2) how such substitution/combination would be made, how the resulting apparatus would be configured, or (3) whether any the combination would yield predictable results. Nowhere has petitioner stated what motivation would prompt a person of ordinary skill in the art to combine the disclosures of Theiss and Beuchat.

Petitioners asserted grounds of obviousness are short and conclusory, failing to specifically articulate the rationale underlying the assertions of obviousness as required by 37 C.F.R. § 42.104(b)(4). The Petition thus fails to present a *prima facie* case of obviousness.

Dependent claims 4 and 13 recite the apparatus of claims 1 and 10, respectively, “further comprising a separate ink module attachable to an opening in the disposable module for filling the ink receiving portion, the separate ink module having a quantity of sterile ink sufficient for one application. (’530 Patent at col. 5, ll. 48-52). Beuchat is stated to disclose “a disposable adapter for

attachment to a head of a pigment implanting unit, wherein the adapter houses the pigment reservoir and transfer tube in an angled relationship with the axis of the reciprocating needle to control the dispensing of pigment to the needle.”

(Petition, p. 45 and Beuchat at col. 1, ll. 13–20).

The sum total of petitioner’s argument as to the obviousness of claims 4 and 13 based on the combination of references is as follows:

Therefore, Theiss in view of Beuchat renders obvious claims 4 and 13 because this is a simple substitution of one known element for another to obtain predictable results.

(Petition, p. 46). Yet petitioner nowhere identifies *which* element in Beuchat is being substituted into which embodiment or apparatus of Theiss. Nor is there any explanation of (1) whether the embodiments are *capable* of being combined, (2) how such substitution/combination would be made, how the resulting apparatus would be configured, or (3) whether any the combination would yield predictable results. Nowhere has petitioner stated what motivation would prompt a person of ordinary skill in the art to combine the disclosures of Theiss and Beuchat.

Petitioners asserted grounds of obviousness are short and conclusory, failing to specifically articulate the rationale underlying the assertions of obviousness as required by 37 C.F.R. § 42.104(b)(4). The Petition thus fails to present a *prima facie* case of obviousness.

Dependent claims 5 and 14 recite the apparatus of claims 4 and 13, respectively, wherein “the separate ink module includes an outlet for discharging ink with each needle stroke”. Petitioner urges that Beuchat’s disclosure of the separate ink reservoir comprising an opening 46 is designed to provide a controlled amount of pigment. Petitioner fails to set forth the factual basis for the combination, fails to identify the motivation to one of ordinary skill in the art to combine the references, fails to identify which elements are being substituted, and fails to explain how the combination would yield predictable results. For these reasons, petitioner’s arguments regarding claims 5 and 14 are legally insufficient and should be denied.

Dependent claims 6 and 15 recite the apparatus of claims 1 and 13, respectively, wherein “the separate ink module includes an outlet for discharging ink into the ink receiving portion.” Petitioner urges that Beuchat’s disclosure of “a pigment reservoir 40, provided as a separate piece, includes a body 41 acting as a pigment reservoir with an outer chamber 44 terminating at its lower end in an opening 46 for receiving a transfer tube 47 in a press-fit relationship.” (Petition, p. 47 and Beuchat at col. 5, lines 13-18). Beuchat further discloses that “[t]he body 29 of the adapter 30 further defines an obliquely inclined chamber 36 having an outer chamber portion 37 which communicates with an inner chamber

portion 38 which terminates at its lower end in the wall of the chamber 34 of the axially aligned chamber 32.” (Petition, p. 47 and Beuchat at col. 5, lines 3-8).

For the same reasons as set forth above with respect to claims 4, 5, 13 and 14, petitioner’s arguments are insufficient. Petitioner fails to set forth the factual basis for the combination, fails to identify the motivation to one of ordinary skill in the art to combine the references, fails to identify which elements are being substituted, and fails to explain how the combination would yield predictable results. For these reasons, petitioner’s arguments regarding claims 6 and 15 are legally insufficient and should be denied.

B. Ground 5: Claims 7, 8, 16 and 17 are not obvious over Theiss in view of U.S. Patent No. 4,582,060 to Bailey

Claims 7 and 16 depend directly and indirectly from independent claims 1 and 10, respectively and claims 8 and 17 depend directly and indirectly from claims 7 and 16, respectively. Petitioner relies on Theiss as teaching all of the elements of claims 1 and 10. For the reasons set forth above in sections X and Y, Theiss does not teach all of the elements of claims 1 and 10, and so petitioner's arguments with respect to claims 7, 8, 16 and 17 fail to establish a *prima facie* case of obviousness. In addition, petitioner’s arguments are necessarily noncompliant with 37 C.F.R. § 104, since petitioner has not “specif[ied] where each element of the claim is found in the prior art patents” or “identif[ied]

specific portions of the evidence that support the challenge,” 37 C.F.R.

§§42.104(b)(4)-(5).

Claim 7 recites the device of claim 1 wherein “the portion that can contact the integrated needle drive is the needle shaft” and claim 16 recites the device of claim 10 wherein “the portion that is connectable to the integrated needle drive is the needle shaft” Bailey is stated to disclose “a tattooing device comprising a housing and a needle assembly removably attached to the housing, a needle retainer in the housing, a drive means in the housing for reciprocating the needle retainer with respect to the housing, and a needle/cone assembly removably attached to the housing.” (Petition pp. 48-49 and Bailey at col. 1, lines 44–48).

The sum total of petitioner's argument as to the obviousness of claims 7 and 16 based on the combination of references is as follows:

A needle retainer of Bailey, which corresponds to the needle shaft of the ‘530 Patent, contacts the drive means corresponding to the integrated needle drive. A person having ordinary skill in the art would have been motivated to modify Theiss to have a needle shaft contacting the integrated needle drive in accordance with the teaching by Bailey. Therefore, Theiss in view of Bailey renders obvious claims 7 and 16.

(Petition, p. 49). Yet petitioner nowhere identifies *how* Theiss in view of Bailey renders claims 7 and 16 of the ‘530 patent obvious. Petitioner provides no explanation of: (1) whether the embodiments are even capable of being combined,

DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 567 F.3d 1314 (Fed. Cir. 2009) ; (2) which components or structures are to be substituted, (3) how such substitution/combination would be made, (4) how the resulting apparatus would be configured, or (5) whether any the combination would yield predictable results. Nowhere has petitioner stated what motivation would prompt a person of ordinary skill in the art to combine the disclosures of Theiss and Bailey.

Petitioner's asserted grounds of obviousness are short and conclusory, because they do not specifically articulate the rationale underlying the assertions of obviousness as required by 37 C.F.R. § 42.104(b)(4). Petitioner thus fails to present a *prima facie* case of obviousness for Claim 13.

Dependent claims 8 and 17 each recite the apparatus (of their respective independent claims) that "the needle shaft is cylindrical." Petitioner argues that Bailey's disclosure of a needle carrier having a thin tubular forward part, in combination with Theiss renders obvious the subject matter of claims 8 and 17. (Petition, p. 50 and Bailey at col. 3, ll. 63–68). As with claims 7 and 16, petitioner sets forth no factual basis for the combination of selected portions of the references, no motivation by person of ordinary skill in the art to modify the structure of Theiss as petitioner has done, and no basis for and expectation of a predictable result. For all the reasons set forth above, petitioner's arguments with

respect to claims 8 and 17 fail to establish a *prima facie* case of obviousness, and its petition should be denied.

C. Ground 6: Claims 1-3, and 7-20 are not obvious over Theiss in view of Zahn

As with its defective anticipation argument, petitioner's obviousness arguments erroneously focus on the substitution of the "flexible sealing element" of Zahn for the "O-rings" of Theiss as a predicate for a conclusion of obviousness. (Petition, pp. 50-51). Petitioner ignores entirely the other elements missing from Theiss in its analysis, *e.g.* the "disposable module, and fails to explain how the combination of the references discloses or suggests those claimed elements. Under 37 C.F.R. § 42.104(b)(4), the petition must specify where each element of a challenged claim is found in the prior art patents or printed publications. In accordance with 37 C.F.R. § 104(b)(5), the relevance of the evidence supporting the challenge must be provided including identification of specific portions of the evidence that support the challenge.

With regards to at least the "disposable module" and the "means for allowing simultaneous removal of the entire disposable module from the basic module" claim limitations set forth in claim 1, the petition provides no argument or evidence that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Theiss in view of Zahn to obtain those

claimed features. In the absence of such analysis, the Petition has not made a *prima facie* showing of obviousness under *KSR*:

Although the obviousness analysis should “take account of the inferences and creative steps that a person of ordinary skill in the art would employ,” the Supreme Court emphasized that this evidentiary flexibility does not relax the requirement that, “[t]o facilitate review, this analysis should be made explicit.” *Id.* [*KSR*] at 418, 127 S.Ct. 1727 (citing [*In re*] *Kahn*, 441 F.3d [977] at 988 (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”))

Perfect Web Technologies, Inc. v. InfoUSA, Inc., 587 F.3d 1324, 1330 (Fed. Cir. 2009).

Turning to its substantive combination argument with respect to claims 9 and 18, petitioner nowhere explains **how** the flexible sealing element of Zahn could be substituted for an O-ring in the Theiss patent, particularly given the different structures of each of the references. For example, the sealing element of Zahn is affixed to the dye chamber, is disposed within its circumference, and contacts the needle and dye directly. (*See Zahn* at pp. 3-5, 16-21). The O-rings of Theiss are disposed about the outer bore of its grip section and do not, in operation contact the needle or the dye in any way. (*See Theiss* at Figs 1-3, col. 4, l. 14- col. 5, l. 29).

The petitioner has failed to explain how the prior art elements of Zahn and Theiss could have been combined by known methods, or that a person of ordinary skill in the art would have recognized that the results of the combination were predictable. *KSR*, 550 U.S. at 401. Absent any explanation that the prior art elements are capable of being physically combined, the Board and the patent owner are left to guess how one of ordinary skill in the art would be able to adapt the sealing element of Zahn to the apparatus of Theiss, to yield a predictable result. *Id.*; *see also DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1326 (Fed. Cir. 2009) (the “predictable result” discussed in *KSR* requires that the prior art elements are both **capable** of being physically combined, and that they will work for their intended purpose.)(emphasis added).

In addition, the O-rings of Theiss are intended to prevent vibration of the machine during operation, which is one of the express purposes of the invention of Theiss. (*See* Theiss at col. 4, ll. 37-39).² Yet nothing in either reference suggests that Zahn’s sealing element **could** achieve that function, let alone **how** it could do so. Petitioner nowhere explains how the apparatus of Theiss would function with

² The patent states “there remains a need for a new and improved tattoo machine that. . . does not vibrate excessively during use.” ‘530 patent, at col. 1, ll. 47-51. Claims 9 and 21 of the Theiss reference specifically recite the use of the O-rings to “frictionally secure said driven grip tube” within the receiving bore. (Theiss at col. 6, ll. 18-20; col. 7, l. 12- col. 8, l. 2).

reduced vibration using the seal of Zahn. If a proposed modification would render a prior art invention unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984); M.P.E.P. § 2143.

Petitioner's only basis for the combination is stated as follows:

The combination of Theiss and Zhan would have been obvious to a person having ordinary skill because there was teaching, suggestion and motivation to combine the references. Particularly, prevention of ink leakage and viral contamination was a well-known problem to be solved in the art, as evidenced by various prior art publications, such as Theiss, Zhan, Trott and Chou.

(Petition, p. 51).

But "ink leakage and viral contamination" is a statement of a prior art problem; it does not provide motivation to those skilled in the art to combine every reference purporting to solve that problem in unexplained ways. That is especially true where, as here, purported solutions to a prior art problem are vastly different in terms of structure and function. The lack of any particularized analysis by Petitioner and its expert is demonstrated by the fact that the obviousness grounds in both of Bomtech's petitions (Petition, pp. 50-51) and its copending petition relating to the '553 patent (IPR2014-00137, p. 40) rely on the rationale quoted above, ***presented identically***, despite the fact that each of Mt. Derm's '553 and

'530 patents presents a different set of claims with its own particularized claim limitations.

Petitioner's conclusory statements, without more detail, fail to satisfy any of the above-noted requirements and are irreparably lacking in detail. Petitioner does not clearly provide analysis to support the assertion of obviousness over Theiss based on Zahn as required by 37 C.F.R. § 104(b), and its generalized statement of the prior art problem as motivation to combine Theiss with Zahn in the way petitioner has done ignores the disparately different structures and functions of the elements that teach away from – rather than promote – the combination of the references.

D. Ground 7: Claims 9 and 18 are not obvious over Theiss in view of Trott

Petitioner urges the obviousness of claims 9 and 18 of the '530 patent based on the combination of Theiss and Trott, stating that it would have been obvious to employ the “seal” of Trott with the “tattoo device comprising a disposable module of Theiss.” (Petition p. 54).

The petition, however, fails to identify any support in Trott for this element. Instead, the petition points to seal (96) of Trott (Petition, pp. 52-53), which Trott merely describes as “insur[ing] that the liquid 11 within the reservoir 68 does not enter the interior cavity of the body member 14.” (*See* Trott at col. 5, ll. 62-64).

Trott does not disclose the seal 96 as being resilient, or as a diaphragm. Thus, for this reason, Trott fails to cure the deficiencies of Thesis.

In a few short paragraphs, petitioner urges the obviousness of Claims 9 and 18 of the '530 patent based on the combination of Theiss and Trott, stating that it would have been obvious to employ the “seal” of Trott with the “tattoo device comprising a disposable module of Theiss.” (Petition, pp. 53-54). Petitioner's argument does not comply with the requirements of 37 C.F.R. §104, and should be denied for at least three reasons .

First, Petitioner's obviousness arguments erroneously focus only on the substitution of the “seal” of Trott for the “O-rings” of Theiss as a predicate for a conclusion of obviousness. (Petition pp. 52-53). Petitioner ignores entirely the other elements missing from Theiss in its analysis, *e.g.*, the disposable module, and fails to explain how the combination of the references discloses or suggests those claimed elements. To be certain, Theiss does not teach a disposable module as claimed in the '530 patent. At the very least, the '530 patent claims require a needle as part of the disposable module, nowhere taught or even suggested in Theiss. To the contrary, the only optionally disposable element of the Theiss apparatus is the grip tube (*see, e.g.*, Theiss at col. 5, ll. 39-43), and which -- by definition -- does not contain a needle. (*See* Theiss at col. 2, ll. 17-22; 37-45; col. 4, ll. 27-32). Theiss makes clear that the needle must be manually

attached by the user before use by, *e.g.*, soldering, and that the user must prepare each new grip tube in this manner. (*See* Theiss at col. 4, ll. 59-60 and col. 5, ll. 21-24). Neither the grip tubes nor the needles are described as a disposable *unit*, and Petitioner has failed to mention - let alone establish - the prior art suggestion of a disposable module in Theiss as required by 37 C.F.R. § 42.104(b)(4).

Second, petitioner argues that the “seal” of Trott is “essentially identical to and patentably indistinguishable from the diaphragm of *the ’530 Patent*” and can therefore be combined with the apparatus of Theiss. (Petition, p. 54). In support, petitioner relies on Trott solely for its teaching that its seal prevents the flow of liquid from the reservoir into the interior cavity of the body member. (Petition, pp. 53-54, citing to Trott at col. 5, ll. 62-64). Petitioner’s convoluted obviousness analysis improperly uses the disclosure and claims of *the ’530 patent* in hindsight fashion, as a template for re-creating its structure using seal of Trott in the apparatus of Theiss. Petitioner’s argument is improper.

Petitioner also ignores its own proposed claim construction for “diaphragm” in suggesting the combination of references renders claims 9 and 18 obvious. Petitioner has proposed as a construction for “diaphragm” a “*resilient* structure . . .” (Petition, pp. 13-16). Yet nothing in Trott suggests that the seal disclosed therein is *resilient*, and Petitioner fails to identify any support in Trott

for this element.³ Instead, the petitioner improperly compares Figure 2 of the '530 patent with Fig. 4 of Trott (Petition, p. 53) and argues, without evidentiary support, that “the term ‘seal’ used in Trott is a generic term embracing a diaphragm.” *Id.*

If petitioner’s proposed claim construction is considered, the combination of references cannot render obvious claims 9 and 18 because an element of the claim as construed is nowhere taught in the combination. Under 37 C.F.R. § 104(b)(5), the specific portions of the evidence supporting petitioner’s challenge fail to disclose or even suggest the claimed element, and petitioner nowhere states how or why persons of skill in the art would understand the seal of Trott to be adaptable to the structure of Thiess as a diaphragm.

Third, petitioner nowhere explains **how** the seal of Trott could be substituted for an O-ring in the Theiss patent, particularly given the different structures of each of the references. For example, the seal of Trott is disposed within the inner bore of the end member, not the outer surface of the grip tube as in Theiss. (*See* Trott at col. 5, ll. 59-60). The seal of Trott contacts the cam

³ The Stein declaration is entitled to little weight on this point because it ignores petitioners proposed claim construction, and nowhere attempts to demonstrate that the seal of Trott is resilient.

follower and the dye chamber directly (Trott at Fig. 4), whereas the O-rings of Theiss do not contact either the dye chamber of the grip tube or the cam follower of that reference (Theiss at col. 2, ll. 64-67). The petitioner has failed to explain how the prior art elements of Trott and Theiss could have been combined by known methods, or that a person of ordinary skill in the art would have recognized that the results of the combination were predictable. *KSR*, 550 U.S. at 401; *see also DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314 (Fed. Cir. 2009); *See Dominion Dealer Solutions, LLC v. AutoAlert, Inc.*, IPR2013-00220, Paper 8, August 15, 2013 at 22(“Notably absent from Dominion’s stated rationale is a sufficient explanation of **how** the references may be combined, from the perspective of one with ordinary skill in the art, to arrive at the claimed invention, and why the proffered combination accounts for all the features of each claim.”)(emphasis added).

For at least these reasons, petitioner has neither complied with the specific requirements of 37 C.F.R. §42.104 in urging the asserted claims are obvious over Theiss in combination with Trott, nor made a *prima facie* showing of obviousness under *KSR* based on the incomplete allegations of the petition.

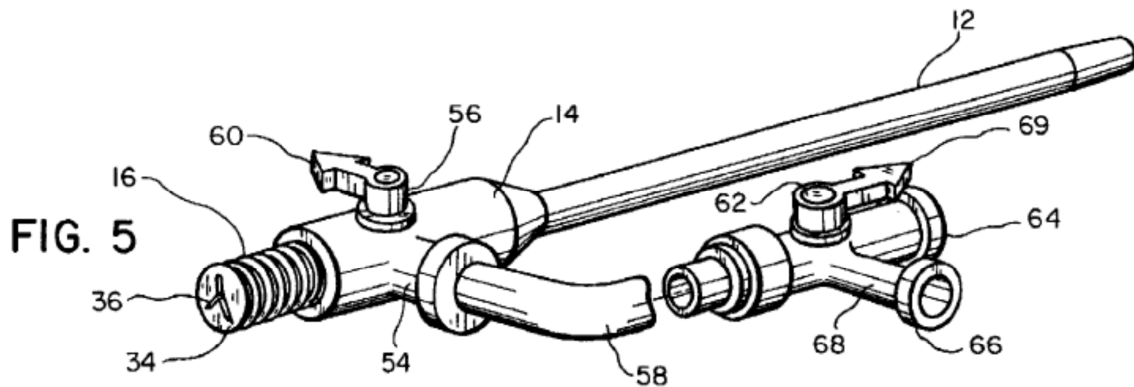
E. Ground 8: Claims 9 and 18 would not have been obvious based on Theiss in view of U.S. Patent No. 5,704,914 to Stocking

Similar to Ground 7, petitioner summarily urges the obviousness of Claims 9 and 18 of the '530 patent based on the combination of Theiss and Stocking, stated to disclose a diaphragm for use in a catheter assembly. (Petition pp. 54-55). Petitioner relies on two specific disclosures of Stocking for its teachings of a “flexible resilient diaphragm or septum 34” (Stocking at col. 4, ll. 24–26), and “[a] flexible, resilient diaphragm or septum 84, preferably containing a slit similar to the slit 36 in the diaphragm 34 of the previous example, forms a liquid sealing means which is affixed to the proximal end of the threaded end portion 83.” (Stocking at col. 6, l. 67–col. 7, l. 4). Petitioner’s statement that the mere substitution of one element (*i.e.*, diaphragm) for another (*i.e.*, O-ring), would result in a predictable and therefore obvious combination is incorrect, and petitioner’s asserted ground of obviousness should be dismissed.

Petitioner nowhere explains *how* the resilient diaphragm of Stocking could be substituted for an O-ring in the Theiss patent in a way that yields a predictable result, particularly given the different structures of each of the references and the different functions of each of the elements.

Structurally, the resilient diaphragm of Stocking is disposed *within* the hub of the assembly or *within* a housing attached to the hub. (Stocking at col. 4, ll. 35-42). The diaphragm is not disposed on the outer periphery of the hub or the housing, as are the O-rings in Theiss. The diaphragm 34 of Stocking contains a

three-way slit 36 through which multiple instruments can pass, as shown below in Figure 5 of Stocking:



(Stocking at col. 4, ll. 30-35 and Fig. 5).

Petitioner has nowhere explained how the Stocking diaphragm having a three-way slit could be adapted to function in the apparatus of Thiess, particularly given the differences in their structures -- a tattoo machine containing O-rings vs. a catheter placement assembly including an internal septum. Petitioner's declarant, Mr. Stein, offers neither explanation nor analysis, stating only that it would have been obvious to substitute the diaphragm of Stocking into the device of Thiess. (Stein Declaration, ¶¶ 87-88). The present record is devoid of any credible factual evidence showing that the resilient diaphragm of Stocking is capable of being physically combined with the tattoo machine of Thiess in a way that yields a predictable result. *KSR* at 401; *DePuy Spine*, 567 F.3d at 1326.

As stated, the O-rings of Theiss are intended to prevent vibration of the machine during operation. Yet nothing in either reference suggests that Stocking's resilient diaphragm *could* achieve that function, let alone *how* it could do so. Petitioner nowhere explains how the apparatus of Theiss would function with reduced vibration using the Stocking diaphragm. If a proposed modification would render a prior art invention unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984); M.P.E.P. § 2143.

Finally, nothing in the Stocking reference refers to a “disposable module,” and as stated above, nothing in the Theiss reference teaches a disposable module either. By failing to “specify where each element of the claim is found in the prior art patents,” Petitioner has failed to comply with 37 C.F.R. §41.104 and its petition should be dismissed.

E. Ground 9: Claims 9 and 18 would not have been obvious based on Theiss in view of U.S. Patent 5,580,030 to Proni

Petitioner urges that the combination of Theiss and Proni would have rendered obvious Claims 9 and 18 of the '530 patent based on Proni's teaching of a diaphragm flow control assembly. (Petition, pp. 55-57). Petitioner relies upon Proni's diaphragm assembly to form a fluid-tight seal when a tube or needle is inserted through the diaphragm. (Petition, p. 56 and Proni at col. 1, ll. 59–63). In

essence, Proni is cumulative of other references, relied on for its teaching of a septum.

But, as with Grounds 7-8, Petitioner has nowhere explained how the Proni diaphragm could be adapted to function in the apparatus of Thiess, particularly given the differences in their structures. For example, the diaphragm of Proni is “a perforated circular disc of rubber or other suitable material” (Proni at col. 2, ll. 12-13) and is used to provide a leak proof seal for fluid containing structures (vials, etc). (Proni, Abstract). The O-rings of Theiss are by definition toroidal structures that prevent vibration, facilitate cleaning, and prevent fluid penetration. (See Theiss at col. 1, ll. 64-67; col. 4, ll. 39-40, 49-50; col. 5, ll. 25-29). Petitioner's declarant, Mr. Stein, offers neither explanation nor analysis explaining *how* the references can be combined, stating only that it would have been obvious to substitute the diaphragm of Proni into the tattoo device of Theiss. (Stein Declaration, ¶¶92-95). Because the present record is devoid of any evidence showing that the diaphragm of Proni is even *capable* of being physically combined with the tattoo machine of Theiss in a way that yields a predictable result *KSR* at 401; *DePuy Spine*, 567 F.3d at 1326, the petition should be denied. See *Dominion Dealer Solutions*, above (requiring a sufficient explanation of *how* the references may be combined and why the proffered combination accounts for all the features of each claim.”).

Proni and Theiss nowhere disclose or suggest to persons of ordinary skill in the art that Proni's diaphragm could *function* to reduce the vibration of the Thiess apparatus during operation, or how it could do so even if it could be done. Neither Petitioner nor its declarant explain how the apparatus of Theiss would function with reduced vibration using the Proni diaphragm. If a proposed modification would render a prior art invention unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984); M.P.E.P. § 2143.

Petitioner offers no evidence suggesting that those of ordinary skill in the art would be even motivated to combine the teachings of Proni with those of Theiss, a required showing in an obviousness challenge. To the extent "prevention of contamination" is the sum total of petitioner's motivation argument, it must fail because it is an art recognized goal – not a teaching to combine the Theiss and Proni disclosures the way petitioner has done.

As with the references relied upon in Grounds 7-8 nothing in the Proni reference refers to the diaphragms therein as "disposable module," and as stated above, nothing in the Theiss reference teaches a disposable module either. By failing to "specify where each element of the claim is found in the prior art patents," Petitioner has failed to comply with 37 C.F.R. § 104. Moreover, where a combination of two (or more) references fails to teach a claimed element, it is not

possible for that combination to render the claim obvious. *See Microsoft Corp. v. Proxyconn, Inc.*, Case IPR2012-00026 at 19 (PTAB, Dec. 21, 2012) (“To establish obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.”).

F. Ground 10: Claims 1 and 19 would not have been obvious based on U.S. Patent No. 5,586,473 to Chou in view of Bailey

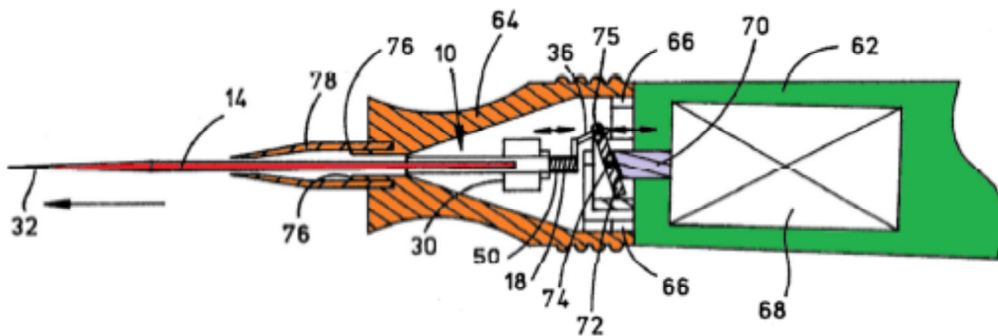
Petitioner asserts that Claims 1 and 19 are unpatentable as obvious under 35 U.S.C. § 103 Chou in view of Bailey. (Petition, pp. 57-59).

As presently understood, petitioner argues that it would have been obvious to a person of ordinary skill in the art to combine the diaphragm of Bailey with the tattoo device of Chou “to improve sanitation of a tattoo device.” (Petition p. 59). Petitioner's generalized and conclusory arguments about the combination of these references are fatally defective because they are unsupported, do not address all of the elements of claims 1 and 19 and do not comply with the exacting requirements of 37 C.F.R. § 104.

First, petitioners have failed to identify the “specific portions of the evidence that support the challenge.” 37 C.F.R. § 104(b)(5). Petitioner states that Chou is designed to provide “sanitary” tattoo devices to “improve sanitation of a tattoo device” (Petition p. 59), but identifies no specific portions of the Chou in support of that argument. Petitioners’ citation to the Stein Declaration (Stein

Declaration, ¶¶ 108-112) is unhelpful, since Stein offers only generalized and unsupported conclusions, rather than “identifying the specific portions of the [Chou reference] that support challenge.”

The only other substantive reference to Chou found in the petition or supporting Declaration is to Figure 5. (Petition, p. 57). As shown below. Petitioner present a highlighted version of that figure, without explanation as to the significance of the shaded portions:



Id. But Petitioner has nowhere explained **how** the Bailey diaphragm could be adapted to function in the apparatus of Chou shown above. Petitioner does not set forth any rationale as to how a person of ordinary skill in the art would understand, *e.g.*, (1) where the Bailey diaphragm should be located in the Chou apparatus, (2) how it should be configured, (3) how it would function in respect of the other elements of the Chou apparatus, (4) how it would yield predictable results or (5) how it would render all of the separate elements in Chou to allow simultaneous removal of the entire disposable module from the basic module. Because

petitioner has presented no evidence showing that the diaphragm of Bailey is even *capable* of being physically combined with the tattoo machine of Chou in a way that yields a predictable result *KSR* at 401; *DePuy Spine*, 567 F.3d at 1326, the arguments presented in Ground 10 should be denied.

Even beyond the evidentiary failures associated with the attempted combination of the Bailey diaphragm with Chou's apparatus, petitioner has not addressed the other elements of claims 1 and 19 that are not met by the combination of Bailey and Chou. Nowhere does Chou disclose a "disposable module" having a needle disposed therein, connectable to a needle drive. The only portion of the Chou apparatus taught as *optionally* disposable is the needle itself (Chou at col. 2, ll. 13-14); Petitioner does not direct the patent owner or the Board to any specific teachings of a "disposable module"⁴ By failing to "specify where each element of the claim is found in the prior art patents," Petitioner has failed to comply with 37 C.F.R. § 104.

⁴ In an embodiment Chou discloses -- as an alternative to needle disposal -- cleaning and sanitizing the *needle* prior to reuse. (Chou, col. 2, ll. 22-24) . But that is not a disclosure of a " disposable module" comprising other components in addition to the needle.

For the reasons set forth above in Grounds 4-9, petitioner has failed to adequately set forth the elements of obviousness in Ground 10, and its petition should be denied.

G. Ground 11: Claim 10 would not have been obvious based on Chou in view of Bailey and further in view of Thesis

Petitioner relies on Chou in view of Bailey as teaching all of the elements of Claim 10 (without any explanation of how all elements are taught) except for the limitation “sealing means disposed between the ink receiving portion and the basic module for preventing liquids from reaching the basic module”. (Petition p. 59). However, Chou in view of Bailey do not teach all of the elements of Claim 10 because there is no explanation as to how they do so, and so petitioner’s arguments fail to establish a *prima facie* case of obviousness. In addition, petitioner’s arguments are necessarily noncompliant with 37 C.F.R. § 104, since petitioner has not “specif[ied] where each element of the claim is found in the prior art patents” or “identif[ied] specific portions of the evidence that support the challenge,” 37 C.F.R. §§42.104(b)(4)-(5).

Petitioner nowhere identifies *how* Chou in view of Bailey and further in view of Theiss renders claim 10 of the ’530 patent obvious. Petitioner provides no explanation of: (1) whether the embodiments are capable of being combined, *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314 (Fed. Cir.

2009); (2) which components or structures are to be substituted, (3) how such substitution/combination would be made, (4) how the resulting apparatus would be configured, or (5) whether any the combination would yield predictable results. Nowhere has petitioner stated what motivation would prompt a person of ordinary skill in the art to combine the disclosures of Chou and Bailey and Theiss.

Petitioner's asserted grounds of obviousness are short and conclusory, because they do not specifically articulate the rationale underlying the assertions of obviousness as required by 37 C.F.R. § 42.104(b)(4). Petitioner thus fails to present a *prima facie* case of obviousness for Claim 10.

For all the reasons set forth above, petitioner's arguments with respect to claim 10 fail to establish a *prima facie* case of obviousness, and its petition should be denied.

VII. THE PETITION INCLUDES CONCLUSORY AND REDUNDANT PROPOSED GROUNDS OF REJECTIONS

As stated by the Board, “multiple grounds, which are presented in a redundant manner by a petitioner who makes no meaningful distinction between them, are contrary to the regulatory and statutory mandates, and therefore are not all entitled to consideration.” *See Liberty Mutual Insurance Co. v. Progressive Casualty Insurance Co.*, CBM2012-00003, Paper No. 7 at pg. 2 (Oct. 25, 2012). Here, petitioner has set forth redundant proposed grounds through its repeated use of multiple secondary references having essentially the same teaching to meet the same claim limitation. For instance, Ground 7 (Thiess in view of Trott), Ground 8 (Theiss in view of Stocking), and Ground 9 (Theiss in view of Proni) are all premised on the alleged obviousness of modifying Thiess’ disclosure of O-rings with various sealing elements from the multiple secondary references. The Petition does not articulate a meaningful distinction in terms of relative strengths and weaknesses with respect to applying the various combinations of Theiss and Chou to the claims. Accordingly, the obviousness grounds are redundant as to each other and as to the § 102 grounds, and the redundant grounds should not be entertained by the Board. *See Liberty Mutual Ins. Co.* at *2; *see also Oracle Corp. v. Clouding IP, LLC*, IPR2013–00088, Paper No. 13, at *4–5 (PTAB June 13, 2013).

Second, it is clear that the Declaration testimony provided with the Petition is merely conclusory with respect to how the prior art anticipates or renders obvious the claimed inventions the problems the prior art is expected to solve. (See *e.g.*, Stein Declaration, ¶¶71-108). For example, Stein declares the “teachings [of Theiss and Zhan] would have motivated one of ordinary skill in the art in 1999 to combine Theiss and Zhan in the manner suggested in claims 9 and 18,” without providing any underlying reasoning or data or the conclusory statement. (See Stein Declaration, ¶74). Many of the statements in the Stein declaration cite no supporting evidence, no underlying facts, and recite only general conclusions. Declaration testimony that is merely conclusory in nature, without providing any information on which the conclusions are drawn, should be given no weight and may be the basis for denying IPR. See *Monsanto Co. v. Pioneer Hi-Breed International, Inc.*, Case IPR2013-00022, Paper No. 43 * at 7 (PTAB April 11, 2013) (denying IPR on the basis that the Declaration submitted with the Request “fails to provide sufficient underlying data such that one of ordinary skill in the art would have a reasonable basis to believe that [the conclusions therein]...are correct); 37 C.F.R. § 42.65(a) (“Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight”); 37 C.F.R. § 42.104(b)(5) (“The Board may exclude or give no weight to

the evidence where a party has failed to...identify specific portions of the evidence that support the challenge.”).

The Petition is based on unsubstantiated conclusory statements that should be given no weight.

VIII. CONCLUSION

For the reasons set forth above, it is respectfully submitted that the Petition should be denied. The Petition fails to establish a reasonable likelihood that any of claims of the '530 patent are anticipated by the Adler, Theiss or Zhan references, or would have been obvious to a person of ordinary skill in the art based on any of the combinations suggested by Petitioner. For the foregoing reasons, the patent owner respectfully submits the petition should be denied.

Date: February 19, 2014

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing MT. DERM GMBH'S
PRELIMINARY RESPONSE TO PETITION FOR *INTER PARTES* REVIEW
UNDER 37 C.F.R § 42.107 was served electronically via overnight mail and e-
mail on February 19, 2014, in their entirety on the following:

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