UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, DC

Before the Honorable Charles E. Bullock
Chief Administrative Law Judge

In the Matter of

CERTAIN INK APPLICATION DEVICES AND COMPONENTS THEREOF AND METHODS OF USING THE SAME

Investigation No. 337-TA-832

COMPLAINANTS' INITIAL MARKMAN BRIEF

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Pursuant to Order No. 9, Complainants MT. Derm GmbH and Nouveau Cosmetique USA, Inc. ("Complainants") submit their Initial Claim Construction Brief.

I. INTRODUCTION

The parties dispute the proper construction of four claim terms of U.S. Patent No. 6,505,530 ("the '530 Patent"). In the case of each disputed term, Complainants present herein proposed constructions that align with the specification and prosecution history and reflect the understanding of one of ordinary skill in the art.

Respondent T-Tech Tattoo, Inc. ("T-Tech") has proposed improper constructions for the disputed terms that unduly restrict the scope of the claims by importing limitations into the claims – limitations for the most part not even found in the specification. T-Tech's flawed constructions exclude the embodiments disclosed in the '530 Patent, and are legally flawed and should be rejected.

Complainants and the OUII Staff ("Staff") have reached agreement on one of the terms in dispute, but the Staff has proposed its own construction for the three remaining terms. Notwithstanding, Complainants' proposals for these terms should be adopted because the constructions offered by Complainants are consistent with, and supported by, the intrinsic evidence including the claims, the specification, the prosecution history, and the understanding of one of ordinary skill in the art.

For all these reasons and for the reasons provided below, Complainants' proposed constructions should be adopted.

II. BACKGROUND

A. Background of Relevant Technology

The '530 Patent relates to devices for applying ink to the skin for tattooing or permanent makeup procedures. These devices are conventionally referred to as "tattoo machines," and their

basic purpose is to inject ink, dye, or some other marking fluid below the surface of the skin so that the ink is retained in the skin and that the design formed by the ink is visible.

Tattoo machines are typically constructed with some form of needle that will penetrate the skin while conveying a quantity of ink beneath the skin surface. A mechanism is provided to drive the needle in a reciprocating fashion such that the needle repeatedly punctures the skin and the ink is injected under the surface. Typically this would include a small electric motor and mechanical linkage that converts the rotatory motion of the motor into the reciprocating motion needed to drive the needle.

The process of applying tattoos and permanent makeup can pose significant health risks. The repeated puncturing of the skin by the reciprocating needle in a tattooing procedure results in the release of blood and other bodily fluids. Exposure to these fluids presents a potential for components of the tattoo machine to become contaminated during use, thereby exposing subsequent customers to these bodily fluids. If appropriate steps are not taken to either replace or sanitize the potentially contaminated components, the tattoo machine may inadvertently transmit infectious diseases such as HIV and hepatitis to customers receiving tattoos or permanent makeup procedures. (See Exh. A, Declaration of David L. Trumper, Ph.D. Regarding Claim Construction Issues Concerning U.S. Patent No. 6,505,530, hereinafter "Trumper Decl.," at ¶¶ 23-25.)

B. Brief Overview of U.S. Patent No. 6,505,530

The '530 Patent (attached as Exh. C), entitled "Ink Application Device for Tattooing or for Making Permanent Make-up," issued on January 14, 2003. Claims 1-3, 7, 8, 19 and 20 of the '530 Patent are asserted against T-Tech in this Investigation.

The application for the '530 Patent (Application Serial No. 10/072,991) was filed on February 12, 2002 as a continuation of an earlier filed application. That application, Application

Serial No. 09/671,553, was filed on September 28, 2000 and ultimately issued as U.S. Patent No. 6,345,553 ("the '553 Patent") on February 12, 2002.[1] Both the '530 Patent and the '553 Patent claim priority to a German application (DE 299 19 199 U) filed October 22, 1999. The named inventors of the '553 Patent and '530 Patent are Frank Adler, Walter Lisec, and Gerhard Turk.

The disclosure of the '530 Patent includes a unique disposable needle cartridge design for an ink application device, such as the type used for tattooing or applying permanent makeup.

Due to these hygienic concerns, certain parts of the tattoo machine, including the needle, are removed and disposed after each use. Other parts that could potentially become contaminated must be disassembled in order to carefully clean and sterilize them before reassembling the components for another tattooing procedure. This process of disassembling multiple components of the tattoo machine after each use, cleaning and sterilizing the contaminated reusable parts, replacing the disposable needle, and reassembling all the components for use with another customer entailed a considerable amount of time, particularly when multiple tattoo procedures are performed during the course of a day. Also, the user was required to expend considerable effort to ensure that all the reusable parts were properly decontaminated and sanitized to ensure that subsequent customers were not exposed to contagions from another's bodily fluids. ('530 Patent at 1:37-67.)

Considering these problems with conventional tattoo machines, the '530 Patent discloses a modular or 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

[1] The '553 Patent and the '530 Patent are attached as Exhibits B and C, respectively. The prosecution histories of the '553 Patent and the '530 Patent are attached as Exhibits D and E, respectively.

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 2:11-58.)

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 handle 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 3:43-48.)

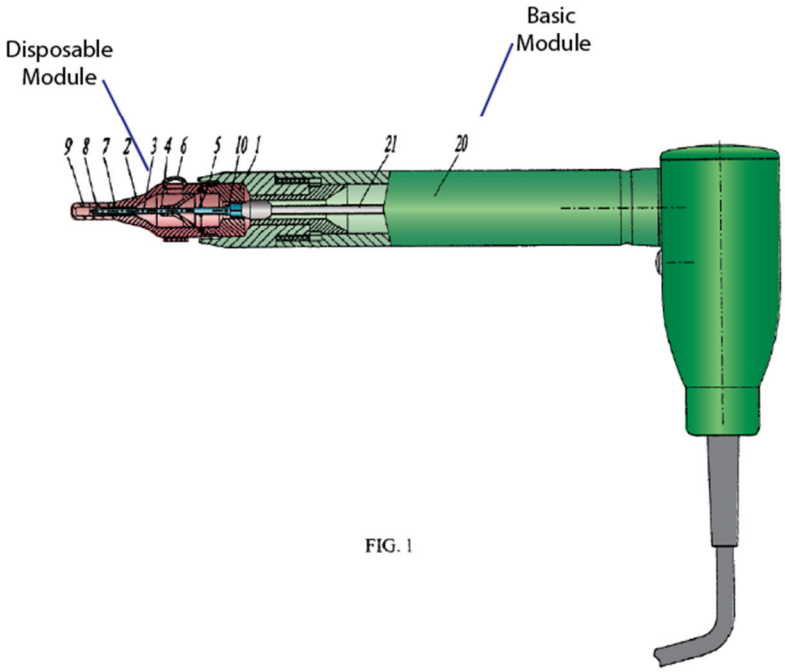


FIG. 1

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 3:49-65.)

The interior of the disposable module provides an ink tank 14 (see also Figure 3 of the '530 Patent), which is closed by a collar 6. ('530 Patent at 3:66-4:3.)

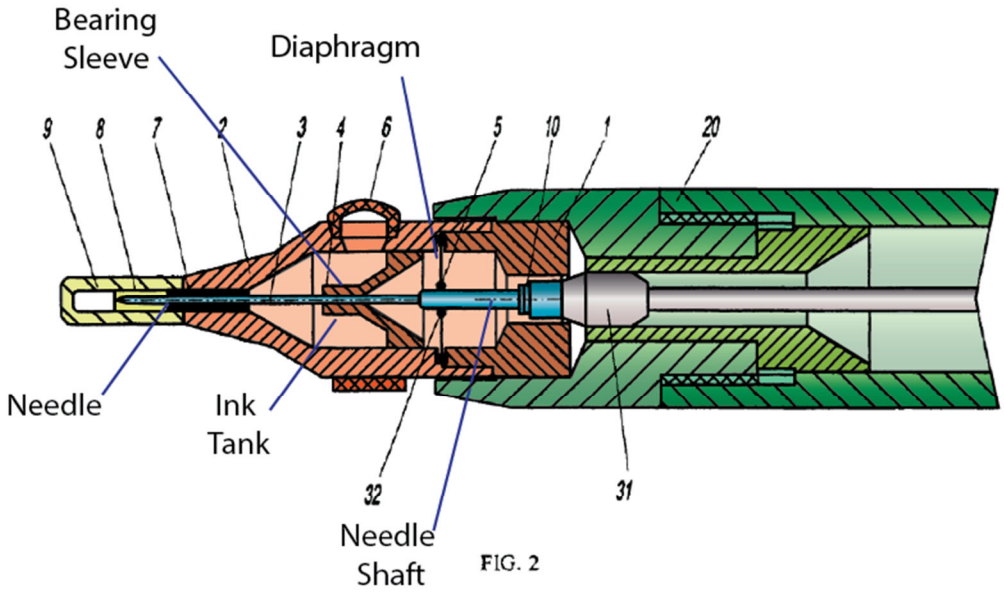


FIG. 2

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 4:12-25.)

The disposable module is operatively installed into the basic module for use in a tattooing procedure by inserting the rear housing part of the disposable module into the basic module. The basic module is provided with a generally cylindrical cavity at its end that receives the

corresponding outer dimension of the rear housing of the disposable module. This connection between the basic module and the disposable module provides a simple one-piece installation and disposal operation. ('530 Patent at 2:49-52)

A magnetic connection may also be provided between the distal end of the needle shaft 13 and the drive member shown at element 21. Here, a magnet 10 is attached at the distal end of the needle shaft 13, which couples with a corresponding magnetic counter piece 31 on the drive member. ('530 Patent at 4:26-34.)

The '530 Patent also discloses a further embodiment in which the needle shaft 13 is formed cylindrically at its distal end so that it engages a clamping device in the basic module. In this configuration, the clamping device may be a collet chuck that establishes the drive connection to the needle. ('530 Patent at 4:51-55.)

Another embodiment provides a modification to the diaphragm structure. In particular, the diaphragm is formed without an opening for the needle such that the diaphragm fully encloses the disposable module in the direction of the basic module, such that the diaphragm provides a sealing barrier between the rear of the disposable module and the basic module. Indirect coupling of the needle shaft to the drive mechanism is employed in this configuration. ('530 Patent at 4:56-61.)

The needle shaft can be modified in yet another embodiment such that it is formed as a pressure absorber at its distal end. Here, the needle can be driven either directly if the diaphragm is open, or indirectly if the diaphragm is closed. A return spring 12 provides the return force for the needle driving action. ('530 Patent 4:62-67.) This return spring configuration is also used in the embodiments shown in Figures 5 and 6. ('530 Patent at 5:1-15.)

III. RELEVANT LEGAL PRINCIPLES

Claim construction is a question of law. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (*en banc*), *aff'd*., 517 U.S. 370 (1996); *Cybor Corp. v. FAS Techs.*, 138 F.3d 1448, 1456 (Fed. Cir. 1998) (*en banc*). The claim construction inquiry is an objective test that focuses on what one of ordinary skill in the art, at the time of the invention, would have understood the term to mean. *Id*. at 986. Three sources or elements, known as "intrinsic evidence," are used to construe the meaning of words and phrases in the claims: (1) the language of claims themselves, (2) the specification, and (3) the prosecution history. *Id.* at 979.

As a general rule, claim terms should be given their ordinary and customary meaning to persons of skill in the art as of the effective date of a patent application. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed Cir. 2005) (*en banc*). However, to ascertain the scope and the meaning of asserted claims, the words of the claims themselves, the written description, the prosecution history, and, lastly, any relevant extrinsic evidence may be used. *See id.* at 1312-19.

A. Intrinsic Evidence

1. Claim Language

In construing claims, the analytical focus begins and remains centered on the language of the claims themselves, for it is that language that the patentee chose to use to particularly point out and distinctly claim the subject matter regarded as the invention. *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001). In the absence of an express intent to impart a novel meaning to the claim terms, the words take on the full breadth of the ordinary and customary meanings attributed to them by those of ordinary skill in the art. *Teleflex, Inc. v. Ficosa North America Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002); *see also Phillips*, 415 F.3d at 1312.

2. Specification

The second element of the intrinsic evidence is the specification of the patent, which the Federal Circuit states "acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." *Vitronics Corp. v. Conceptronic, Inc*., 90 F.3d 1576, 1582 (Fed. Cir. 1996). The specification is the single best guide to the meaning of a disputed claim term, and, usually, the specification's use of a claim term is dispositive, and thus the specification is always highly relevant to the claim construction analysis. *See Phillips* at 1315.

The use of the words in the context of the written description and as customarily used by those skilled in the relevant art accurately reflects both the ordinary and customary meaning of claim terms in a patent. Therefore, meanings gleaned from reference sources, such as dictionaries, must be compared against the use of the term in the context of the patent. Where several common meanings exist, the patent disclosure serves to point away from improper meanings and toward proper meanings. *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc*., 334 F.3d 1294, 1300 (Fed. Cir. 2003).

The Federal Circuit has also consistently adhered to the proposition that courts cannot alter what the patentee has chosen to claim as his invention, that limitations appearing in the specification will not be read into claims, and that interpreting what is meant by a word in a claim is not to be confused with adding an extraneous limitation appearing in the specification, which is improper. *Burke, Inc. v. Bruno Independent Living Aids, Inc.*, 183 F.3d 1334, 1340 (Fed. Cir. 1999).

3. Prosecution History

The third element of intrinsic evidence is the prosecution history of the patent while it was pending in the U.S. Patent and Trademark Office ("PTO"). The prosecution history limits the interpretation of claims as to exclude any interpretation that may have been disclaimed or

disavowed during prosecution in order to obtain claim allowance. *Southwall Technologies, Inc. v. Cardinal IG, Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995) *cert. denied*, 516 U.S. 987 (1995).

In *Phillips*, the Federal Circuit stated that "the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips, 415 F.3d at* 1316-17. Statements made during prosecution which clearly disclaim a particular claim interpretation will limit the scope of the claims. *Ballard Medical Products v. Allegiance Healthcare Corp.*, 268 F.3d 1352, 1359 (Fed. Cir. 2001); *see also ACCO Brands, Inc. v. Micro Security Devices, Inc.*, 346 F.3d 1075 (Fed. Cir. 2003).

B. Extrinsic Evidence

Courts may also refer to a second category, known as "extrinsic evidence," to construe the claims. Extrinsic evidence includes expert information and technical documents which are not of record in the file history. *See Storage Tech. Corp. v. Cisco Sys.*, 329 F.3d 823, 832 (Fed. Cir. 2003); *ACTV, Inc. v. Walt Disney Co.*, 346 F.3d 1082, 1089-90 (Fed. Cir. 2003). Resorting to extrinsic evidence is appropriate only when an ambiguity remains after consulting the intrinsic evidence of record. *Storage Tech.*, 329 F.3d at 832. The Federal Circuit has held that extrinsic evidence is less significant and less reliable than intrinsic evidence in determining claim scope. *C.R. Bard, Inc. v. United States Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004).

C. Means Plus Function Limitations

"Means plus function" limitations are construed in accordance with 35 U.S.C. §112, sixth paragraph, which states:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function, without the recital of structure, material or acts in

> support thereof, and such claim shall be construed to cover the corresponding structure, materials, or acts described in the specification and equivalents thereof.

To determine whether a claim element is a "means plus function" element, courts first assess whether or not the term "means" is recited in the claim limitation. If the term "means" is used, the limitation is presumed to be a "means plus function" limitation. *See Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 1302 (Fed. Cir. 1999). However, two situations exist which can rebut this presumption. The first situation is where the claim recites the word "means" but does not designate a specific function that the "means" performs. The second situation is where the claim recites sufficient structure for performing the function of the "means." *See id.*

After a court establishes that a limitation is a "means plus function" limitation, it must determine (1) the function recited in the claim and (2) what structures have been disclosed in the specification. In other words, 35 U.S.C. § 112, sixth paragraph, requires the identification of the claimed function, along with the identification of the structure in the written description that is necessary to perform that function.

An additional requirement for a means-plus function claim is that the written description must clearly link or associate structure to the claimed function. *Biomedino, LLC v. Waters Techs. Corp.,* 490 F.3d 946, 950 (Fed. Cir. 2007). This requirement may be satisfied if an ordinary artisan would understand which element in the written description performs the claimed function. *See Telcordia Techs., Inc. v. Cisco Sys.*, 612 F.3d 1365, 1377 (Fed. Cir. 2010).

IV. DISPUTED TERMS IN U.S. PATENT NO. 6,505,530

The asserted claims of the '530 Patent are directed to an ink application device (claims 1-3, 7, and 8) and a method of using an ink application device (claims 19 and 20). All the claims describe the ink application in terms of a basic module and a disposable module, and the disputed claim terms relate to these features.

Complainants' proposed constructions for the disputed terms, as would be understood by one of ordinary skill in the art at the time of the invention and the reasons they should be adopted, are set forth below.[2]

A. "integrated needle drive" (claims 1, 7, and 19)

Complainants' Proposed Construction	Staff's Proposed Construction	Respondent T-Tech's Proposed Construction
Plain and ordinary meaning	"a unified structure comprising all of the components required to drive a needle"	"a needle drive that consists of different parts for driving the needles, that are installed together by manufacturer"

1. Construction is not Required

Nothing in the specification or prosecution history compels any meaning of the term "integrated needle drive" beyond its plain and ordinary meaning. *See Prima Tek II, L.L.C. v. Polypap, S.A.R.L.*, 318 F.3d 1143, 1148 (Fed. Cir. 2003) ("Generally, terms in a patent claim are given their plain, ordinary, and accustomed meaning to one of ordinary skill in the relevant art.") The claim language in this term is plain and unambiguous, and the meaning would have been readily understood by one of ordinary skill in the art without requiring any further construction. (Trumper Decl. at ¶ 101.) Construction of "integrated needle drive" is thus not required. *See Teleflex*, 299 F.3d at 1325 (claim terms take on the full breadth of the ordinary meanings attributed to them by those of ordinary skill in the art absent an express intent to deviate from the ordinary meanings.); Any intent to redefine the meaning of a particular claim term away from its ordinary meaning must be clearly and unambiguously expressed in the specification. *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1370 (Fed. Cir. 2005). "In short, a court must presume that the terms in the claim mean what they say, and, unless otherwise compelled, give

[2] The qualifications of one of ordinary skill in the 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 experience. (Trumper Decl. at ¶ 18.)

full effect to the ordinary and accustomed meaning of claim terms." *Johnson Worldwide Assocs. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 1999).

The specification broadly describes the needle drive without evidence that the patentee intended to limit the term to specific structures or the manner in which those structures would be installed. In the context of the claim language, the "integrated needle drive" is simply a component of the basic module. The specification broadly describes the basic module as a "handle which includes the drive." ('530 Patent at 2:25-32.) The specification further describes the basic module as "compris[ing] a drive 21 for a needle 3..." ('530 Patent at 3:43-49.)

However, beyond describing a "drive" as being included in or comprising an element of the basic module, the specification places no restriction on the type of needle drive, the particular components that constitute a needle drive, or even how the needle drive must be "integrated" into the basic module. For instance, the specification is silent on whether the "needle drive" is completely integrated into the basic module or whether some portion (i.e., "partial" integration) of the "needle drive" is sufficient. Thus, the only practical limitation on the needle drive is that a needle drive component is in some fashion made a part of the basic module. (Trumper Decl. at ¶¶ 104-108.)

Further, nothing in the prosecution history imposes any limitation of how the "needle drive" is "integrated." Indeed, the feature of the "integrated needle drive" was not specifically addressed in the prosecution history in any fashion that would require deviating from the plain and ordinary meaning.

2. The Staff and T-Tech Proposed Constructions Improperly Limit the Term

The proposed constructions of the Staff and T-Tech for the "integrated needle drive" improperly depart from the plain and ordinary meaning and proceed to import limitations into

plain and unambiguous claim language. Both of these proposed constructions are incorrect and should not be adopted.

The ITC Staff's proposal would narrow the claim scope to require "a unified structure comprising ***all of the components*** required to drive a needle." However, nothing in the specification or prosecution history requires restricting the meaning of this claim term such that "all of the components" that drive the needle must be comprised in a "unified structure" in the basic module. In fact the '530 specification specifically teaches otherwise by expressly stating in the Abstract that "[o]ne of the modules is formed as a reusable base module with an integrated needle drive." (Abstract, p. 1). The Summary of the Invention makes clear that the inventive ink application device includes:

> at least two modules releasably connected to one another, wherein one of the modules is formed as a reusable base module with an integrated needle drive. . .

(Col. 2, lines 19-22). The "integrated needle drive" is distinct from the base module in which it is disposed. Clearly the base module (basic module) is *required* for the integrated needle drive to operate, but it is a *separate* component as defined in the patent, and not part of the integrated needle drive. ("Then, it is necessary for the subsequent treatment to plug a new disposable module onto the basic module to make the device ready to operate for the next customer." (Col. 2, lines 41-45). The Staff's proposed construction -- requiring ***all of the components*** required to drive a needle is inconsistent with the specification which defines the basic module as a separate component from the integrated needle drive.

Even assuming the embodiments in the specification could considered to have a needle drive in which "all of the components" were unified in a common structure, this alone would not justify restricting the claim scope. *See Playtex Prods., Inc. v. Procter & Gamble Co.*, 400 F.3d

901, 908 (Fed. Cir. 2005) ("Claims of a patent may only be limited to a preferred embodiment by the express declaration of the patentee."); *CCS Fitness, Inc. v. Brunswick Corp*., 288 F.3d 1359, 1366 (Fed. Cir. 2002) (explaining that the "heavy presumption" of ordinary meaning cannot be rebutted "simply by pointing to the preferred embodiment").

Further, the Staff's proposal is at odds with commonly understood meaning of "integrated," as evidenced by dictionary definitions of this term. *See Vitronics*, 90 F.3d at 1584 n. 6 (reference to dictionary definitions when construing claims is proper so long as the definition does not contradict the intrinsic evidence); *Phillips*, 415 F.3d at 1317. "Integrated" can broadly refer to making some component "part of a larger unit," or joining a component "with something else" as shown from the second definition below:

> **1.** To make whole by bringing all parts together; unify. **2.a.** To join with something else; unite. **b.** To make part of a larger unit. **3.** To open to people of all races or ethnic groups without restriction; desegregate. **4.** *Math*. **a.** To calculate the integral of. **b.** To perform integration on. **5.** *Psychol*. To bring about the integration of (personality traits).
>
> (American Heritage College Dictionary, 3d ed. (1997) at 706 (excerpt provided as Exh. F).)

Of the remaining definitions for "integrate" that could be relevant to a mechanical device, the only other applicable definition would be the first definition, which is "to make whole by bringing all parts together; unify." However, nothing in the specification or prosecution history suggests that such a restrictive interpretation of "integrated" was intended at the expense of the more general understanding of the word. The term "integrated" is in fact commonly understood by those of skill in the art in the design of mechanical devices as referring to some portion of one component being integrated with another. In other words, complete integration (i.e., "all of the components") is not necessarily required. (Trumper Decl., at ¶¶ 102-103, 112.)

Additionally, the proposal from the Staff creates further ambiguity as to what components are "required to drive a needle." This could conceivably include any number of elements, such as a power cord, power supply, wiring, switches, speed controls, etc., that could be considered as being "required" to drive the needle. However, the specification does not restrict the needle drive in terms of specific "required" elements and such a limitation should not be imported into the claim language. (Trumper Decl., at ¶ 113.)

Moreover, the usage of the term "drive" in the tattoo machine art commonly is used to refer to far less than all the components that could potentially be "required to drive the needle." In particular, "drive" often refers specifically to the ***motor*** of the device, while there are other separately identified structures that are connected between the motor and the needle itself that cause the needle to move. For instance, the Chou '449 Patent (U.S. Patent No. 5,472,449), which was cited in the prosecution of the '530 Patent, uses the term "drive" to refer to the motor, while additional components (e.g., the shaft 34, rocker assembly 40, and needle coupler 20) are connected to the "drive" to transfer motion to the needle:

with the description below). Within the housing **12** is a suitable conventional drive such as a d.c. motor and associated drive collectively and schematically represented as structure **32**. The specific type of drive can be selected accordingly to ordinary skill in the art to meet the intended functions disclosed herein. Power for the drive **32** may be supplied by an external power supply (not shown), build-in rechargeable battery (not shown) or alkaline battery (not shown).

The drive **32** rotates a shaft **34** which has a terminating flat cam surface **36** at an angle to the shaft axis. A rocker assembly **40** surrounds the shaft **34**. The rocker assembly **40** includes a rocker **42** which is pivotally supported on a pivot pin **44** and at a point along the line of the axis of the shaft **34**. The rocker **42** has an eye **43** at one end which axis is aligned parallel to the axis of the pivot pin **44**. As the shaft **44** rotates, the cam surface **36** rocks the rocker **42** in a reciprocal motion in the axial direction of the shaft **34** and about the pivot pin **44**.

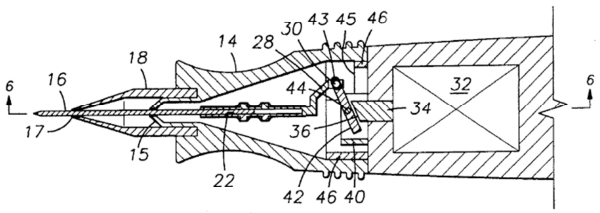


FIG. 5

(Exh. G (Chou '449) at 3:13-33 and Fig. 5; Trumper Decl. at ¶¶ 110-111.)

The restriction of "all components required to drive a needle" in the Staff's proposed construction is thus inconsistent with not only the specification but with the usage of the terms in prior art of record. *See Home Diagnostics, Inc. v. Lifescan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004) (cited prior art that shows persons of skill knew of multiple ways of implementing the subject matter of a claim term is evidence that the term should not be limited to the implementation in a preferred embodiment.) For these reasons, the Staff's proposed construction should be rejected.

T-Tech's proposed construction of "integrated needle drive" attempts to severely limit the claim scope to "a needle drive that consists of different parts for driving the needles, that are installed together by manufacturer." Nothing in the specification imposes any limitation on who installs elements of the needle drive, when the elements are installed, how the elements are installed, or even that the needle drive must "consist of different parts." Similarly, nothing in the prosecution history requires narrowing the meaning of "integrated needle drive" in the manner T-Tech proposes. (Trumper Decl. at ¶ 115.) The only reference in the entire '530 Patent to the actions of a manufacturer refer to sterile packaging of the *disposable module* (Col. 3, lines 55-57). Nothing in the '530 Patent refers to a manufacturer's activity regarding the *integrated needle drive* in the *basic module*. T-Tech's proposed construction is wholly without support. Because it is unsupported by the intrinsic record, T-Tech's proposed construction should be rejected. *See Certain Laser Bar Code Scanners and Scan Engines*, Inv. No. 337-TA-551, ID on Violation of Section 337 and RD on Remedy and Bonding, 2007 ITC LEXIS 135 (Jan. 29, 2007) (cautioning that "[i]n interpreting particular limitations within each claim, adding limitations to claims not required by the claim terms themselves, or unambiguously required by the specification or prosecution history, is impermissible.")

B. "simultaneous removal of the entire disposable module from the basic module" (claim 1)

Complainants' Proposed Construction	Staff's Proposed Construction	Respondent T-Tech's Proposed Construction
"removal of the entire disposable module as a single piece from the basic module"	"removal of the entirety of the disposable module at the same time"	"every part of the disposable module that is in contact with the basic module is to be removed from the basic module simultaneously"

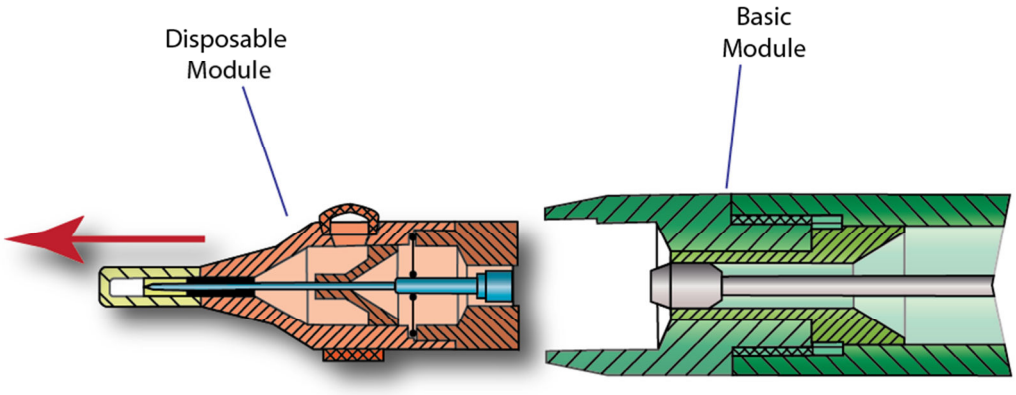
1. Complainants Proposed Construction Comports with the Intrinsic Record

The term "simultaneous removal of the entire disposable module from the basic module" (as used in claim 1 of the '530 Patent) should be construed, consistent with the intrinsic evidence, to mean "removal of the entire disposable module as a single piece from the basic module."

This construction is consistent with the specification, which describes the modular construction of the ink application device in terms of the disposable module being removed from the basic module and disposed of after use. This configuration allows a new disposable module to be plugged onto the basic module. ('530 Patent at 2:39-44.) As seen from the embodiment shown in Figures 1 and 2 of the '530 Patent, the disposable module is inserted into the end of the basic module as a single piece, such that the rear housing of the disposable module occupies a cylindrical cavity at the end of the basic module where the drive element contacts the needle shaft of the disposable module. ('530 Patent at 3:43-58.) The '530 Patent describes the connection between the basic module and disposable module as one that "can be established and released in a simple manner so that the device can be also be simply and safely used even by less experienced users." ('530 Patent at 2:49-52.)

Removal of the disposable module is simply the reverse of the installation procedure. This is accomplished by pulling the disposable module from the basic module in order to withdraw the disposable module from the cylindrical cavity in the basic module and to ultimately

separate the two modules. This process is shown below in the adapted Figure 2 of the '530 Patent, which illustrates how the disposable module is separated from the basic module. ("Trumper Decl.," at ¶ 118.)

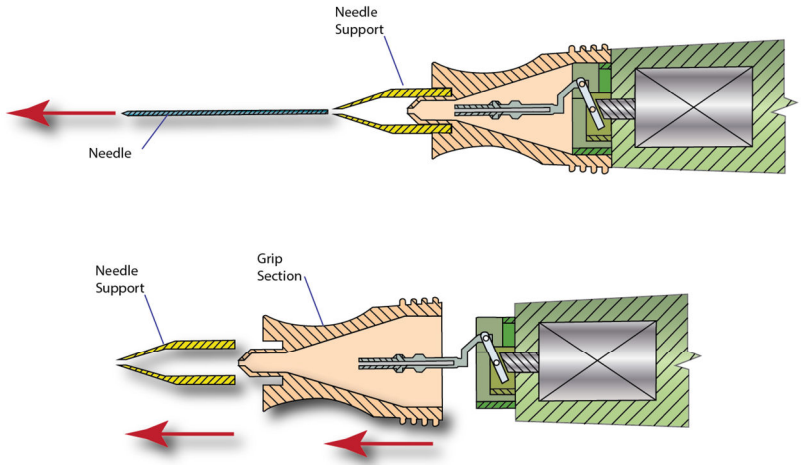


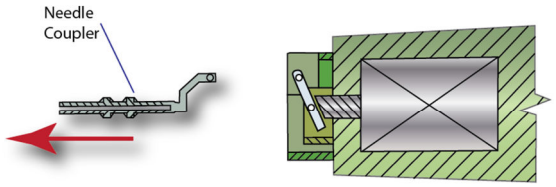
Properly construed, the "simultaneous removal of the entire disposable module" refers to the components of the disposable module *relative to each other*, *i.e.*, housing, bearing, needle, ink tank. In this way, all parts that can become infected are simultaneously removed from the basic module (or manual device) so that it can be safely used with the next customer. (Col. 2, lines 33-48). The prosecution history of the '530 Patent confirms that the "simultaneous removal" language refers to the disposable module being removed as a ***single piece*** from the basic module. Specifically, the applicant explained that the similar language of "simultaneously removing the entire disposable module from the basic module," which appears in claim 19 of the '530 Patent and is essentially identical to the "simultaneous removal" phrase of claim 1, was not present in the Chou '449 patent because the Chou '449 device "***comes apart in pieces*** and he does not have the ability to remove the entire disposable module simultaneously." (Exh. D, '530 Prosecution History, Amendment of September 9, 2002 at 10.) This distinction was further explained as follows:

> Chou discloses a needle connectable to a coupling portion 50 (cfg. Figure 5 and the description in columns 4-5), a body portion 62 and a grip section 64 which are detachably attached to the body portion. The needle 50 and the grip section 64; however, need to be separately connected to and detached from the body portion 62. In contrast, the disposable module according to the present application including a needle and a needle nozzle is connectable to an integrated needle drive as one single unit.

('530 Prosecution History, Amendment of September 9, 2002 at 11.)

Thus, the Applicant explained that "simultaneous removal," in the context of the claim language, refers to the disposable module being removed as a single piece as opposed to the multi-piece removal required in the Chou '449 configuration. Chou '449 describes this removal process as consisting of a number of discrete steps, where the needle is first removed, the needle support removed from the grip section, the grip section removed from the housing, and the needle coupler detached from the rocker mechanism.





(Trumper Decl., at ¶¶ 76-99, 119-120.)

Complainants' proposed construction the "simultaneous removal of the entire disposable module from the basic module" as "removal of the entire disposable module as a single piece from the basic module" aligns with Applicant's explanation of the meaning of the claim language provided in the prosecution history and is consistent with the disclosure in the specification. *See Honeywell, Inc. v. Victor Co. of Japan, LTD.*, 298 F.3d 1317, 1324 (Fed. Cir. 2002) (inventor's definition of claim term provided during prosecution was "relevant in indicating the meaning that the inventor ascribed to the term" even though it did not have a narrowing effect); *Vitronics*, 90 F.3d at 1582. T-Tech's Proposed Construction Excludes the Disclosed Embodiments

T-Tech's proposed construction of the "simultaneous removal" term to be "every part of the disposable module that is in contact with the basic module is to be removed from the basic module simultaneously" is improper because it excludes the disclosed embodiments. T-Tech's tactic in construing this term has been repeatedly found to be "rarely, if ever, correct." *See Mems Tech. Berhad v. ITC*, 2011 U.S. App. LEXIS 11350 at *16 (Fed. Cir. June 3, 2011) (quoting *C.R. Bard*, 388 F.3d at 865, *Vitronics*, 90 F.3d at 1583. Indeed, "there is a strong presumption against a claim construction that excludes a disclosed embodiment." *In re Katz Interactive Call Processing Patent Litig.*, 639 F.3d 1303, 1324 (Fed. Cir. 2011).

The embodiments of the disposable module in the '530 Patent are first inserted within the basic module such that the rear housing of basic module is received within a cylindrical cavity at the end of the basic module.

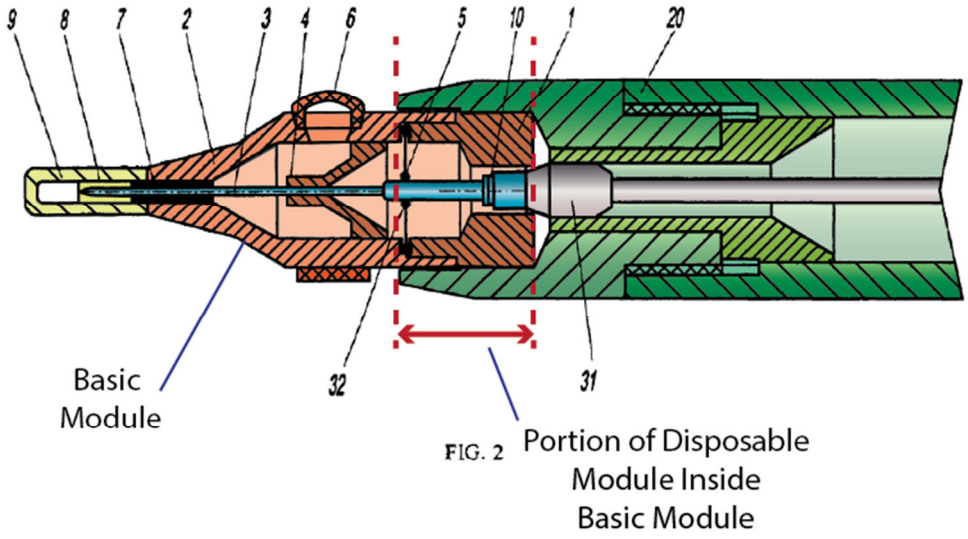
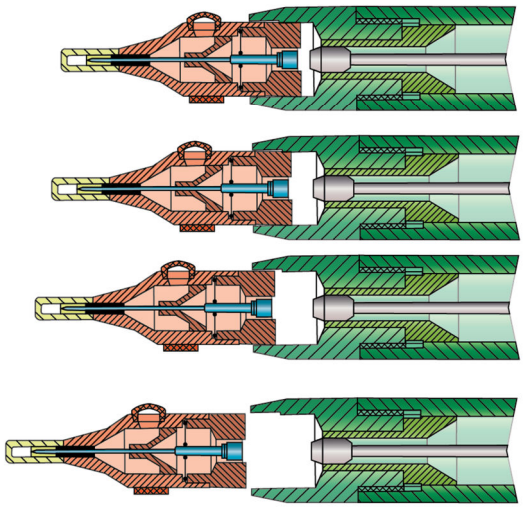


FIG. 2

(Trumper Decl., at ¶¶ 122-123.)

In these embodiments, removal of the disposable module from the basic module requires that this portion of the housing of the disposable module is withdrawn from the basic module. However, the portion of the disposable module within the basic module would not ***instantaneously*** be separated from the basic module in the manner that T-Tech's construction would require. Rather, the illustrated embodiments of the basic module and disposable module would have the different "parts" of the disposable module continually breaking contact with corresponding parts of the basic module until the disposable module is completely withdrawn. As shown in the sequence adapted from Figure 2 of the '530 Patent below, the disposable module would be initially withdrawn such that the connection between the needle shaft and the drive element of the basic module is broken, and the basic module would be continually withdrawn from the basic module until the two components are completely separated:



(Trumper Decl., at ¶ 124.)

Further, nothing in the specification or the prosecution history requires the limiting interpretation that T-Tech proposes. There is no intrinsic support for the requirement that every part of the disposable module that is in contact with the basic module is to be removed from the basic module simultaneously, and T-Tech has pointed to none. To the contrary, simultaneous removal in the '530 patent is intended to ensure that the portions of the disposable module that can become contaminated (i.e., housing, needle, ink tank, etc.) are simultaneously removed relative to each other -- as a single piece -- so that the contaminated contents do not infect the basic module. (Col. 2, lines 33-48). For these reasons, the T-Tech proposed construction of the "simultaneous removal…" term is improper and should be rejected.

2. The Staff's Proposed Construction does not Fully Consider the Intrinsic Record

The Staff has proposed that the "simultaneous removal…" term should be interpreted as "removal of the entirety of the disposable module at the same time." This proposal should be rejected at least because it does not take into account the Applicant's explanation of simultaneous removal from the prosecution history. *See Honeywell*, 298 F.3d at 1324.

C. "means for allowing simultaneous removal of the entire disposable module from the basic module" (claim 1)

Complainants' Proposed Construction	Staff's Proposed Construction	Respondent T-Tech's Proposed Construction
35 USC §112, ¶ 6 **Function:** allowing simultaneous removal of the entire disposable module from the basic module **Structure:** (1) a rear housing part 1 of the disposable module that is connected to, and detachable from, the basic module, as shown in Figures 1 and 2 of the '530 patent; (2) an optional magnetic connection between elements 10 and 31, as shown in Figure 2 and discussed at col. 4, lines, 26-34; (3) an optional clamping device provided in the basic module to connect with the needle.	Adopts Complainants' proposal	"means for allowing every part of the disposable module that is in contact with the basic module to be removed from the basic module simultaneously"

1. Interpretation Under 35 U.S.C. § 112, Sixth Paragraph, is Required

The phrase "means for allowing simultaneous removal of the entire disposable module from the basic module" is a means-plus-function limitation and should be construed accordingly.

The term uses "means" language, thus creating a presumption that means-plus-function analysis applies. *Rodime*, 174 F.3d at 1302. This presumption may be rebutted if the claim limitation provides sufficient structure within the claim itself to perform entirely the recited function. *Id.*

Here, no structural details sufficient to carry out the corresponding function of "allowing simultaneous removal of the entire disposable module from the basic module" are recited in the claim. (Trumper Decl. at ¶¶ 127-129.)

Having concluded that the term should be treated as a means-plus-function limitation, the next step in interpreting the claim is to identify the function. Here, the function is "allowing simultaneous removal of the entire disposable module from the basic module." *See JVW Enters., Inc. v. Interact Accessories, Inc.*, 424 F.3d 1324 (Fed. Cir. 2005) (in performing the first step, "a court may not construe a means-plus-function limitation by adopting a function different from that explicitly recited in the claim.")

Next, the structure disclosed in the specification that performs the function is to be identified. *Biomedino*, 490 F.3d at 950. The first component of the corresponding structure relates to the connection of the rear housing of the disposable module to the basic module. The disposable module is operatively installed into the basic module for use in a tattooing procedure by inserting the rear housing part of the disposable module into the basic module. The basic module is provided with a generally cylindrical cavity at its end that receives the corresponding outer dimension of the rear housing of the disposable module. This connection between the basic module and the disposable module provides a simple one-piece installation and disposal operation. (Trumper Decl. at ¶131.)

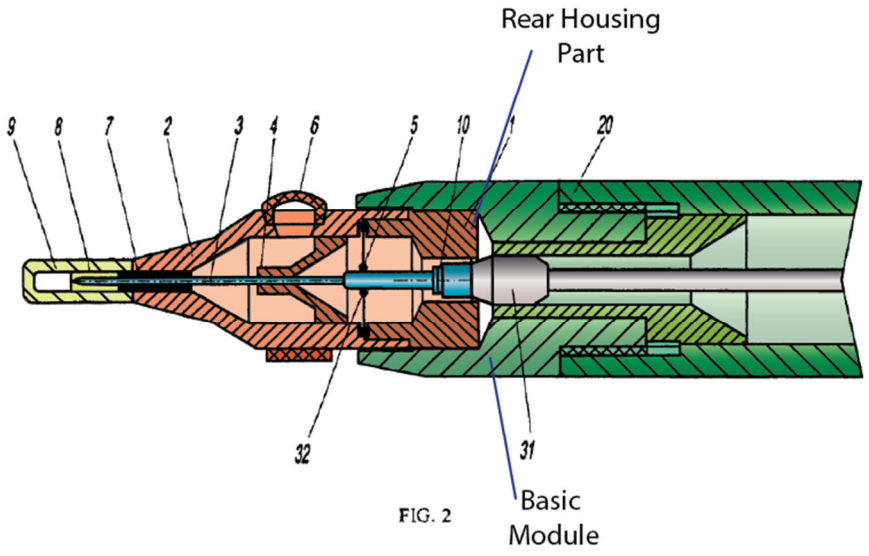


FIG. 2

The ‘530 Patent describes a magnetic coupling between the needle shaft of the disposable module and the drive element of the basic module. The specific structures disclosed for this coupling are the magnetic counter piece 31 at the end of the drive element and the magnet 10 on the end of the needle shaft. (‘530 Patent at 4:26-34; Trumper Decl. at ¶ 132.)

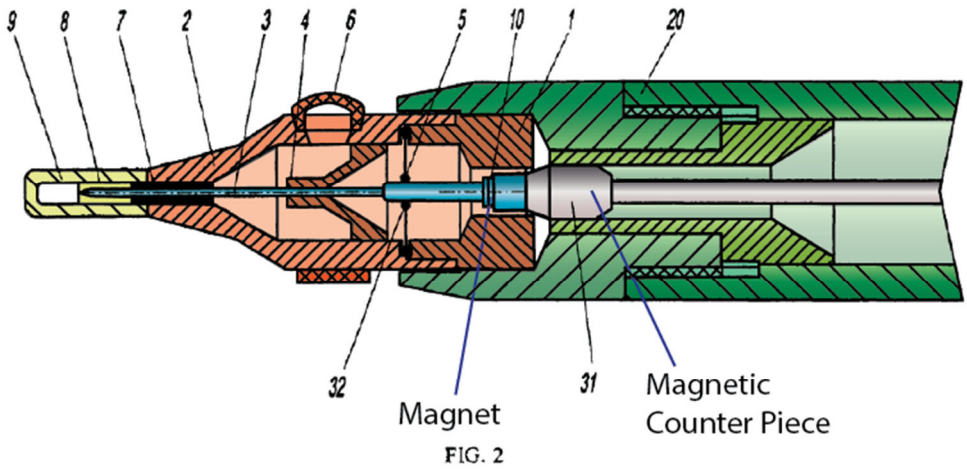


FIG. 2

The ‘530 Patent also describes a number of embodiments where this magnetic coupling is not used, such as the disposable modules that incorporate a return spring. As such, the magnetic coupling is an optional structure. (‘530 Patent at 4:62-5:12; Trumper Decl. at ¶ 133.)

The ‘530 Patent also describes an embodiment in which an optional “clamping device” is provided in the basic module to connect to the needle:

> In a further embodiment, which is not shown, the needle shaft 13 can be formed cylindrically at its distal end so that it engages a clamping device provided in the basic module, preferably with a collet chuck to establish the drive connection for the needle 3. (‘530 Patent at 4:50-55.)

Thus, the structures that are identified in the specification as performing the “allowing simultaneous removal of the entire disposable module from the basic module” include the rear housing part of the disposable module that is connected to, and detachable from, the basic module; the optional magnetic connection between elements 10 and 31; and the optional

clamping device provided in the basic module to connect with the needle, as identified above. (Trumper Decl. at ¶¶128-135.)

2. T-Tech's Proposal Ignores 35 U.S.C. § 112, Sixth Paragraph and is Improper

T-Tech's proposed construction for "means for allowing simultaneous removal…" does not interpret the term as a means plus function limitation. T-Tech's proposal does not identify the function and it does not identify the corresponding structure that performs the function. Instead. T-Tech again attempts to construe the claim language by importing limitations not even found in the specification and excluding the disclosed embodiments in the process. At least for this reason, T-Tech's proposed construction of this term is improper and should be rejected.

D. "simultaneously removing the entire disposable module from the basic module" (claim 19)

Complainants' Proposed Construction	Staff's Proposed Construction	Respondent T-Tech's Proposed Construction
"removing the entire disposable module as a single piece from the basic module"	"removing the entirety of the disposable module at the same time"	"every part of the disposable module that is in contact with the basic module is to be removed from the basic module at the same time"

The term "simultaneously removing of the entire disposable module from the basic module" (as used in claim 19 of the '530 Patent) should be construed to mean "removing the entire disposable module as a single piece from the basic module."

This phrase is substantially identical to the "simultaneous removal…" limitation in claim 1, which is addressed above. Complainants' proposed construction should be adopted the same rationale set forth previously. Specifically, this construction is consistent with the specification and the manner in which the Applicant explained this term in the prosecution history. Since the T-Tech and Staff Attorney proposals are substantially identical to their proposals for the

"simultaneous removal…" term in claim 1, they should be rejected for the same reasons as provided above.

V. CONCLUSION

For the reasons herein, Complainants respectfully request that the ALJ adopt their proposed constructions.

Dated: November 16, 2012

Respondent by its attorneys,

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