Filed on behalf of Bomtech Electronics, Co. Ltd.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Bomtech Electronics, Co. Ltd. Petitioner

v.

Medium-Tech Medizingeräte GmbH Patent Owner

Case No. To be Assigned U.S. Patent No. 6,505,530

DECLARATION OF MATTHEW STEIN

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I, Matthew Stein, hereby declare as follows:

I. BACKGROUND

- 1. I am over 18 years of age and otherwise competent to make this declaration.
- 2. I have been retained as an expert witness to provide testimony on behalf of Bomtech Electronics, Co. Ltd. ("Bomtech") as a part of an *inter partes* review ("IPR") directed to U.S. Patent No. 6,505,530 (Ex. 1002, "the '530 Patent"). I am being compensated for my time in connection with this IPR at a rate of \$250 per hour.
- 3. I have been asked to provide my opinion relative to the patentability of claims 1–20 ("the challenged claims") of the '530 Patent. The '530 Patent includes three independent claims. Independent claims 1 and 10 of the '530 Patent are directed to an ink application device for tattooing or for making permanent make-up comprising a basic module and a sterilized disposable module. Independent claim 19 is drawn to a method of using an ink application device of claim 1. I have reviewed the following documents:
 - U.S. Patent No. 6,505,530 ("Ex. 1002")
 - U.S. Patent No. 6,033,421 to Theiss ("Ex. 1005")
 - Taiwan Patent No. TW326643B to Zhan ("Ex. 1006")
 - U.S. Patent No. 4,796,624 to Trott ("Ex. 1009")

- U.S. Patent No. 5,704,914 to Stocking ("Ex. 1010")
- U.S. Patent No. 5,580,030 to Proni ("Ex. 1011")
- U.S. Patent No. 5,472,449 to Chou ("Ex. 1017")
- U.S. Patent No. 4,582,060 to Bailey ("Ex. 1008")
- File History of U.S. Patent No. 6,505,530 ("Ex. 1015")
- 4. My opinions are based on the documents listed above, and my general understanding of the field of mechanical engineering, before October 1999, which I understand to be before the earliest possible priority of the '530 Patent. Claims 10–18 of the '530 Patent are entitled to a priority date that is no earlier than Feb. 12, 2002. My analysis would be the same regardless of which date is used, and the earliest possible priority date is used throughout this document.
- 5. I have considered the disclosure of the '530 Patent in light of general knowledge in the art in October 1999. Further, in forming the opinion expressed herein, I have given claims terms their broadest reasonable meaning as it would be construed by one of ordinary skill in the art in view of the disclosure of the '530 Patent.

II. MY EXPERIENCE AND QUALIFICATIONS

6. I am a National Merit Scholar and was awarded a Bachelor of Science in Mechanical Engineering at the Massachusetts Institute of Technology ("MIT") in June of 1978. After graduating from MIT, I have worked as a design engineer

in a variety of fields, including the design of various medical filters, sterile medical devices with needles and/or ports for transmitting medicines and/or bodily fluids via hollow sterile needles, and a tattooing device for the application of permanent eyeliner, which included modular disposable sterilized tattoo needle cartridges for reducing the likelihood of transmission of blood-borne diseases via re-used or sterilized needles. Over the prior 30+ years, I have designed scores of different products, several of which went on to become the top selling product in the world within their respective fields. I am a named inventor on twelve U.S. patents. My design experience also includes working for such other well-known companies as Hewlett Packard, Seagate, Duraflame, and IGT.

7. The opinions I have formed are from the perspective of a person of ordinary skill in the art. I have direct experience with tattoo design, having spent two years as a design engineer working for Healthtek Corporation, located in Nevada City, CA, designing and developing medical products, including the above mentioned tattoo device. Additionally, from the fall of 1986 through the spring of 1994 I was director of engineering for Haws Company where I designed numerous products involved with fluid flows, safety equipment and chemical decontamination, often dealing directly with various fluid sealing applications, including the use of elastomeric diaphragms.

- 8. My extensive engineering background, comprising a Bachelor of Science in Mechanical Engineering from MIT, combined with more than 30 years of direct experience with product design, qualifies me as an expert witness well skilled in the appropriate field of concern, and capable of expertly evaluating the alleged prior art with respect to the '530 Patent.
- 9. Compensation for my expert opinions, analysis, testimony, and reports is \$250 per hour, which is my standard rate for matters of this nature. My compensation is in no way dependent upon the outcome of this legal matter.
- 10. Additionally, I have attached my resume hereto that sets forth the summary of my qualifications. Ex. 1022. Included is a list of U.S. patents naming me as an inventor, an engineering and design client list from the prior 15 years, and a list of my publications.

III. A PERSON OF ORDINARY SKILL IN THE ART

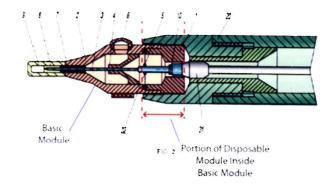
- 11. I understand that a person having ordinary skill in the art is one who is presumed to be aware of all the pertinent art, who approaches problems consistent with the conventional wisdom in the art, and is a person having ordinary creativity.
- 12. A person having ordinary skill in the relevant art would have the knowledge of cosmetic or medical devices, particularly cosmetic or medical devices containing a needle. A person having ordinary skill in the art at the time of the '530 Patent invention would be a mechanical engineer or the like familiar with

mechanism design and fluidic handling mechanisms, having a Bachelor's degree in engineering or its equivalent and about two to four years of experience.

IV. THE '530 PATENT

A. SUBJECT MATTER OF THE '530 PATENT

- 13. The '530 Patent is directed to an ink application device for tattooing or for making permanent make-up. Ex. 1002.
- 14. The '530 Patent uses the terms "tattoo," "permanent eyeliner" and "permanent make-up" interchangeably. Ex. 1002, col. 1, lines 11-15 and col. 2, lines 11-14. A person having ordinary skill in the art would understand that a tattoo device (or permanent eyeliner or permanent make-up device) can perform both tattoo and permanent make-ups without any changes in mechanical design. Thus, a tattoo device and a permanent make-up device are the same, at least in the context of this Petition.
- 15. The '530 Patent states that the ink application device "achieves the special hygienic conditions necessary for applying tattoos or PMUs with simple handling procedures to ensure sterility of the elements contacting the customer's skin." Ex. 1002, col. 3, lines 10–13. Figure 2 of the '530 Patent (reproduced below, annotations added by the Patent Owner) illustrates one embodiment of the ink application device for tattooing or for making permanent make-up.



B. CLAIMS OF THE '530 PATENT

- 16. I understand that claims 1–20 are challenged in Bomtech's Petition for *inter partes* review (IPR). I have reviewed the challenged claims as part of my review of the '530 Patent.
- 17. The claims of the '530 Patent include two independent claims (*i.e.*, claims 1 and 10) directed to an ink application device and one additional independent claim (*i.e.*, claim 19) directed to a method of using an ink application device of claim 1.

C. PROSECUTION HISTORY OF THE '530 PATENT

- 18. I understand that the '530 Patent was filed as a continuation of Ser. No. 09/671,650, filed on Sep. 28, 2000 (now issued as U.S. 6,345,553) which claims priority to German Patent Application No. DE 299 19 199 U1, filed on Oct. 22, 1999. I have reviewed the entire file wrapper for the '530 Patent (Ex. 1017).
- 19. Claims 9 and 18 are dependent claims reciting a "diaphragm". I understand that the feature, "diaphragm" was the only limitation that was found to be patentable over the cited art by U.S. Patent Office during prosecution of its

parent application (*i.e.*, the '553 Patent) of the '530 Patent. Thus, invalidity of the limitation, *i.e.*, a "diaphragm," is the main focus of this declaration, though other claim language is also addressed for completeness.

V. PRIOR ART CITED IN PETITION

- 20. The prior art discussed in this Declaration is directed to medical and cosmetic devices. More particularly, each cited reference is directed to devices used for applying a needle directly to the skin (either to apply ink or for a medical purpose).
- 21. Tattoo/permanent make-up devices use a needle to introduce a pigment beneath the skin and the operation requires perforation of the skin. Ex, 1002, col. 1, lines 5–9. Needle-containing medical devices use the same principle, *i.e.*, using a needle to perforate the skin for injection or withdrawal of bodily fluids. Therefore, the design principles of tattoo/permanent make-up devices and needle-containing medical devices are quite similar and related.
- 22. I have provided summaries of the prior art references below, and explained how the relevant portions of the prior art reference would have been understood by one skilled in the art in 1999.

A. THEISS

- 23. I have reviewed U.S. 6,033,421 ("Theiss," Ex. 1005). I understand that Theiss is prior art to the '530 Patent.
- 24. Theiss discloses an ink application device comprising a basic module 10 (colored GREEN and LIGHT GREEN) and a disposable module 12 (colored ORANGE and YELLOW). See Ex. 1005 and Figure 3 of Theiss below. The basic module 10 comprises a handle and an integrated needle drive 16. See Ex. 1005 and Figure 3 of Theiss below. Figure 3 of Theiss discloses a disposable module 12 comprising: a housing 44 (colored ORANGE), a needle (not shown in the figure, but described in the detailed description), a needle nozzle 54, another end of the sterilized disposable module having a portion that is connectable to the integrated needle drive 34, sealing means 48, 50, 58, 60 (colored PINK), and a bearing element 36 (colored LIGHT YELLOW) disposed inside the housing and supporting the needle in the housing. See Ex. 1005 and Figure 3 of Theiss below.

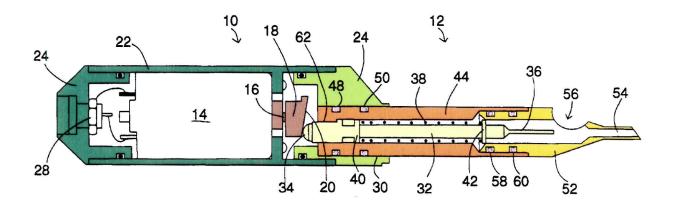
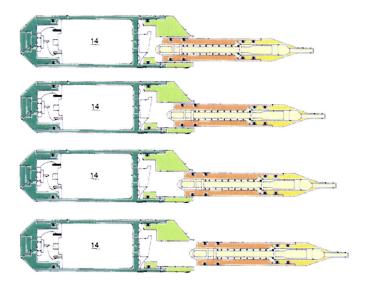


FIG. 3 of Theiss



- 25. The needle, the sealing means (colored PINK), the bearing element (colored LIGHT YELLOW) and the housing (colored ORANGE) form a disposable module that is detachable from the basic module (colored GREEN and LIGHT GREEN). As stated by Theiss, the apparatus is designed to be easily sterilized by providing a disposable module. Ex. 1005, col. 3, lines 10–12.
- 26. As explained in more detail below, Theiss also discloses standard features that a person of ordinary skill in the art would expect to be a part of a tattoo device with a disposable needle module, *i.e.*, "the ink receiving portion has a volume sufficient for one application of ink" (*i.e.*, the '530 Patent, claims 2 and 11), "the needle disposed at least partially in said ink receiving portion" (*i.e.*, the '530 Patent, claims 3 and 12), "the portion that can contact the integrated needle drive is the needle shaft" (*i.e.*, the '530 Patent, claims 7 and 16), "the needle shaft

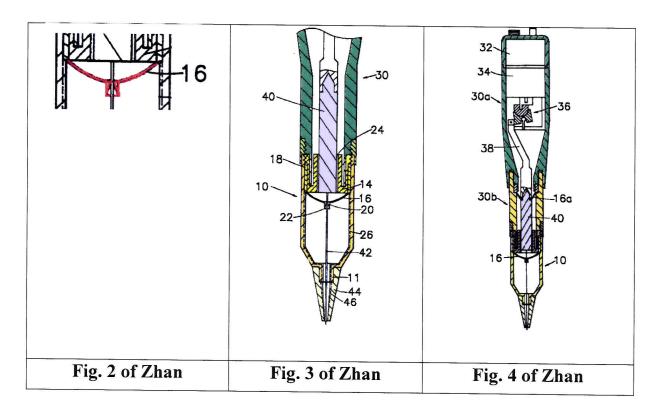
is cylindrical" (*i.e.*, the '530 Patent, claims 8 and 17), "a diaphragm disposed between the ink receiving portion and the basic module" (*i.e.*, the '530 Patent, claims 9 and 18), and "replacing another disposable module on the basic module to allow another application of ink" (*i.e.*, the '530 Patent, claim 20). See Ex. 1005 and Figure 3.

- 27. With regard to the functional limitation of claims 2 and 11 of the '530 Patent (*i.e.*, "the ink tank having a volume sufficient for one application of ink"), a person having ordinary skill would understand that the ink tank of Theiss has a volume sufficient for one application of ink because an ordinarily skill person would know an ink tank is necessary for operation without interruption.
- 28. With regard to the limitation of claims 3 and 12, Theiss discloses the needle disposed at least partially in said ink tank so that needle movement transports ink through the needle nozzle. Ex. 1005, col. 4, lines 45–48, and Figure 3.
- 29. With regard to the limitation of claims 7 and 16, Figure 3 of Theiss illustrates needle bar 32 and cam follower 34 (corresponding to the needle shaft) that is connectable to cam 18 (corresponding to a needle drive). Ex. 1005, Figure 3.
- 30. With regard to the limitation of claims 8 and 17, Figure 3 of Theiss illustrates needle bar 32 is cylindrical. Ex. 1005.

- 31. With regard to the limitation of claims 9 and 18 reciting a "diaphragm," Figure 3 of Theiss illustrates O-rings 48, 50, 58, 60. Ex. 1005, col. 5, lines 25-29 and Figure 3.
- 32. With regard to the functional limitation of claim 20 of the '530 Patent, *i.e.*, Theiss discloses that the driven grip tube (corresponding to a disposable module) is "designed to be easily insertable into the receiving bore of the drive unit housing." Ex. 1005, col. 2, lines 17–21.

B. ZHAN

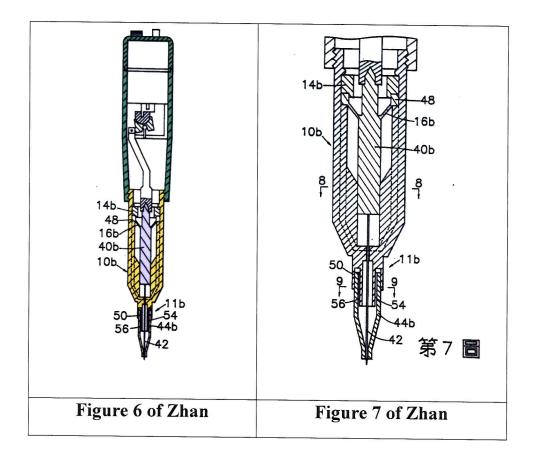
33. I have reviewed TW326643B ("Zhan," Ex. 1006). I understand that Zhan is prior art to the '530 Patent.



- 34. Zhan relates to an ink application device containing a cartridge type pigment tube, as shown in Figures 2, 3 and 4 and described in the detailed description. Ex. 1006.
- 35. The ink application device of Zhan comprises a basic module 30 (colored GREEN) and a disposable module 10 (colored YELLOW and LIGHT YELLOW). Ex. 1006 and Figures 3 and 4. The basic module 30 comprises a handle and an integrated needle drive 38. Ex. 1006 and Figures 3 and 4. Figures 3 and 4 of Zhan discloses a disposable module 10 comprising: a housing, a needle 42, a needle nozzle, another end 40 of the sterilized disposable module having a portion that is connectable to the integrated needle drive 38, a diaphragm 16 (see element 16 of Figure 2, colored RED), and a bearing element 14 (colored YELLOW) disposed inside the housing and supporting the needle in the housing. Ex. 1006 and Figures 3 and 4.
- 36. Note the diaphragm 16 is disposed between an ink tank and the basic module 30 (colored GREEN). Ex. 1006 and Figures 2, 3 and 4.
- 37. As explained in more detail below, Zhan also discloses standard features that a person of ordinary skill in the art would expect to be a part of a tattoo device with a disposable needle module, *i.e.*, "the ink receiving portion has a volume sufficient for one application of ink" (*i.e.*, the '530 Patent, claims 2 and 11), "the needle disposed at least partially in said ink receiving portion" (*i.e.*, the

'530 Patent, claims 3 and 12), "the portion that can contact the integrated needle drive is the needle shaft" (*i.e.*, the '530 Patent, claims 7 and 16), "the needle shaft is cylindrical" (*i.e.*, the '530 Patent, claims 8 and 17), "a diaphragm disposed between the ink receiving portion and the basic module" (*i.e.*, the '530 Patent, claims 9 and 18), and "replacing another disposable module on the basic module to allow another application of ink" (*i.e.*, the '530 Patent, claim 20). See Ex. 1005 and Figures 2, 3 and 4.

38. In addition, Zhan further discloses that "the flexible seal element 16b is positioned inside the dye cartridge 10b, and the flexible seal element 16b is on top of the clamping needle holder... and the flexible seal element 16b is stretchable, allowing it to oscillate up and down along with the reciprocating movement of the clamping needle holder 40b." Ex. 1006, English translation, p. 7, lines 25–30, and Figures 6 and 7. In other words, Zhan teaches the use of a "diaphragm" sealing element.



- 39. With regard to the functional limitation of claim 2 of the '530 Patent, Zhan discloses that "allowing pre-filled sufficient dye inside the (eyebrow) tattooing machine, eliminating the needs to interrupt the tattooing operation for dye refills." Ex. 1006, English translation, p. 3, lines 13–15 (emphasis added).
- 40. With regard to the limitation of claims 3 and 12, Figures 3 and 4 of Zhan above illustrate a needle 42 disposed at least partially in said ink tank. Ex. 1006 and Figures 3 and 4.
- 41. With regard to the limitation of claims 7 and 16, Figures 3 and 4 of Zhan illustrate a clamping needle holder 40 (colored PURPLE) that contacts an integrated needle drive. Ex. 1006, Figures 3 and 4.

- 42. With regard to the limitation of claims 8 and 17, Figures 3 and 4 of Zhan illustrate a needle holder 40 (colored PURPLE) which has a cylindrical shape. Ex. 1006, Figures 3 and 4.
- 43. With regard to the limitation of claims 9 and 18, Figures 2, 3, 4, 5, 6 and 7 of Zhan illustrate a diaphragm 16, 16a, 16b (colored RED in Figure 2 above) blocking backflow of dye and body fluid into the main body 30. Ex. 1006, Figures 2, 3, 4, 5, 6 and 7.
- 44. With regard to the functional limitation of claim 20, Zhan discloses a disposable module that "can be detached from the main body 30 of the tattooing machine." Ex. 1006, English translation, p. 6, lines 27–30 and Figures 3, 4, 5, 6 and 7.

C. TROTT

- 45. I have reviewed U.S. Patent No. 4,796,624 ("Trott," Ex. 1009). I understand that Trott is prior art to the '530 Patent.
- 46. Trott relates to a disposable ink application device, as shown in Figure 4 and described in the detailed description. Ex. 1009. Trott discloses a "seal cooperates with the reciprocal coupling means for sealing the reservoir from the interior cavity of the body member." Ex. 1009, col. 2, lines 58–61.

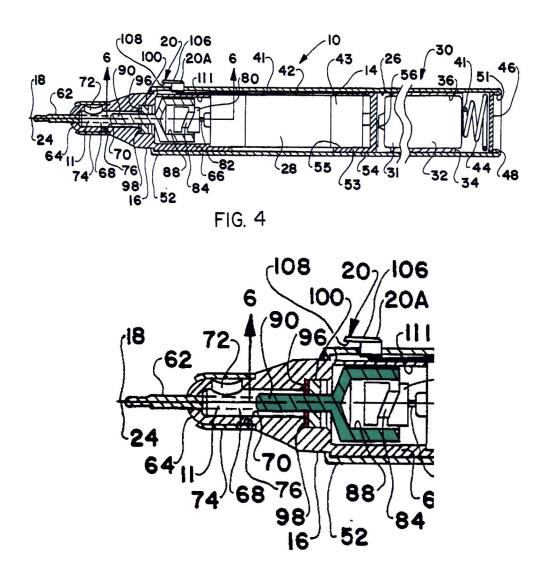


Figure 4 of Trott

47. Of particular note, Figure 4 of Trott illustrates an ink application device comprising a seal 96 (colored RED) that corresponds to a diaphragm of the '530 Patent. Ex. 1009, Figure 4. A "seal" is a generic term encompassing various structures designed to prevent leakage, and the generic term encompasses a diaphragm. The seal is disposed between the ink tank 68 and the basic module (not shown in Figure 4 above).

D. STOCKING

- 48. I have reviewed U.S. Patent No. 5,704,914 ("Stocking," Ex. 1010). I understand that Stocking is prior art to the '530 Patent.
- 49. Stocking relates to a catheter assembly containing a "diaphragm" for preventing the spillage of a biological liquid. Ex. 1010, col. 1, lines 9–12. See also Figure 4 reproduced below. Ex. 1008.

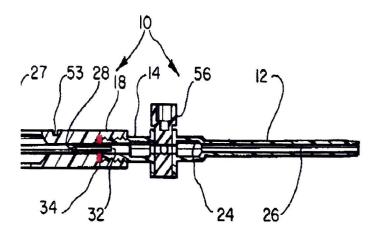


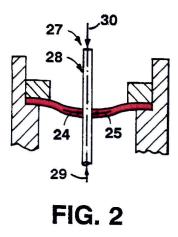
Fig. 4 of Stocking

50. Figure 4 of Stocking discloses a flexible, resilient diaphragm 34 to forms a liquid sealing means in a catheter assembly. Ex. 1010, col. 4, lines 24–26.

E. PRONI

51. I have reviewed U.S. Patent No. 5,580,030 ("Proni," Ex. 1011). I understand that Proni is prior art to the '530 Patent.

52. Proni relates to a "diaphragm" fluid flow control assembly which seals against fluid leakage. Ex. 1011, col. 1, lines 5–8. See also Figure 2 reproduced below. Ex. 1011.



53. Figure 2 of Proni discloses a self-sealing, fluid-tight, perforated "diaphragm" easily penetrable by a moderately sharp or blunt-ended plastic tube or needle to form a fluid-tight seal. Ex. 1009, col. 1, lines 59–63.

F. CHOU

- 54. I have reviewed U.S. Patent No. 5,472,449 ("Chou," Ex. 1017). I understand that Chou is prior art to the '530 Patent.
- 55. I understand that Chou relates to an ink application device. Ex. 1017. I also understand that Chou was cited by U.S. Patent Office and the Patent Owner identified two arguably distinguishable limitations over Chou, *i.e.*, (1) the needle being movable relative to the outer housing as recited in claim 1 and (2)

simultaneously removing the entire disposable module from the basic module as recited in claim 19. Ex. 1010.

56. I understand that Chou relates to an ink application device comprising disposable parts, as shown in Figure 7 and described in the detailed description.

Ex. 1017.

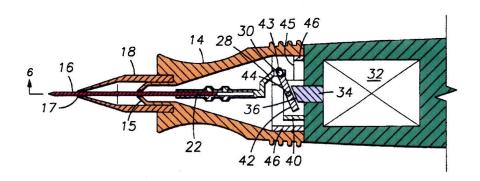


Figure 7 of Chou

G. BAILEY

- 57. I have reviewed U.S. Patent No. 4,582,060 ("Bailey," Ex. 1008). I understand that Bailey is prior art to the '530 Patent.
- 58. I understand that Bailey relates to a tattoo device comprising a disposable module, as shown in Figure 1 and described in the detailed description. Ex. 1008.

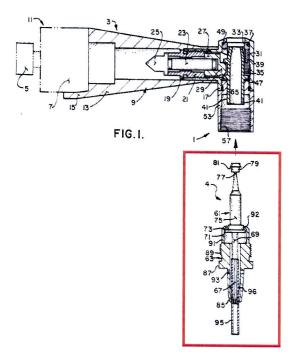


Figure 1 of Bailey

59. Figure 1 of Bailey discloses a needle/cone assembly 4 (shown in RED box) removably attached to the basic module. Ex. 1008

VI. THE PRIOR ART RELATIVE TO CLAIMS OF THE '530 PATENT

- 60. I have reviewed claims 1–20 of the '530 Patent.
- 61. In my opinion, in view of the prior art references cited above, each element of claims 1–3 and 7–20 in the '530 Patent is disclosed or taught by Theiss or Zhan. Further, those references would have taught a person of ordinary skill how to make and use devices within the scope of those claims. In addition, each of claims 1–3 and 7–20 would have been obvious to a person of ordinary skill in light of the teachings of Theiss, Zhan, Trott, Stocking, Proni, Chou and Bailey, as explained in detail below.

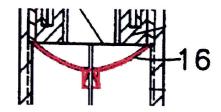
A. THEISS

- 62. Theiss is in the same field of endeavor as the '530 Patent, *i.e.*, an ink application device or tattoo machine. Theiss and the '530 Patent are designed to address the same known problem in using a medical/cosmetic device applied to the customer's skin, *i.e.*, providing a sanitary ink application device, particularly with a disposable module. Ex. 1005, col. 4, lines 12–13. In other words, Theiss is directed to the same subject matter of the '530 Patent.
- 63. As shown in ¶¶ 24–26 of this document, Theiss discloses all limitations of independent claims 1, 10 and 19 including means for allowing simultaneous removal. Thus, Theiss anticipates claims 1, 10 and 19.
- 64. With regard to the element, "diaphragm" of claims 9 and 18, Theiss discloses O-rings 48, 50, 56, 58 disposed in a disposable module to substantially eliminate the transmission of fluids into the drive unit. Ex. 1005, col. 5, lines 26–29 and Fig. 3 Insofar as the "diaphragm" of claims 9 and 18 is means "a resilient structure ensuring substantially no ink leakage from the ink tank of the disposable module", Theiss anticipates dependent claims 9 and 18. Furthermore, the disclosure of Theiss would have enabled a person of ordinary skill in the art to practice the invention of claims 9 and 18, without undue experimentation.
- 65. As shown in $\P\P$ 28–32 of this document, Theiss discloses further limitations of dependent claims 2, 3, 7, 8, 11, 12, 16, 17 and 20. Thus, Theiss

anticipates the dependent claims. Likewise, the disclosure of Theiss would have enabled a person of ordinary skill in the art to practice the invention of claims 2, 3, 7, 8, 11, 12, 16, 17 and 20 without undue experimentation.

B. ZHAN

- 66. Zhan is in the same field of endeavor as the '530 Patent, *i.e.*, an ink application device. Zhan and the '530 Patent are designed to address the same known problem in using a medical/cosmetic device applied to the customer's skin, *i.e.*, providing a sanitary ink application device, particularly with a disposable module containing a diaphragm. Ex. 1006, English translation, p. 5, lines 13–15. In other words, Zhan is directed to the same subject matter of the '530 Patent.
- 67. As shown in ¶¶ 35–38 of this document, Zhan discloses each element of the independent claims. Ex. 1017. Thus, Zhan anticipates claims 1, 10 and 18.
- 68. With regard to the element, "diaphragm" of claims 9 and 18, Zhan discloses a flexible sealing element 16 (colored RED in Figure 2) designed to block backflow of the body fluid and prevent virus transmission, as shown in Figure 2 reproduced below. Ex. 1006, p. 3, lines 22–28. The flexible sealing element is essentially the same as the diaphragm described in the '530 Patent.



- 69. Zhan discloses a tattoo device comprising a disposable module with a "diaphragm" disposed between an ink tank and the basic module. Thus, Zhan anticipates dependent claims 9 and 18. Furthermore, the disclosure of Zhan would have enabled a person of ordinary skill in the art to practice the invention of claims 9 and 18, without undue experimentation.
- 70. As shown in ¶¶ 39–44 of this document, Zhan also anticipates dependent claims 2, 3, 7, 8, 11–18 and 20. Likewise, the disclosure of Zhan would have enabled a person of ordinary skill in the art to practice the invention of claims 2, 3, 7, 8, 11–18 and 20, without undue experimentation.

C. THEISS AND ZHAN

- 71. As mentioned above, Theiss and Zhan are directed to the same subject matter of the '530 Patent.
- 72. Even if Theiss does not disclose a "diaphragm", Zhan does, and it would have been obvious to one of ordinary skill in the art in 1999 to combine Theiss and Zhan to yield the ink application device comprising a disposable module with a diaphragm as recited in challenged claims 9 and 18.

- 73. It would have been obvious to one skilled in the art to incorporate the "diaphragm" of Zhan into the tattoo device of Theiss because the common primary goal of Theiss and Zhan is to prevent contamination.
- 74. Each of Thiess and Zhan teaches use of O-rings and a diaphragm to minimize the transmission of fluids into the basic module. The teachings 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. The combination would result in achieving sterility of the tattoo device with predictable and expected results.
- 75. The suggested combination amounts to switching interchangeable elements (*i.e.*, O-rings and a diaphragm) with each performing the same function (*i.e.*, sealing) to yield no more than predictable results (*i.e.*, prevention of contamination).
 - 76. Nothing in Thiess or Zhan teaches away from their combination.
- 77. Based on the above, the ink application device of claims 9 and 18 would have been obvious to one skilled in the art in 1999.

D. THEISS AND TROTT

- 78. As mentioned above, Theiss and Trott are directed to the same subject matter of the '530 Patent.
- 79. Even if Theiss does not disclose a "diaphragm", it would have been obvious to one of ordinary skill in the art in 1999 to combine Theiss and Trott to

yield the ink application device comprising a disposable module with an elastomeric seal to perform the same function as the diaphragm as recited in challenged claims 9 and 18.

- 80. It would have been obvious to one skilled in the art in 1999 to incorporate the seal of Trott into the tattoo device of Theiss because the common primary goal of Theiss and Trott is to prevent contamination.
- 81. Thiess and Trott teach use of O-rings and a seal to minimize the transmission of fluids into the basic module. The teachings would have motivated one of ordinary skill in the art in 1999 to combine Theiss and Trott in the manner suggested in claims 9 and 18. The combination would result in sterility of the tattoo device, but not provide any unpredictable or unexpected results.
- 82. The suggested combination amounts to switching known interchangeable elements (*i.e.*, O-rings and a seal) with each performing the same function (*i.e.*, sealing) to yield no more than predictable results (*i.e.*, prevention of contamination).
 - 83. Nothing in Thiess or Trott teaches away from their combination.
- 84. Based on the above, the ink application device of claims 9 and 18 would have been obvious to one skilled in the art in 1999.

E. THEISS AND STOCKING

- 85. Stocking is in the same field of endeavor as the '530 Patent, *i.e.*, a device containing a diaphragm to prevent the spillage of a biological liquid.

 Stocking is designed to address the same known problem in using a medical/cosmetic device applied to the customer's skin, *i.e.*, providing a sanitary device by including a diaphragm. Stocking is analogous art to the subject matter of the '530 Patent.
- 86. It would have been obvious to one of ordinary skill in the art in 1999 to combine Theiss and Stocking to yield the ink application device comprising a disposable module with a diaphragm as recited in challenged claims 9 and 18.
- 87. It would have been obvious to one skilled in the art in 1999 to incorporate the "diaphragm" of Stocking into the tattoo device of Theiss because the common primary goal of Theiss and Stocking is to prevent contamination.
- 88. The suggested combination amounts to switching known interchangeable elements (*i.e.*, O-rings and a diaphragm) with each performing the same function (*i.e.*, sealing) to yield no more than predictable results (*i.e.*, prevention of contamination).
 - 89. Nothing in Thiess or Stocking teaches away from their combination.
- 90. Based on the above, the ink application device of claims 9 and 18 would have been obvious to one skilled in the art in 1999.

F. THEISS AND PRONI

- 91. Proni is in the same field of endeavor as the '530 Patent, *i.e.*, a device containing a diaphragm to provide a fluid-tight seal. Proni is designed to address the same known problem in using a medical/cosmetic device applied to the customer's skin, *i.e.*, providing a sanitary device including a diaphragm. Proni is analogous art to the subject matter of the '530 Patent.
- 92. Even if Theiss does not disclose a "diaphragm", it would have been obvious to one of ordinary skill in the art in 1999 to combine Theiss and Proni to yield the ink application device comprising a disposable module with a diaphragm as recited in challenged claims 9 and 18.
- 93. It would have been obvious to one skilled in the art in 1999 to incorporate the diaphragm of Proni into the tattoo device of Theiss because the common primary goal of Theiss and Proni is to prevent contamination.
- 94. The suggested combination amounts to switching known interchangeable elements (*i.e.*, O-rings and a diaphragm) with each performing the same function (*i.e.*, sealing) to yield no more than predictable results (*i.e.*, prevention of contamination).
 - 95. Nothing in Thiess and Proni teaches away from their combination.
- 96. Based on the above, the ink application device of claims 9 and 18 would have been obvious to one skilled in the art in 1999.

G. CHOU AND BAILEY

- 97. Chou and Bailey are in the same field of endeavor as the '530 Patent, *i.e.*, a tattoo device containing a disposable module. Both Chou and Bailey are designed to address the same known problem in using a tattoo device applied to the customer's skin, *i.e.*, providing a sanitary tattoo device. Chou and Bailey are analogous art to the subject matter of the '530 Patent.
- 98. It would have been obvious to one of ordinary skill in the art in 1999 to combine Chou and Bailey to yield the ink application device comprising a disposable module as recited in challenged claims 1 and 19.
- 99. It would have been obvious to one skilled in the art in 1999 to incorporate the disposable module of Bailey into the tattoo device of Chou to achieve the common primary goal of preventing contamination.
- 100. The suggested combination amounts to arranging known elements (*i.e.*, disposable parts and a disposable assembly) with each performing the same function (*i.e.*, replacement of a needle unit) to yield no more than predictable results (*i.e.*, easy replacement of a needle unit to achieve prevention of contamination).
 - 101. Nothing in Chou or Bailey teaches away from their combination.
- 102. Based on the above, the ink application device of claims 1 and 19 would have been obvious to one skilled in the art in 1999.

H. CHOU, BAILEY AND THEISS

- 103. As discussed above, Chou, Bailey and Theiss all are analogous art to the subject matter of the '530 Patent.
- 104. It would have been obvious to one of ordinary skill in the art in 1999 to combine Chou, Bailey and Theiss to yield the ink application device comprising a disposable module comprising sealing means as recited in claim 10.
- 105. It would have been obvious to one skilled in the art in 1999 to incorporate the sealing means of Theiss into the tattoo device of Chou and Bailey to achieve the common primary goal of preventing contamination.
- 106. The suggested combination amounts to arranging known elements (*i.e.*, disposable parts and a disposable assembly) with each performing the same function (*i.e.*, replacement of a needle unit) to yield no more than predictable results (*i.e.*, easy replacement of a needle unit to achieve prevention of contamination).
- 107. Nothing in Chou, Bailey or Theiss teaches away from their combination.
- 108. Based on the above, the ink application device of claim 10 would have been obvious to one skilled in the art in 1999.

* * *

I, Mathew Stein, declare under penalty of perjury of the laws of the United States, that the foregoing is true and correct.

Executed this 7th day of November, 2013 in Truckee, California.