Case No. 19-2145

United States Court of Appeals
for the Federal Circuit

EMED TECHNOLOGIES CORPORATION,
Plaintiffs–Appellant

v.

REPRO-MED SYSTEMS, INC., dba KORU Medical Systems,
Defendant–Appellee

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF TEXAS IN Civil Action No. 2:15-CV-01167-JRG-RSP, Honorable Judge Rodney Gilstrap

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PETITION FOR REHEARING AND REHEARING *EN BANC*

Attorneys for Appellants:

Ramey & Schwaller, LLP

/s/ William P. Ramey, III
William P. Ramey, III
Texas Bar No. 24027643
wramey@rameyfirm.com
5020 Montrose Blvd., Suite 800
Houston, Texas 77006
(713) 426-3923
(832) 900-4941 (fax)

CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rule 47.4(a) and Federal Rule of Appellate Procedure 26.1, counsel for Appellant EMED Technologies Corporation ("EMED") certifies the following:

1. The full name of every party represented by the undersigned is EMED Technologies Corporation, 1264 Hawks Flight Court, Suite 150, El Dorado Hills, CA 95762.

2. The real party in interest is EMED Technologies Corporation.

3. EMED Technologies Corporation has no parent corporation and there is no publicly held corporation that owns 10% or more of the stock of either corporation.

4. The names of all law firms and the partners or associates that appeared for EMED Technologies Corporation in the district court or are expected to appear in this Court are:

William P. Ramey, III
Donald H. Mahoney III
Ramey & Schwaller, LLP

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. See Fed. Cir. R. 47. 4(a)(5) and 47.5(b).

EMED Technologies Corporation v. Repro-Med Systems, Inc. 1:18-cv-05880;

Repro-Med Systems, Inc. v. EMED Technologies Corp. 2:13-cv-

01957; and

EMED v. Repro-Med Systems 19-cv-00598

Date: April 23, 2020

/s/ William P. Ramey, III
William P. Ramey, III

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Parties

Appellant/Plaintiff	EMED Technologies Corporation
Appellee/Defendant	Repro-Med Systems, Inc. d/b/a RMS Medical Products (d/b/a Koru Medical Systems)

Patents-in-Suit

The ’476 patent	U.S. Patent 8,961,476

Defined Terms

District Court	United States District Court for the Eastern District of Texas, the Honorable Judge Rodney Gilstrap
Court of Appeals	United States Court of Appeals for the Federal Circuit

All emphasis in this brief is added unless otherwise indicated.

I. FEDERAL CIRCUIT RULE 35(b) STATEMENT

Based on my professional judgment, I believe the panel decision found at *EMED Techs. Corp. v. Repro-Med Sys.*, No. 2019-2145, 2020 U.S. App. LEXIS 11240 (Fed. Cir. 2020) ("Decision" or "Written Opinion") is contrary to the following decision(s) of the U.S. Supreme Court or the precedent(s) of this Court:

1. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 117 S. Ct. 1040 (1997);
2. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 122 S. Ct. 1831, 152 L. Ed. 2d 944 (2002);
3. *Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005 (Fed. Cir. 2006); and,
4. *Cadence Pharm., Inc. v. Exela PharmSci Inc.*, 780 F.3d 1364 (Fed. Cir. 2015),

and consideration by the full Court is thus necessary to secure and maintain uniformity of the Court's decisions.

Based on my professional judgment, I believe this proceeding involves one or more questions of exceptional importance, namely:

1. while the United States Supreme Court instructs the Federal Circuit to have a "focus on individual elements and a special vigilance against allowing the concept of equivalence to eliminate completely any such [claim]

elements,"[1] the application of vitiation of a claim element must be supported by the evidence of record. Otherwise, the principle of vitiation swallows the doctrine of equivalents, thus rendering it meaningless.

2. While "[a] holding that the doctrine of equivalents cannot be applied to an accused device because it 'vitiates' a claim limitation is nothing more than a [legal] conclusion that the evidence is such that no reasonable jury could conclude that an element of an accused device is equivalent to an element called for in the claim, or that the theory of equivalence to support the conclusion of infringement otherwise lacks legal sufficiency[,]"[2] an explanation of how the claim limitation or element is vitiated must be made or the protection of the patent grant is converted into a hollow and useless thing.[3]

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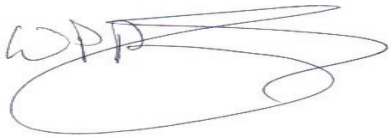
[1] *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39-40, 117 S. Ct. 1040 (1997).

[2] *Cadence Pharm., Inc. v. Exela PharmSci Inc.*, 780 F.3d 1364, 1371 (Fed. Cir. 2015).

[3] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731, 122 S. Ct. 1831, 152 L. Ed. 2d 944 (2002).



ATTORNEY OF RECORD FOR APPELLANT

II. POINTS OF LAW OR FACT OVERLOOKED OR MISAPPREHENDED BY THE PANEL OF THE COURT

Appellant requests rehearing and *en banc* reconsideration of this appeal to maintain the availability of infringement under the doctrine of equivalents. The United States Supreme Court and this Court instruct federal trial judges to "focus on individual elements and a special vigilance against allowing the concept of equivalence to eliminate completely any such [claim] elements."[4] However, the vitiation of a claim element must be supported by the evidence of record, otherwise, the use of vitiation swallows the doctrine of equivalents, thus rendering it meaningless.[5] In other words, when a trial court is allowed to use the principle of claim element vitiation to deny, as a matter of law, the availability of infringement under the doctrine of equivalents, all reasonable inferences from the record evidence must support such vitiation such that no reasonable jury could conclude that an element of an accused device is equivalent to an element called for in the claim.[6]

While "[a] holding that the doctrine of equivalents cannot be applied to an accused device because it 'vitiates' a claim limitation is nothing more than a [legal] conclusion that the evidence is such that no reasonable jury could conclude that an element of an accused device is equivalent to an element called for in the claim, or

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[4] *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39-40, 117 S. Ct. 1040 (1997).

[5] *See, e.g., Festo*, 535 U.S. at 731.

[6] *Id.*

that the theory of equivalence to support the conclusion of infringement otherwise lacks legal sufficiency[,]"[7] in the context of summary judgment of noninfringement, an explanation of how the claim limitation or element is vitiated[8] must be made to show all reasonable inferences were taken for the non-movant, the party alleging infringement under the doctrine of equivalents.[9] Regardless of the test used to determine infringement under the doctrine of equivalents, the sole issue is whether a reasonable jury could conclude that an identified structure of an accused device is equivalent.[10]

III. ARGUMENT IN SUPPORT OF REHEARING

The sole issue for consideration is whether the principle of claim element vitiation can be used to prevent, without explanation, whether a reasonable jury could find infringement under the doctrine of equivalents when the record evidence illustrates infringement. EMED's position is that it cannot because the United States Supreme Court and precedent from this Court never intended for the vitiation

[7] *Cadence Pharm., Inc. v. Exela PharmSci Inc.*, 780 F.3d 1364, 1371 (Fed. Cir. 2015).

[8] or not insubstantially different.

[9] *See, e.g., Xiaohua Huang v. Huawei Techs. Co.*, 735 F. App'x 715, 720 (Fed. Cir. 2018) c*iting IMS Tech., Inc. v. Haas Automation*, *Inc.*, 206 F.3d 1422, 1429 (Fed. Cir. 2000).

[10] *Cadence Pharm., Inc.*, 780 F.3d at 1371.

principle to swallow the doctrine of equivalents, as such a result renders the doctrine meaningless.[11]

A. The Panel Acknowledges that the Needle is Positioned Between the Two Wings.

In the underlying appeal, the Panel stated:

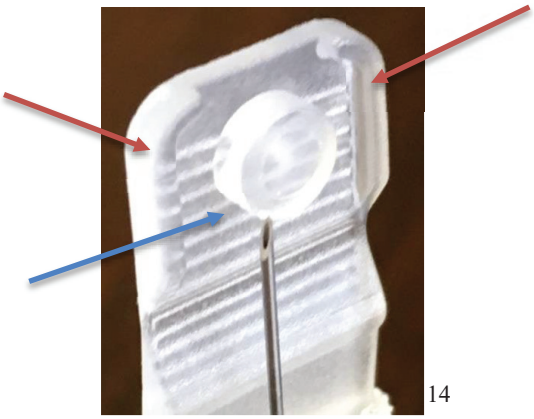
> The Accused Products lack a "groove" as claimed and protect the user from needle injuries in a different way. Where the claimed device houses the needle in a groove in one of the wings—i.e., a long narrow cut or depression—the needle in the Accused Products is merely positioned between the two wings, as shown below. [12]

Thus, the Panel acknowledged that the needle is positioned between the two wings. However, the panel failed to acknowledge that when positioned between the two wings, the medical needle[13] is located at least partially within EMED's identified "groove," i.e. the cut or depression surrounded by the edge walls on the wing as shown in the following figure (with the blue arrow pointing to the base of the groove and the red arrows pointing to the edges or sidewall of the groove):

[11] *See, e.g., Festo*, 535 U.S. at 731.

[12] *EMED Techs. Corp. v. Repro-Med Sys.*, No. 2019-2145, 2020 U.S. App. LEXIS 11240, at *9 (Fed. Cir. 2020).

[13] At least a portion of the medical needle, as required by claim 9 of the '476 patent. (Appx0070, claim 9 depends from claim 8 which depends from claim 1).

 [14]

B. It is Undisputed that the RMS Needle Extends into EMED's identified "Groove."

Claim 9 reads, in its relevant part:

> A device for protecting a user from a sharp tip of a medical needle, the device comprising:
> a central body portion;
> the medical needle… including the sharp tip;
> a pair of wings...;
> a mechanical fastener …
> wherein at least one of
> the pair of wings is formed with a groove having a size configured for housing at least a portion of the medical needle when the pair of wings are in the closed position, wherein the groove is
> formed in a single one of the pair of wings.[15]

It is undisputed that the medical needle extends into EMED's identified "groove," at least for this embodiment. Thus, for at least this embodiment, EMED's identified "groove" is housing at least a portion of the medical needle, in the "groove," when the wings are in the closed position, that portion including the sharp tip.

[14] Appx0242.
[15] Appx0030 at claim 9 (emphasis added).

The Panel acknowledges as much by providing that at least one embodiment of RMS's needle reaches what the Panel calls the plug and socket structure:

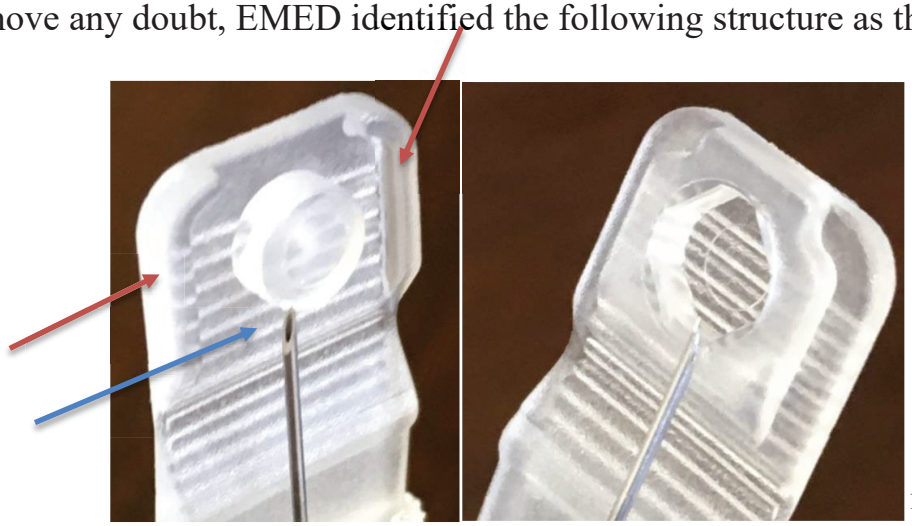
> As shown in the far-right photograph above, the needle of at least one embodiment of the Accused Products appears to reach the plug and socket structure when the wings are closed. But the plug and socket structure does not contain any long narrow cut or depression that houses the needle, as shown in the close-up images below: [16]

However, the relevant issue is not the plug and socket structure, as it are not claimed, but rather whether EMED's identified "groove" is equivalent to the claimed "groove." The images used by the Panel clearly show one embodiment of an RMS device wherein the needle extends at least partially into EMED's identified "groove" when the pair of wings are in the closed position:

[16] *EMED Techs. Corp. v. Repro-Med Sys.*, No. 2019-2145, 2020 U.S. App. LEXIS 11240, at *10 (Fed. Cir. 2020).

 [17]

To remove any doubt, EMED identified the following structure as the "groove:"

 [18]

The "groove" is the depression on the left wing (the base of which is identified by the blue arrow) that is formed by the sidewall at the left and right edges of

[17] *EMED Techs. Corp. v. Repro-Med Sys.*, No. 2019-2145, 2020 U.S. App. LEXIS 11240, at *10 (Fed. Cir. 2020).

[18] Appx0242.

the left wing (identified by the red arrows).[19] The "groove" is formed in only one wing and is capable of protecting the user from the sharp tip of the needle by housing at least a portion of the needle,[20] as required by claim 9.

The Panel proceeds to say:

> phasis added). It may be true that the needle, in one accused embodiment, contacts the plug-socket structure in the closed position, but mere contact is not sufficient to establish a genuine dispute that one of the wings might contain a groove "configured for housing" any portion of the needle.[21][22]

The Panel's Written Decision did not consider EMED's identified "groove," rather it searched for a separate groove without addressing EMED's identified "groove" and discussed an unclaimed plug and socket structure.

C. The Panel's Written Decision Improperly Starts With Vitiation Without Considering Equivalency.

The Panel starts its analysis by providing that EMED's identified

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[19] Appx0242. That lip corresponds to the feature at the tip of the wing recited as a lip forming in part the "mechanical fastener" element recited in claim 9.

[20] *See id*.

[21] *EMED Techs. Corp. v. Repro-Med Sys.*, No. 2019-2145, 2020 U.S. App. LEXIS 11240, at *10 (Fed. Cir. 2020).

[22] *EMED Techs. Corp. v. Repro-Med Sys.*, No. 2019-2145, 2020 U.S. App. LEXIS 11240, at *11 (Fed. Cir. 2020).

"groove" vitiates a claim element, thus making vitiation a threshold inquiry rather than determining if the structure is equivalent and then determining if vitiation applies. Specifically, the Panel, without explanation stated:

> claims explicitly require that the "groove" must house the needle when the wings are in the closed position. '476 patent at claim 8. To extend the claimed "groove" to encompass structures that do not house the needle would vitiate that claim limitation. In that same vein, EMED did not and cannot plausibly argue, without vitiating the limitation, that the area to which it refers as a "depression" is insubstantially different from a structure that is long and narrow.[23]

Thus, the Panel failed to take all reasonable inferences in EMED's favor, as the "groove" identified by EMED does in fact, for this embodiment at least, house the sharp point of the medical needle.[24] The undisputed claim language is that the "groove" must house at least a portion of the medical needle.[25] The Panel's assertion that EMED's identified "groove" is substantially different than a long narrow cut or depression ignores the claim language and takes an issue away

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[23] *EMED Techs. Corp. v. Repro-Med Sys.*, No. 2019-2145, 2020 U.S. App. LEXIS 11240, at *12 (Fed. Cir. 2020).

[24] *See, e.g., Xiaohua Huang v. Huawei Techs. Co.*, 735 F. App'x 715, 720 (Fed. Cir. 2018) c*iting IMS Tech., Inc. v. Haas Automation*, *Inc.*, 206 F.3d 1422, 1429 (Fed. Cir. 2000).

[25] At least a portion of the medical needle, as required by claim 9 of the '476 patent. (Appx0070, claim 9 depends from claim 8 which depends from claim 1).

from the jury which rightfully belongs with the jury.

The plain language of the relevant claim term is "having a size configured for *housing at least a portion of the medical needle*…."[26] The parties agreed and the District Court adopted a construction for this term as "having a size designed for housing at least a portion of the medical needle that includes the sharp tip…"[27] The District Court construed the term "groove" as "a long narrow cut or depression."[28] The remainder of the claim element is "when the pair of wings are in the closed position."[29] Accordingly, at least the sharp tip portion of the medical needle must be housed in the "groove" when the pair of wings are in the closed position.

D. The Panel's Written Decision Illustrates EMED's Identified "Groove" Housing the Sharp Tip of the Medical Needle.

Reference to the Figures from the Panel's Written Decision illustrates that the sharp tip of the medical needle is in EMED's identified "groove" when the pair of wings are in the closed position:

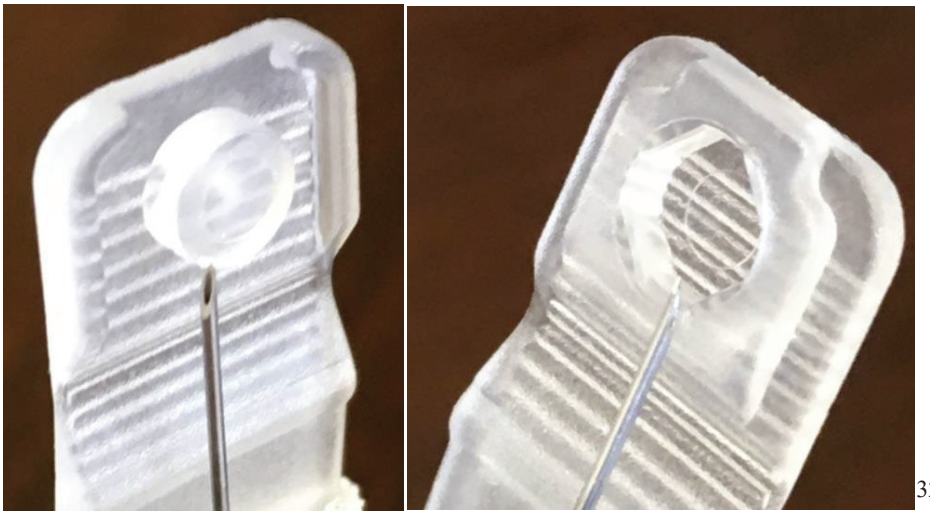
[26] Appx0070 at Claim 8 (emphasis added).
[27] Appx0335 and 0337-8.
[28] Appx0340-2 (Thus, it is not surprising that EMED would identify the "groove" as a depression).
[29] Appx0070.

 [30]

The Panel's Written Decision" addresses this apparent contradiction by stating that EMED cannot say that it's identified "groove" is insubstantially different than a structure that is long and narrow. However, this is precisely EMED's position, that EMED's identified "groove" is insubstantially different than "a long narrow cut of depression." In fact, this is precisely the type of situation for the doctrine of equivalents.

[30] *EMED Techs. Corp. v. Repro-Med Sys.*, No. 2019-2145, 2020 U.S. App. LEXIS 11240, at *10 (Fed. Cir. 2020).

There can be no dispute that EMED's identified "groove" is a cut or depression in the wing because the base of EMED's identified "groove" is lower than its sidewalls or edges:[31]

 [32]

EMED consistently identified the "groove" as the structure in the left panel of this illustration.

Likewise, the Panel agrees that at least in this one embodiment the needle extends into the EMED's identified "groove."[33]

Further, EMED's identified "groove" is at least as long as the wing, thus it would defy logic that EMED's identified "groove" is not long.

[31] Moreover, the Panel refers to its as EMED's "depression" at page 12 of the Written Decision.

[32] Appx0242.

[33] *EMED Techs. Corp. v. Repro-Med Sys.*, No. 2019-2145, 2020 U.S. App. LEXIS 11240, at *11 (Fed. Cir. 2020).

Accordingly, the only issue is whether a reasonable jury could consider EMED's identified "groove," the cut or depression, as equivalent to a *narrow* cut or depression. The Panel held that EMED's identified groove is substantially different than the claimed structure but provided no explanation of its reasoning. The Panel makes passing reference to EMED's identified "groove" by saying it "is filled by the socket structure from the other wing when the wings are attached in the closed position."[34] However, the claim language only requires that the sharp tip of the needle be housed by the "groove" when the wings are in the closed position. In the embodiment under discussion, the needle is in EMED's identified "groove" even assuming EMED's identified "groove" is filled by the socket structure. Thus, the needle's sharp tip is housed in EMED's identified "groove" when the pair of wings are in the closed position, sandwiched between the socket structure from the other wing and the base of EMED's identified "groove."

Taking all reasonable inferences in EMED's favor, a reasonable jury could determine that EMED's identified "groove" is equivalent to "*a long narrow cut or depression*." In fact, Appellee RMS itself explains that the photographs show "the needle tip is *sandwiched* between the outer surfaces."[35] Thus, there is no question that, for at least one embodiment, that the sharp tip portion of the medical needle

[34] *EMED Techs. Corp. v. Repro-Med Sys.*, No. 2019-2145, 2020 U.S. App. LEXIS 11240, at *11 (Fed. Cir. 2020).

[35] Appx0115 (emphasis added).

extends into and is housed by EMED's identified "groove" when the pair of wings are in the closed position.

EMED put forward its theory of infringement under the doctrine of equivalents in its Supplemental infringement contentions as follows:

> Any cut or depression with a shape designed of sufficient size to house the medical needle including the sharp tip would infringe under the doctrine of equivalents because under the law if one of ordinary skill in the art would understand that any size cut or groove with a shape designed of sufficient size to house the medical needle performs substantially the same function as a narrow cut or groove, in substantially the same way, by providing a cut or groove designed to house the medical needle including the sharp tip, thereby producing substantially the same result, by being capable of housing the medical needle including the sharp tip. The groove in the claimed medical needle is designed of sufficient size (i.e., is large enough to house the medical needle including the sharp tip) to house the medical needle including the sharp tip.
>
> Any size cut or depression with a shape designed of sufficient size to house the medical needle including the sharp tip achieves the same result (housing of the medical needle including the sharp tip) in substantially the same way as a narrow cut or depression designed to house the medical needle including the sharp tip because a user is protected from the sharp tip.
>
> Further, at all times relevant to the patents-in-suit, persons reasonably skilled in the art would have known of the interchangeability of the sized grooves.

[36] [37]

However, the Panel's Written Decision never addressed EMED's contention of why

[36] Appx0271.
[37] Appx0272.

RMS's device infringes under the doctrine of equivalents. Rather, the Panel applies the principle of vitiation without ever addressing equivalency or explaining how EMED's identified "groove" vitiates the claim limitation of a "groove" that is a long narrow cut or depression.

E. This Court Has to Date Applied Vitiation More Narrowly and the Panel's Written Decision Effectively Broadens Vitiation to a Point Rendering the Doctrine of Equivalents Meaningless.

This Court applies vitiation only when the

> 'all elements' rule forecloses resort to the doctrine of equivalents because, on the facts or theories presented in a case, a limitation would be read completely out of the claim--*i.e.*, the limitation would be effectively removed or 'vitiated.' … [This Court has] concluded that in some cases, the evidence was such that no reasonable jury could determine a proffered equivalent to be insubstantially different from the claimed limitation. (internal citation omitted) (holding that a limitation was vitiated in part because the structural difference in the accused device "is not a 'subtle difference in degree,' but rather 'a clear, substantial difference or difference in kind'" … the "all elements" rule barred application of the doctrine of equivalents because, on the facts presented, no reasonable jury could find the differences to be insubstantial…. the patentee's theory of equivalence was legally insufficient because, rather than demonstrate an insubstantial difference between a limitation and an element in the accused device, the theory effectively eliminated a limitation in its entirety…. Thus, the "all elements" rule generally is not met--and therefore a claim limitation can be said to be vitiated--if the theory or evidence of equivalence is legally incapable of establishing that the differences between the limitation in the claim and the accused device are insubstantial; *i.e.*, if the theory or evidence is so legally insufficient as to warrant a holding of non-infringement as a matter of law.[38]

[38] *Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1017-18 (Fed. Cir. 2006).

However, the Supreme Court cautioned this application by providing "[s]trictly speaking, evidence is said to be insufficient in law only in those cases where there is a total absence of such proof, either as to its quantity or kind, as in the particular case some rule of law requires as essential to the establishment of the fact."[39] Here, EMED's identified "groove" is some evidence and applying vitiation was inappropriate.

IV. ARGUMENT IN SUPPORT OF REHEARING EN BANC

V.

Rehearing *en banc* is necessary to maintain the uniformity of this Court's decisions. The Panel Decision is in direct conflict with precedent from the U.S. Supreme Court and precedent from this Court, as follows:

1. Because the Panel Decision applies vitiation as a threshold rather than a limitation on infringement under the doctrine of equivalents. While the United States Supreme Court instructs the Federal Circuit to have a "focus on individual elements and a special vigilance against allowing the concept of equivalence to eliminate completely any such [claim] elements,"[40] the application of vitiation of a claim element must be supported by the evidence of record. Otherwise, the principle of vitiation swallows the doctrine of equivalents, thus rendering it meaningless.

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[39] *Warner-Jenkinson*, 520 U.S. at 39 n.8; *Metro. R.R. Co. v. Moore*, 121 U.S. 558, 569, 7 S. Ct. 1334, 30 L. Ed. 1022 (1887)

[40] *Warner-Jenkinson Co.*, 520 U.S. at 39-40.

2. Because the Panel Decision reaches a legal conclusion of vitiation of a claim element without taking all reasonable inferences in favor of EMED, the Panel did not properly consider whether the evidence is such that no reasonable jury could conclude that an element of an accused device is equivalent to an element called for in the claim, or that the theory of equivalence to support the conclusion of infringement otherwise lacks legal sufficiency. Thus, an issue that is properly decided by a jury was decided by the Court.

VI. CONCLUSION

Appellants respectfully request this Court grant this Petition for a rehearing and reconsideration *en banc*.

Date: April 23, 2020

Respectfully submitted,

Ramey & Schwaller, LLP

/s/ William P. Ramey, III
William P. Ramey, III
Texas State Bar No. 24027643
5020 Montrose Blvd., Suite 800
Houston, Texas 77006
713-426-3923 (Telephone)
832-900-4941 (Facsimile)

ATTORNEYS FOR EMED TECHNOLOGIES CORPORATION

ADDENDUM

NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

EMED TECHNOLOGIES CORPORATION,
Plaintiff-Appellant

v.

REPRO-MED SYSTEMS, INC., DBA KORU MEDICAL SYSTEMS,
Defendant-Appellee

2019-2145

Appeal from the United States District Court for the Eastern District of Texas in No. 2:15-cv-01167-JRG-RSP, Judge J. Rodney Gilstrap.

Decided: April 9, 2020

WILLIAM PETERSON RAMEY, III, Ramey & Schwaller, LLP, Houston, TX, for plaintiff-appellant.

ROBERT M. ISACKSON, Leason Ellis LLP, White Plains, NY, for defendant-appellee. Also represented by HENRY GABATHULER, MATTHEW L. KAUFMAN, HODA RIFAI-BASHJAWISH.

Before CHEN, SCHALL, and HUGHES, *Circuit Judges*.

CHEN, *Circuit Judge*.

Plaintiff EMED Technologies Corporation (EMED) sued Repro-Med Systems, Inc. (Repro-Med) for infringement of U.S. Patent No. 8,961,476 (the '476 patent). Following claim construction, the district court granted Repro-Med's motion for summary judgment of noninfringement. EMED appeals the noninfringement ruling. We *affirm*.

BACKGROUND

I. The '476 Patent

The '476 patent describes medical needle devices with built-in safety structures "to protect a user from the sharp tip of the medical needle." '476 patent at Abstract. The specification describes various embodiments, and both parties refer to Figure 10 as depicting the relevant embodiment:

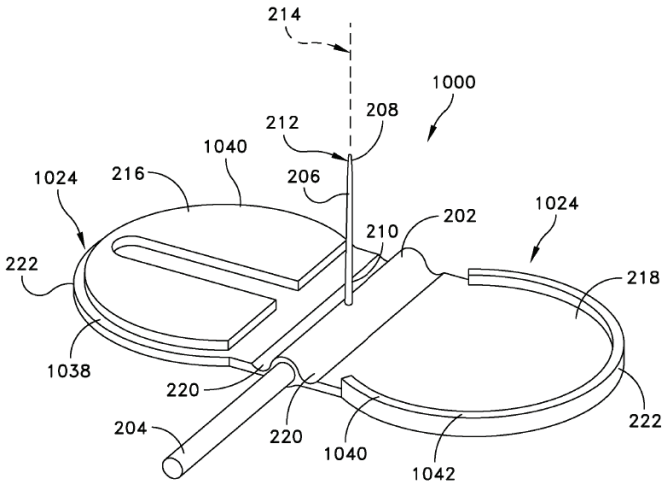


FIGURE 10

Id. at Fig. 10.

As shown in Figure 10, the safety device includes needle 208 between a pair of opposing "wings" 216 and 218. To

protect a user from the needle, the wings rotate into a closed position in which the needle fits into a "groove" that is "sized for housing" the needle. *Id.* at col. 6, ll. 35–38; *see also id.* at claim 8. Although not labeled in Figure 10, the parties do not appear to dispute that the groove is depicted as the long and narrow recess in wing 216 on the left-hand side of Figure 10. In the closed position, the two wings are attached via mechanical fastener 1024, which includes protruding lip 1042 of wing 218 that engages with matching recess 1038 in the perimeter of opposing wing 216. *Id.* at col. 6, ll. 19–29.

The sole claim at issue on appeal is claim 9. Claim 9 depends from claim 8, which in turn depends from independent claim 1. Claim 1 is directed to a "device for protecting a user from a sharp tip of a medical needle," and recites, *inter alia*, a "pair of wings" and a "mechanical fastener" including a "lip" on at least one wing and a "mating portion" on at least the other wing. *Id.* at claim 1. Claim 8 further recites a "groove having a size configured for housing at least a portion of the medical needle when the pair of wings are in the closed position." *Id.* at claim 8. Claim 9 further specifies that the "groove is formed in a single one of the pair of wings." *Id.* at claim 9. Claims 1, 8, and 9 are reproduced below:

> 1. A device for protecting a user from a sharp tip of a medical needle, the device comprising:
>
> a central body portion;
>
> the medical needle having a first end in fluid connection with a delivery tube, and a second end distal from the central body portion including the sharp tip;
>
> a pair of wings, each wing of the pair of wings having an inner region and an outer region, the inner region of each wing in attachment to the central body portion, the outer region of each wing

extending away from the central body portion, the pair of wings disposed in opposition to one another with the medical needle positioned therebetween, and the pair of wings being selectively positionable from an open position to a closed position, where the wings in the open position are spaced apart from each other to expose the medical needle to allow placement of the medical needle into a treatment site and delivery of a medicinal fluid, and wherein the wings in the closed position cover the medical needle to protect against accidental needle stick injury from the medical needle;

a mechanical fastener disposed on at least one wing of the pair of wings, the mechanical fastener configured to selectively attach the pair of wings together with the medical needle positioned therebetween so as to protect against accidental needle stick injury from the sharp tip of the medical needle;

the mechanical fastener including a lip extending along at least a portion of a perimeter of at least one wing of the pair of wings, and a mating portion along a perimeter of at least one other wing of the pair of wings, and wherein the mating portion and the lip are configured to align the at least one wing relative to the at least one other wing in the closed position.

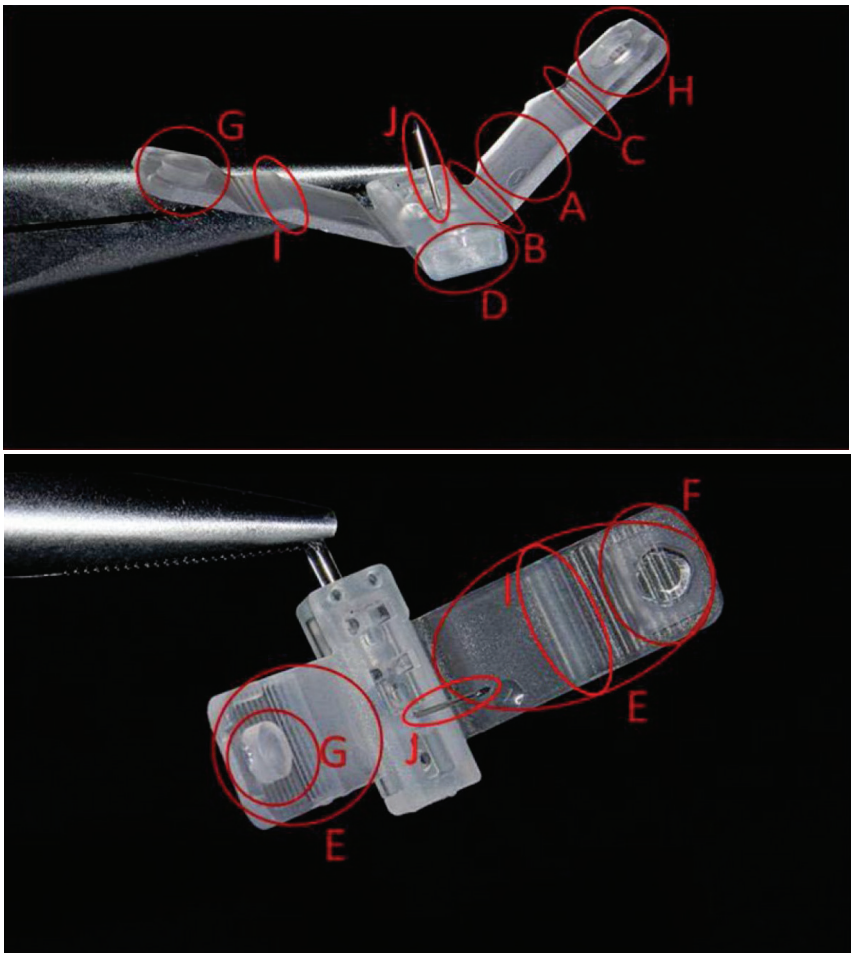
8. The device in accordance with claim 1, wherein at least one of the pair of wings is formed with *a groove having a size configured for housing at least a portion of the medical needle when the pair of wings are in the closed position.*

9. The device in accordance with claim 8, *wherein the groove is formed in a single one of the pair of wings.*

Id. at claims 1, 8, 9 (emphases added).

II. The Accused Products

EMED accuses various models of Repro-Med's safety needle devices (the Accused Products), which for the purposes of this appeal differ with respect to the exposed length of the needle as measured from the housing to the sharp tip. Repro-Med provides the following annotated diagrams of the Accused Products:



J.A. 113.

Repro-Med also provides the following description of the Accused Products, which EMED does not dispute:

> [E]ach wing (E) has a needle facing surface that includes a smooth rectangular section (A) interposed between two thinned areas (B and C). A first thinned area (B) is provided between the housing (D) and the wing (E), thereby allowing each wing (E) to move between open and closed positions. A second thinned area (C) is provided between the rectangular section (A) and the outer section (F) of the wing (E) bearing the plug (G) and the wing (E) bearing the socket (H). This second thinned area (C) allows the outer section (F) of each wing (E) to bend relative to its adjacent smooth rectangular section (A), allowing the plug (G) and the socket (H) to engage and thereby lock the wings together in the closed position about the medical needle. Each of the rectangular surface sections (A) have a ridge (I) adjacent the second thinned area (C), the ridge (I) extending perpendicular to the length (J) of the medical needle extending from the housing.

Appellee's Br. at 3–4.

III. Procedural History

In 2015, EMED filed a complaint in the Eastern District of Texas alleging infringement of the '476 patent by the Accused Products. In response, Repro-Med petitioned for inter partes review (IPR), challenging claims 1–10 of the '476 patent. The Board instituted IPR and subsequently found claims 1–8 and 10 unpatentable. *Repro-Med Sys., Inc. v. EMED Techs. Corp.*, IPR2015-01920, 2017 WL 378978, at *1 (P.T.A.B. Jan. 12, 2017). This court affirmed, leaving dependent claim 9 as the sole claim at issue in the district court litigation. *EMED Techs. Corp. v. Repro-Med Sys., Inc.*, 725 F. App'x. 1005, 1008 (Fed. Cir. 2018), *cert. denied*, 139 S. Ct. 418 (2018).

After the Board's IPR decision, the district court conducted a *Markman* hearing and construed various terms relating to the "groove" of claim 9. Three of these claim terms are relevant to this appeal, and the parties do not contest the district court's constructions of any of the claim terms. First, the district court construed "groove" to mean "a long narrow cut or depression." *EMED Techs. Corp. v. Repro-Med Sys., Inc.*, No. 2:15-cv-1167-JRG-RSP, 2019 WL 1040604, at *9 (E.D. Tex. Mar. 4, 2019). As the district court noted, "[t]he parties agree that the recited 'groove' is a 'long narrow' something," with EMED proposing "a long narrow cut" and Repro-Med proposing "a long narrow depression." *Id.* at *8. The district court's construction combined those two proposals. Second, the district court accepted the parties' agreed-upon construction of the claimed groove "having a size configured for housing at least a portion of the medical needle" to mean "having a size designed for housing at least a portion of the medical needle that includes the sharp tip." *Id.* at *7. Third, the district court also adopted the parties' construction of "wherein the groove is formed in a single one of the pair of wings" to mean "wherein the groove is formed in only one of the pair of wings." *Id.*

Following claim construction, Repro-Med moved for summary judgment of noninfringement on all Accused Products under either literal infringement or the doctrine of equivalents. The magistrate judge recommended that summary judgment be granted in favor of Repro-Med.

As to literal infringement, the magistrate judge explained that the claimed groove must house the needle, but "[i]n the Accused Products, there is no space to house anything, much less a medical needle, in the mechanical fastener once the fastener is closed." J.A. 19. Instead, the needle in the Accused Products is "merely positioned between the wings," and there was "no genuine dispute that the Accused Products' alleged mechanical fastener does not meet the limitations of a groove." *Id.* Moreover, the

magistrate noted that "EMED points to no long narrow cut or depression on either wing of the Accused Products." J.A. 20.

The magistrate judge further reasoned that applying the doctrine of equivalents to capture portions of the mechanical fastener as the claimed "groove," as urged by EMED, would vitiate the claim limitations "groove having a size configured for housing at least a portion of the medical needle when the pair of wings are in the closed position" and "wherein the groove is formed in a single one of the pair of wings." J.A. 21–22.

The district court adopted the magistrate judge's recommendation and granted summary judgment of non-infringement. EMED appeals. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

We review a grant of summary judgment in accordance with the law of the regional circuit, here the Fifth Circuit. *Ineos USA LLC v. Berry Plastics Corp.*, 783 F.3d 865, 868 (Fed. Cir. 2015). The Fifth Circuit reviews de novo a district court's grant of summary judgment. *Id.* (citing *Triple Tee Golf, Inc. v. Nike, Inc.*, 485 F.3d 253, 261 (5th Cir. 2007)).

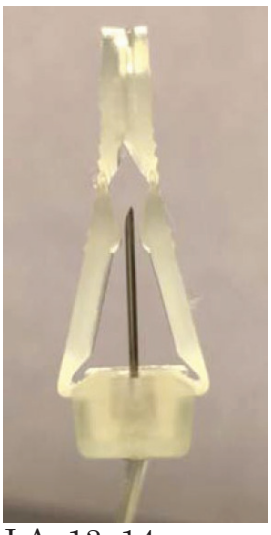
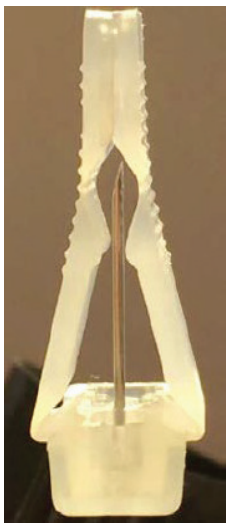
I. Literal Infringement

We apply a two-step analysis to determine whether accused devices literally infringe a patent's claims. First, the claims are "construed to determine their scope." *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1330 (Fed. Cir. 2001). Second, "the claims must be compared to the accused device." *Id.* "Literal infringement exists when every limitation recited in the claim is found in the accused device." *Akzo Nobel Coatings, Inc. v. Dow Chem. Co.*, 811 F.3d 1334, 1341 (Fed. Cir. 2016). "[O]n appeal from a grant of summary judgment of noninfringement, we must determine whether, after resolving reasonable factual

inferences in favor of the patentee, the district court correctly concluded that no reasonable jury could find infringement." *IMS Tech., Inc. v. Haas Automation, Inc.*, 206 F.3d 1422, 1429 (Fed. Cir. 2000).

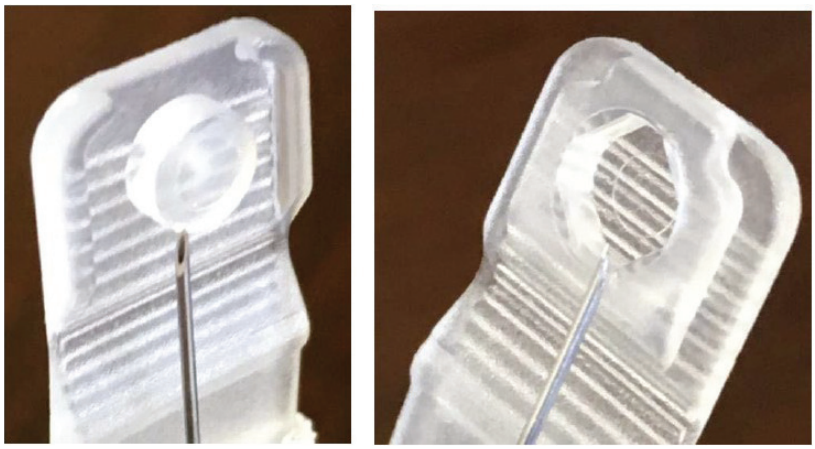
Under the district court's undisputed constructions, the claimed groove is a "a long narrow cut or depression" formed in "only one of the pair of wings," 2019 WL 1040604, at *9, and "ha[s] a size designed for housing at least a portion of the medical needle that includes the sharp tip." *Id.* at *7. Moreover, the groove must perform the specific function of housing the needle "when the pair of wings are in the closed position." '476 patent at claim 8. Effectively, the claimed groove protects the user from the needle's sharp tip while the wings are closed.

The Accused Products lack a "groove" as claimed and protect the user from needle injuries in a different way. Where the claimed device houses the needle in a groove in one of the wings—i.e., a long narrow cut or depression—the needle in the Accused Products is merely positioned between the two wings, as shown below.


J.A. 13–14.

As shown in the far-right photograph above, the needle of at least one embodiment of the Accused Products appears to reach the plug and socket structure when the wings are closed. But the plug and socket structure does not contain any long narrow cut or depression that houses the needle, as shown in the close-up images below:



J.A. 14.

EMED argues that the claimed groove is self-evident from the above photographs. According to EMED, the "groove is the depression on the left wing that is formed by the lip at the left and right edges of the left wing." Appellant's Br. at 8. We disagree. EMED's theory fails to account for the requirement that the groove "house[s]" the needle "when the pair of wings are in the closed position." '476 patent at claim 8. When the wings of the Accused Products are in the closed position, the surfaces of outer section (F) of the respective wings contact and mate with each other, thereby filling and eliminating any area in the left wing alleged to be a "groove" that may house the needle. As the magistrate judge explained, "there is no space to *house* anything, much less a medical needle, in the mechanical fastener once the fastener is closed." J.A. 19 (emphasis added). It may be true that the needle, in one accused embodiment, contacts the plug-socket structure in the closed position, but mere contact is not sufficient to

establish a genuine dispute that one of the wings might contain a groove "configured for housing" any portion of the needle.

Nor is the area surrounding the plug on which EMED relies "a long narrow cut or depression" as required by the district court's construction of "groove." 2019 WL 1040604, at *9. The perimeter of this area appears to be roughly square, and the plug protrudes from the center of it. EMED's briefing is markedly silent on how the region surrounding the plug could possibly be "a long narrow cut or depression." Likewise, the report of EMED's expert, Dr. Stoker, does not even attempt to explain how the Accused Products contain the claimed groove as construed. Thus, on the evidence in the record, we agree with the district court that there is no genuine dispute that the Accused Products do not contain the claimed groove.

II. Doctrine of Equivalents

Under the doctrine of equivalents, "a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997). But an argument under the doctrine of equivalents fails if it "renders a claim limitation inconsequential or ineffective." *Akzo Nobel Coatings*, 811 F.3d at 1342. As the Supreme Court instructed, "if a theory of equivalence would entirely vitiate a particular claim element, partial or complete judgment should be rendered by the court, as there would be no further *material* issue for the jury to resolve." *Warner-Jenkinson*, 520 U.S. at 39 n.8.

As we explained above, the photographic evidence of the Accused Products establishes that what EMED alleges is the claimed "groove"—i.e., the area surrounding the plug—is filled by the socket structure from the other wing when the wings are attached in the closed position. The

claims explicitly require that the "groove" must house the needle when the wings are in the closed position. '476 patent at claim 8. To extend the claimed "groove" to encompass structures that do not house the needle would vitiate that claim limitation. In that same vein, EMED did not and cannot plausibly argue, without vitiating the limitation, that the area to which it refers as a "depression" is insubstantially different from a structure that is long and narrow.

CONCLUSION

We have considered EMED's remaining arguments and find them unpersuasive. For the reasons stated above, we *affirm* the district court's grant of summary judgment of noninfringement.

AFFIRMED

CERTIFICATE OF SERVICE

I certify that I served a copy on counsel of record on April 23. 2020, by ECF filing.

By: /s/ William P. Ramey, III

William P. Ramey, III
Ramey & Schwaller, LLP
Texas State Bar No. 23027643
5020 Montrose Blvd., Suite 800
Houston, Texas 77006
(713) 426-3923 (Telephone)
(832) 900-4941 (Facsimile)
wramey@rameyfirm.com

ATTORNEYS FOR EMED TECHNOLOGIES CORPORATION

CERTIFICATE OF COMPLIANCE WITH FED. R. APP. P. 32(a)(7)(B)

The undersigned counsel of records for Appellant EMED Technologies Corporation, certifies that this Request for Rehearing and Rehearing *en banc* complies with the typeface requirement provided in Rule 32(a)(5) and type-volume limitation provided in Rule 32(a)(7)(B) of the Federal Rules of Appellate Procedure. In preparing this certificate, I relied on word-count program of Microsoft Word. This Brief contains 2545 words.

Dated: April 23, 2020 By: /s/ William P. Ramey, III

William P. Ramey, III
Ramey & Schwaller, LLP
Texas State Bar No. 23027643
Federal Circuit Bar No.
5020 Montrose Blvd., Suite 800
Houston, Texas 77006
(713) 426-3923 (Telephone)
(832) 900-4941 (Facsimile)
wramey@rameyfirm.com

ATTORNEYS FOR EMED TECHNOLOGIES CORPORATION