STATE OF INDIANA

COUNTY OF MARSHALL

IN THE MARSHALL CIRCUIT COURT

CAUSE NO. 50C01-1806-PL-27

Rick C. Sasso, M.D.

Plaintiff,

v.

Warsaw Orthopedic, Inc., Medtronic, Inc. and Medtronic Sofamor Danek, Inc.,

Defendants.

DEFENDANTS' MEMORANDUM IN SUPPORT OF MOTION TO CORRECT ERROR

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Pursuant to Trial Rule 59, Defendants Warsaw Orthopedic, Inc., Medtronic, Inc., and Medtronic Sofamor Danek, Inc. ("Medtronic")[1] respectfully submit this memorandum in support of their motion to correct error. The verdict was unsupported by and contrary to the evidence, and at the very least against the weight of the evidence. Additionally, this Court lacks jurisdiction over Dr. Sasso's claims. Medtronic respectfully requests that the Court (1) enter judgment for Medtronic and/or amend the judgment by reducing damages to zero, (2) grant a new trial; and/or (3) dismiss the case.

I. BACKGROUND

In this case, Dr. Sasso alleged Medtronic breached two contracts: the December 1999 Purchase Agreement (the "1999 Agreement," PX3), and the July 2001 Purchase Agreement (the "2001 Agreement," PX1). The jury found Dr. Sasso had breached both, and awarded a total of $112 million, including $79.8 million on the 1999 Agreement and $32.7 million on the 2001 Agreement. Judgment (Nov. 29, 2018).

As to the 1999 Agreement, the jury awarded Dr. Sasso nearly $80 million in royalties on products he admittedly did not invent and that are identified nowhere in the contract as royalty-bearing. This was in direct contradiction to the agreement itself. By its express terms, the 1999 Agreement is narrow; it requires Medtronic to pay royalties only on ***only two*** types of devices: those relating to "***a facet screw instrumentation***" and "***a headless facet screw fixation system***…." PX3 §§ 1(A), 1(C), 4(B), Schedule A (emphasis added).

Contrary to the jury's verdict, it was undisputed at trial that:

- A "headless facet screw fixation system" was never developed and therefore generated no revenues or royalties;

[1] Medtronic acquired Sofamor Danek in 1999. Throughout this brief, "Medtronic" is used to refer to Defendants collectively.

- Medtronic paid all royalties due to Dr. Sasso on products "relating to a facet screw instrumentation";

- Dr. Sasso never asked that the parties amend the agreement's relevant schedule to add ***other*** products besides the two types of products specified in the contract—and no mutual agreement to amend was ever reached; and

- The royalties Dr. Sasso sought at trial were on products that he did not invent and that are ***unrelated*** to facet screw instrumentation or headless facet screws.

Nevertheless, the jury found Medtronic breached the 1999 Agreement and awarded Dr. Sasso the full $80 million he sought. That verdict is unsupported by and contrary to the evidence and judgment should be entered for Medtronic on Count III of the Third Amended Complaint.

The jury's finding that Medtronic breached the 1999 Agreement was also clearly erroneous because the agreement expired by its terms in 2009. In order for the agreement to extend for more than seven years (beyond 2009), the agreement required that a valid patent claim cover a Medtronic product. PX3 § 7 (requiring "valid claim coverage of the Medical Device" as a prerequisite to life-of-patent royalties). Dr. Sasso failed to prove that any claim of a relevant patent covered any Medtronic device. Moreover, the irrefutable fact that the United States Patent and Trademark Office found the asserted patent claims to be ***invalid*** was incorrectly excluded. The result was that Dr. Sasso was repeatedly permitted to testify—over objection, contrary to the actual facts, and without rebuttal—that the patent claims he relied on were "really, really broad" and that the claims sailed through the Patent Office without amendment; his counsel even wrongly emphasized in closing argument that the claims were "in force today." That testimony and argument were not only untrue, but highly misleading and unfairly prejudicial, and requires judgment in Medtronic's favor, or at least a new trial. Further, Dr. Sasso's claim for breach of the 1999 Agreement was barred by the statute of limitations and/or the doctrine of laches, and this Court lacks jurisdiction over it for reasons previously argued. Independently, the damages

award was unsupported by any reliable principles or evidence; Dr. Sasso's damages theories were purely speculative, untethered from his theories of liability, and unsupported by facts.

Given the utter lack of evidence that Medtronic breached its obligations to Dr. Sasso under the 1999 Agreement or that Medtronic owes Dr. Sasso $80 million under it, as well as evidentiary errors during trial and jurisdictional bars, this Court should enter judgment in Medtronic's favor, amend the judgment to reflect zero damages, order a new trial on the 1999 Agreement, or else dismiss.

As to the 2001 Agreement, all of Dr. Sasso's theories of breach relied on showing an entitlement to life-of-patent royalties. But the evidence Dr. Sasso put forward at trial cannot support such a finding—there was no showing of claim coverage by the patent included in the "Intellectual Property Rights" and no showing that any other patent could give rise to life-of-patent royalties. For this and additional reasons described below, this Court should also enter judgment for Medtronic, amend the judgment to reduce the damages award, order a new trial, or dismiss.

II. LEGAL STANDARDS

"The function of the motion to correct errors is to focus on important alleged errors to give the trial judge a closer perspective than might have been available during the regular course of the proceedings." *Macken v. City of Evansville*, 362 N.E.2d 202, 204 (Ind. Ct. App. 1977). "[T]he court shall grant a new trial if it determines that the verdict of a non-advisory jury is against the weight of the evidence; and shall enter judgment, subject to the provisions herein, if the court determines that the verdict of a non-advisory jury is clearly erroneous as contrary to or not supported by the evidence[.]" Ind. Trial Rule 59(J). "'On a motion for a new trial it must clearly appear to the trial court that substantial justice has been done and, if in his opinion the preponderance of the evidence is against the verdict, it is his duty to grant the new trial.'"

Borowski v. Rupert, 281 N.E.2d 502, 505 (Ind. Ct. App. 1972) (quoting *Bailey v. Kain*, 192 N.E.2d 486, 488 (Ind. Ct. App. 1963))).

III. THE $79.8 MILLION VERDICT UNDER THE 1999 AGREEMENT IS CLEARLY ERRONEOUS AS CONTRARY TO OR NOT SUPPORTED BY THE EVIDENCE, AND AT A MINIMUM AGAINST THE WEIGHT OF THE EVIDENCE

The $79.8 million verdict on the 1999 Agreement claim should be set aside, because the evidence does not support Dr. Sasso's breach of contract claim and because the size of the verdict was unsupported by reliable principles or evidence.

A. The Undisputed Evidence Shows That Medtronic Paid Royalties On All Royalty-Bearing Products Defined By The 1999 Agreement, Such That There Was No Breach

Dr. Sasso failed to prove that Medtronic owed any unpaid royalties under the 1999 Agreement. The agreement obligated Medtronic to pay Dr. Sasso 2.5% of the worldwide net sales of the "Medical Device," where a "Medical Device" is "any device, article, system, apparatus or product including the Invention." PX3 §§ 1(C), 4(B). The "Invention," in turn, is "any product, method or system relating to a facet screw instrumentation and a headless facet screw fixation system…." *Id.* § 1(A). The "Medical Devices" on which royalties were to be paid were to "be listed in accordance with [Sofamor Danek] catalog numbers … in Schedule B." *Id.* § 1(C). Schedule B—in 1999 and today—describes only two types of products: "[1] Facet Screw Instrumentation, and [2] A Headless Facet Screw Fixation System." *Id.*, Schedule B. For at least the following reasons, the products for which Dr. Sasso sought royalties were outside of Schedule B and the definition of Medical Device, and therefore not subject to royalties under the 1999 Agreement.

First, the 1999 Agreement requires that all royalty-bearing products be listed by catalog number in Schedule B. Schedule B includes no such catalog numbers (*id.*, Schedule B), so it was undisputed that the products on which Dr. Sasso sought royalties were never listed on

Schedule B. As the Court of Appeals held in an interlocutory appeal in this case, a listing of "Medical Devices" in an addendum to a contract governs a claim of breach based on failure to pay royalties. *See Sasso v. Warsaw Orthopedic, Inc.*, 45 N.E.3d 835, 841 (Ind. Ct. App. 2015) (explaining that the listing of "Medical Devices" attached to a contract between Dr. Sasso's company and Medtronic would serve as the "basis for determining whether a breach occurred"). This by itself suffices to grant judgment in favor of Medtronic, because Schedule B does not list the products for which Dr. Sasso sought royalties.

Second, despite the absence of a product ***list*** in Schedule B, Medtronic paid royalties on all products ***described*** in Schedule B, and no further royalties were owed. Schedule B describes only "Facet Screw Instrumentation" and a "Headless Facet Screw Fixation System." PX3, Schedule B. Dr. Sasso admitted at trial that there was never any "Headless Facet Screw Fixation System." 11/13/2018 Tr. 82:14-23 (Sasso) ("Q As of this time, from November 1, 1999 forward, there has never been a headless facet screw product, has there? A That's correct. Q And there's never been a headless facet screw program? A Correct. Q And there's never been a headless facet screw system? A That's correct.").[2] Dr. Sasso also admitted that Medtronic had already paid royalties on all "Facet Screw" products it sold. 11/9/2018 Tr. 140:3-6 (Sasso) ("Q Okay. And you're owed money on facet screws, right? A Well, I've been paid – I've been – my facet screws."). Dr. Sasso did not allege at trial that Medtronic failed to pay royalties on sales of its facet screws. 11/9/2018 Tr. 142:3-10 (Sasso) (parties agree Dr. Sasso was paid $17,690 owed on $718,000 revenue on facet screws). Thus, Medtronic owed no additional royalties under the 1999 Agreement.

[2] Because final transcripts are not yet available, citations to "Tr." are to the rough transcript.

Indeed, there was a complete lack of evidence to show that the products Dr. Sasso sought royalties on were the "Facet Screw Instrumentation" specified in Schedule B. Although his theories changed before and during trial, Dr. Sasso ultimately sought royalties on a subset of sales of Medtronic's CD Horizon screws and interbody implants (the "Disputed Products"). There is no evidence that these products are "Facet Screws," or even "Instrumentation" at all. Instead, the CD Horizon screws are an entirely different type of screws called pedicle screws. 11/27/2018 Tr. 94:9-13 (Pellegrino) (CD Horizon line consists of pedicle, not facet, screws); *see also* Dep. Ex. 10 (Patterson Tr.) 48:18-23. The Capstone, Clydesdale, and Perimeter interbody implants are not screws at all, but are instead implants inserted between adjacent vertebrae. 11/9/2018 Tr. 143:1-8 (Sasso) (Capstone, Clydesdale, and Perimeter are interbody implants); *see also* 11/8/2018 Tr. 69:7-9 (Parnell); 11/16/2018 Tr. 37:4-21 (Pellegrino). Thus, no evidence demonstrated that the Disputed Products were within the scope of Schedule B, and Dr. Sasso was legally prohibited from recovering royalties on them. *See Sasso*, 45 N.E.3d at 841. [3]

Third, although the agreement requires all royalty-bearing devices to be listed on Schedule B, Dr. Sasso admits that the parties never mutually agreed to amend the 1999 Agreement to add the Disputed Products. To add products to Schedule B, Dr. Sasso needed the mutual written agreement of Medtronic. PX3 § 1(C) ("Schedule B may be updated from time to time by mutual written agreement of the parties hereto to include the appropriate [Medtronic]

[3] At the beginning of the case, Dr. Sasso also sought royalties on Medtronic's METRx and Quadrant outer cannula product families, as well as Anchor FS screws. But by the time of trial, he had dropped his claims as to METRx and Quadrant, and sometime after opening statements, dropped the claim to Anchor FS screws. *See* 11/16/2018 Tr. 73:19-74:22 (Pellegrino) (admitting he calculated damages for Anchor FS, METRx, and Quadrant in June 2018, but did not do so at trial at the direction of Dr. Sasso, even though Mr. Pellegrino was relying on METRx and Quadrant for parts of his analysis); *see also* 11/9/2018 Tr. 142:13-19 (Sasso) (Dr. Sasso explaining Anchor FS was no longer part of the case).

catalog numbers and descriptions of any Medical Device(s)…."). Dr. Sasso himself admitted there was never any mutual written agreement to add parts to Schedule B:

> Q. Let's go to Schedule B [to the 1999 Agreement]. Why are there no part numbers listed there?
>
> A. Because we hadn't developed them. These were not there. This (inaudible).
>
> ...
>
> Q. Did Medtronic ever update schedules to either of these agreements?
>
> A. No, because we needed a mutual – next sentence about mutual written agreement. We never came to a mutual agreement. That was what I was talking about. This was the agreement. We needed to mutually agree to add Schedule B.

Id. at 119:9-12; 119:20-120-1 (Sasso). Dr. Sasso also admitted that prior to filing this lawsuit, he never made a written request to Medtronic to update Schedule B to include additional any medical devices. 11/13/2018 Tr. 94:5-96:4 (Sasso).

As explained above, Dr. Sasso is legally prohibited from recovering royalties for parts not listed in Schedule B. Awarding royalties on such parts would contravene the agreement's plain language. *Allstate Ins. Co. v. Watson*, 195 S.W.3d 609, 611 (Tenn. 2006). The 1999 Agreement's plain language requires the mutual written agreement of the parties before any parts become royalty-bearing. PX3 § 1(C). Dr. Sasso admitted this at trial. 11/9/2018 Tr. 119:25-120:1 (Sasso) ("This was the agreement. We needed to mutually agree to add [to] Schedule B."). Yet there was never any meeting of the minds to amend Schedule B to add the Disputed Products. A contract modification "requires mutuality of assent and meeting of the minds." *Buchholz v. Tennessee Farmers Life Reassurance Co.*, 145 S.W.3d 80, 84 (Tenn. Ct. App. 2003). Dr. Sasso's own testimony confirms that he failed to obtain mutual written agreement from Medtronic to add any other products. 11/9/2018 Tr. 119:20-120:1, 143:1-8, 206:4-6 (Sasso); 11/13/2018 Tr. 82:14-23, 97:6-20 (Sasso).

Fourth, no amendment of Schedule B would have been appropriate or necessary because, for the same reasons that the Disputed Products were outside of the description of Schedule B, they were also outside of the scope of the "Invention," and therefore outside of the definition of "Medical Device." As mentioned above, a "Medical Device" is "any device, article, system, apparatus or product including the Invention," where the "Invention" is "any product, method or system relating to a facet screw instrumentation and a headless facet screw fixation system as described in Schedule A." PX3 §§ 1(A), 1(C). Schedule A likewise defines the Invention as "Facet Screw Instrumentation and a Headless Facet Screw Fixation System consisting of bone screws and associated instruments for installation thereof." *Id.*, Schedule A. As explained above, there was no substantial evidence that the Disputed Products were related to "Facet Screw Instrumentation," and no "Headless Facet Screw Fixation System consisting of bone screws and associated instruments for installation thereof" ever existed. Thus, there was no evidence that the Disputed Products could have been added to Schedule B of the 1999 Agreement.

Finally, Dr. Sasso admits that he did not develop or invent any of the Disputed Products. 11/9/2018 Tr. 143:9-12 (Sasso) ("Q It's true, is it not, Dr. Sasso, that you had nothing to do with the invention of CD Horizon screws? A Correct."), 147:5-16 (Sasso) (Dr. Sasso testifying he had "nothing to do with inventing, developing, or bringing to market the Clydesdale implant," nor Capstone or Perimeter); 11/13/2018 Tr. 58:5-19 (Sasso) (testifying he did not invent any of the components of claim 26 of the '313 patent); *see also* 11/19/2018 Tr. 231:21-232:5 (Lange) (CD Horizon family of pedicle screws was never part of facet project). Thus, royalty payments for those products were outside the scope of his alleged invention, would have exceeded his contributions to Medtronic, and would have been inappropriate. 11/19/2018 Tr. 32:7-33:1 (King); 11/27/2018 Tr. 28:8-16, 30:18-31:17 (Ellis).

In sum, Dr. Sasso presented no evidence that the Disputed Products qualified as either the "facet screw instrumentation" or a "headless facet screw fixation system" which are necessary prerequisites for a product to be royalty-bearing. Thus, there was no breach, and the Court should enter judgment in favor of Medtronic. At the very least, because a contrary finding is against the weight of the evidence, a new trial on the point is required.

B. No Evidence Supports Dr. Sasso's Countertextual Theory That Medtronic Owed Royalties On The Disputed Products

1. Dr. Sasso's Theory Of Breach Was Contrary To The 1999 Agreement

In apparent recognition that the Disputed Products were outside the scope of the 1999 Agreement, Dr. Sasso has consistently advanced a theory of breach divorced from the text of the contract. Specifically, Dr. Sasso attempted to redefine the royalty-bearing products as the Medtronic products within the scope of U.S. Patent No. 6,287,313 (the "'313 patent," PX17), which he assigned to Medtronic in connection with the 1999 Agreement. 11/9/2018 Tr. 51:2-25 (Sasso) (describing the invention of claim 26 of the '313 patent as "what it is that the patent application had that [Dr. Sasso was] turning over to Medtronic"); 11/9/2018 Tr. 115:15-18 (Sasso) ("Q But you were to be paid for those as something that is included in the invention? A As long as they're used in the method that the patent describes."). Since his opening statement, Dr. Sasso has argued that "the system that was developed" based on the 1999 Agreement "are those five things … all of those five things are the elements of this claim 26" of the '313 patent. 11/2/2018 Tr. 44:18-48:23 (Sasso opening statement). Indeed, Dr. Sasso tied the breach to what he called the use of "a technique that is described in the '313 patent":

> Q Okay. ***What does Medtronic owe you on your screw delivery system agreement***?
>
> A Well, we have an expert that's looked at all and he's going to come and tell us.
>
> Q And what has he done an analysis of?

> A He's done an analysis of this, what's ***the value of putting in implants, screws and cages, through a technique that is described in the '313 patent***.

11/9/2018 Tr. 122:11-19 (Sasso) (emphasis added).

Of course, nothing in the 1999 Agreement entitles Dr. Sasso to royalties on parts he did not invent, that are not listed in the agreement's Schedule B, and that do not fall within the definitions of "Medical Device" or "Invention," simply because Dr. Sasso believes they can be used to perform a "technique." Since Dr. Sasso's attempt to rewrite the definition of "Invention" contradicted the plain language of the agreement, judgment should be entered for Medtronic.

2. No Evidence Supports A Finding That Medtronic Ever Made A Product That Met All Limitations Of The Asserted '313 Patent Claims

Even under Dr. Sasso's theory that he was entitled to royalties on products falling within the scope of the '313 patent, Dr. Sasso failed to prove any entitlement to royalties. The only independent claim of the '313 patent that Dr. Sasso's witnesses asserted covered Medtronic's products was claim 26, yet those assertions utterly lacked any supporting evidence.[4] 11/8/2018 Tr. 57:24-58:6 (Parnell). Claim 26 claims a "screw delivery system kit" and requires five components:

> 26. A ***screw delivery system kit*** for providing a minimally invasive portal to a surgical site ***comprising***:

[4] The separate '046 patent, which Dr. Sasso had previously asserted, was never entered into evidence at trial, nor was any evidence of claim coverage offered. Dr. Sasso's technical expert, Dr. Parnell, admitted he offered no opinions regarding the '046 patent. 11/8/2018 Tr. 53:16-24, 75:8-13 (Parnell). Nor was Dr. Sasso's passing reference to the '046 patent's existence sufficient to support a verdict for breach of contract based on coverage by the '046 patent. 11/9/2018 Tr. 50:15-18, 64:22-65:2, 117:2-14 (Sasso). *See also Zenith Labs., Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1424 (Fed. Cir. 1994) (reversing district court's finding of infringement where patent owner failed to compare the asserted claims with the accused product)*; Novartis Corp. v. BenVenue Labs. Inc.*, 271 F.3d 1043, 1054 (Fed. Cir. 2001) (granting summary judgment to defendant because "there is no evidence in the record that the infringing product would form in Ben Venue's proposed manufacturing process").

[1] an outer cannula;

[2] a trocar;

[3] means for drilling an opening in a bone at the surgical site;

[4] means for aiming said means for drilling; ***and***

[5] means for screwing a screw into the opening in the bone.

PX17 at 13:4-10 (emphasis added).

The combination of ***all five items*** is essential to claim coverage; simply selling those five items separately is not sufficient. In fact, Dr. Sasso admitted that he did not invent ***any*** of the components and that they were well-known—individually and in other combinations—long before he filed the application for the '313 patent. 11/13/2018 Tr. 58:5-19 (Sasso). Dr. Parnell—Dr. Sasso's technical expert—similarly confirmed that none of the five required elements of claim 26 was invented by Dr. Sasso:

Q So Dr. Sasso was not the first person to invent an outer cannula, right?

A I believe that's correct.

Q ... Dr. Sasso is not the first person to invent a tool indicate with a [trocar], right?

A Yes.

Q Dr. Sasso is not a first person to invent a spinal tool kit with a drill or drill bit, right?

A Yes.

Q Dr. Sasso was not the first person to invent a tube with an angled handle for spine surgery, right?

A Yes.

Q And Dr. Sasso was not the first person to invent a screwdriver and screw in a tool kit for spinal surgery, right?

A Yes, that's my answer on each of those items, the point here displaying is that these are tools that are used to perform this procedure of delivering the screw. It's not that each of these is a new invention. It's that taken together, to perform a procedure, that's the novelty part.

11/8/2018 Tr. 100:19-101:15 (Parnell). In fact, Medtronic already sold each of the five components long before Dr. Sasso filed his patent application. And Medtronic even sold four of the five components together as one system prior to the patent. 11/20/2018 Tr. 50:14-17 (Melkent). Medtronic simply ***never sold all five components together***, either before or after Dr. Sasso's patent or the facet screw project relating to the 1999 Agreement. Dep. Ex. 10 (Patterson Tr.) 11:13-22; 11/20/2018 Tr. 52:2-54:3 (Melkent).

Indeed, Dr. Parnell, the expert witness tasked by Dr. Sasso with testifying about how the '313 patent supposedly covered Medtronic's products, could not offer any testimony or opinion that Medtronic had ever sold any product having all five required components in a single kit. These products include METRx, Quadrant, Sextant, Capstone, Clydesdale, Perimeter, and CD Horizon. 11/8/2018 Tr. 70:16-21 (Parnell) ("Q But just like you testified in your deposition, sitting here right now, you cannot tell me that any one of those is a true [sic, should be "screw"] delivery system kit with all five of the requirements of claim 26, right? A That's correct.").[5]

Medtronic's own witnesses confirmed that Medtronic never sold the five components of claim 26 combined in one system or kit—though they were available separately before and after Dr. Sasso's patent. Chris Patterson, who worked as a manager in the product development of CD Horizon and also in marketing, testified that Medtronic has never sold a kit of the five components of claim 26. *See* Dep. Ex. 10 (Patterson Tr.) 11:13-22 ("Q Now, with regard to all five of these, Mr. Patterson, if I ask you to accept as true that all five of these are in one kit together, does Medtronic today sell a kit that contains all five of those elements? A No. Q To your knowledge, has Medtronic ever sold a kit that contains all five of those elements in one tray

[5] Dr. Sasso himself admitted that the five components of claim 26 are not "package[d]… in one box." 11/27/2018 Tr. 117:20-118:16 (Sasso).

or one box? A No."). Tony Melkent, who worked in the minimal access spinal technologies group and now works as director of engineering for interbody technologies, testified that the five components of claim 26 were all in the 1997 catalog, but were not then and never were sold together. 11/20/2018 Tr. 52:2-54:3 (Melkent) ("Q So all these five components are in the same catalogue. Here's my question: Are all of those components in 1997 in the same system kits? A They are not, no. Q And has that changed between 1997 and now at Medtronic? A It has not, no.").

The Court properly instructed the jury that all five components together were necessary in order to show claim coverage: "A product claim that consists of several components does not cover the components separately. It only covers the product as described in the claim, including all of its components together. A party that makes the components of a claimed invention but does not combine them together does not make a patented invention." 11/28/2018 Tr. 126:16-23 (final jury instructions). But Dr. Sasso proffered no evidence that Medtronic ever "combine[d]" the five elements of claim 26 together, much less that it did so in a "screw delivery system kit." Given the uncontroverted evidence that Medtronic never sold the five components required by clam 26 together in a single kit, no evidence supports a verdict that claim 26 covers any Medtronic product. *Frank's Casing Crew & Rental Tools, Inc. v. Weatherford Int'l, Inc.*, 389 F.3d 1370, 1378 (Fed. Cir. 2004) ("[L]iteral infringement requires that each and every limitation set forth in a claim appear in an accused product."); *see Jang v. Boston Scientific Corp.*, 532 F.3d 1330, 1332 (Fed. Cir. 2008) (equating "covered by" a patent with "would have infringed" a patent).

Dr. Sasso's counsel sought to bridge this gap before the jury by arguing that ***third-party spine surgeons*** may choose to ***use*** all five components during a surgery. *E.g.*, 11/28/2018 Tr.

107:15-16 ("doctors use this system to put in their screws"). "). Even if true, however, that would not matter. ***First***, under the 1999 Agreement, the only royalty-bearing items are "Medical Devices," which are defined to include only "device[s], article[s], system[s], apparatus[es], or product[s]." PX3 § 1(C). Thus, third-party ***use*** of Medtronic's individual components cannot convert those components into royalty-bearing items when they fail to otherwise satisfy the requirements of the agreement. ***Second***, even under Dr. Sasso's interpretation of the "Invention," claim 26 is a product claim, not a method claim; as the Court instructed the jury, "[a] product claim covers each specific tangible item recited in the claims, not the performance of any steps or method." 11/28/2018 Tr. 126:12-16 (final jury instructions). Claim 26 is for a "kit"—that is, a product including all five components. PX17 at 13:4-10. There is no such Medtronic product. It does not matter whether a surgeon ever chose to use all five components during a single surgery (importantly, though, there was no proof of that use either, except by Dr. Sasso himself). Dr. Sasso was required to prove that Medtronic sold the specific article of manufacture claimed—a "screw delivery system kit" having the five recited components. Dr. Sasso simply could not, and did not, do so. *See In re Kollar*, 286 F.3d 1326, 1332 (Fed. Cir. 2002) (recognizing "the distinction between a claim to a product, device, or apparatus, all of which are tangible items, and a claim to a process, which consists of a series of acts or steps"); *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1468 (Fed. Cir. 1990) ("[A]pparatus claims cover what a device ***is***, not what a device ***does***.").[6]

[6] Induced patent infringement (*see* 35 U.S.C. § 271(b)) is not at issue here. Nowhere in any of his reports or trial testimony did Dr. Parnell ever rely on a theory that Medtronic ***induced*** its customers to satisfy the requirements of claim 26 by ***using*** **or** ***making*** the claimed kit. Nor could he have. Given his admission that Medtronic offers no such kit, Medtronic's customers could not have ***used*** any such kit. Moreover, there is no evidence that Medtronic ever took any affirmative act to encourage its customers to make or use any such kit. *See, e.g., Info-Hold, Inc. v. Muzak LLC*, 783 F.3d 1365, 1372 (Fed. Cir. 2015) ("To prove inducement of infringement, the

In rebuttal closing argument, Dr. Sasso's counsel sought to address this critical gap in the evidence by relying on a PowerPoint presentation regarding a navigated "Guide Wireless MAST TLIF Presentation." *See* PX727; 11/28/2018 Tr. 106:7-15 (Dr. Sasso's rebuttal closing); 11/27/2018 Tr. 124:7-17 (Sasso) (explaining that PX727 describes a navigated MAST TLIF procedure). Dr. Sasso's counsel argued that this presentation described a procedure in which all five elements of claim 26 were used. Medtronic did not have an opportunity to refute this argument because Dr. Sasso made it in rebuttal closing, but ***there is no evidence whatsoever that the navigated guide wireless MAST TLIF procedure ever resulted in sales of a "screw delivery system kit" containing the five necessary components*** (in fact, it never was), and therefore could not have given rise to any royalty obligations under the 1999 Agreement. 11/7/2018 Tr. 91:17-24. (McAdoo) ("The navigated TLIF in my tenure was not commercialized that I'm aware of."). Likewise, there was no evidence whatsoever—for example, in a surgical technique guide, product brochure, or any other marketing material where it would logically be found—that Medtronic ever commercially promoted a guide wireless MAST TLIF technique using all five necessary components, or indeed that Medtronic ever received FDA approval to do so. Nor does PX620, the exhibit counsel referred to in rebuttal closing (11/28/2018 Tr. 106:7-23), fill the evidentiary gap. Only two pages of the exhibit (its cover and the Bates page ending in -1507) were admitted, and those two pages fail to describe or disclose any five-component kit or surgical technique or the commercialization of any such kit or the promotion of any such procedure by Medtronic. At most these two pages disclose that certain unexplained projects related to MAST TLIF and DLIF were "In Progress/Complete." Nothing in this exhibit permits

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patentee must show that the accused inducer took an affirmative act to encourage infringement with the knowledge that the induced acts constitute patent infringement." (internal quotation marks omitted)).

an inference that Medtronic ever sold a product that met all limitations of claim 26. Indeed and most tellingly, ***Dr. Sasso never sought royalties*** during trial or introduced any evidence or revenues whatsoever ***for any purported navigated guide wireless MAST TLIF kit or procedure***.

In short, Dr. Sasso was incorrect to redefine the "Invention" to mean the '313 patent claims, but in any event, he failed to produce any evidence showing that any revenue-generating Medtronic product was ever covered by claim 26. And if claim 26 does not cover any of Medtronic's products, its dependent claims do not either, since they include all of claim 26's requirements as well as additional requirements. 11/8/2018 Tr. 58:7-12 (Parnell); 11/5/2018 Tr. 214:24-2154 (Rappaport); *see also Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n.9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim."); 11/28/2018 Tr. 126:16-23 (final jury instructions) ("A product claim that consists of several components does not cover the components separately. It only covers the product as described in the claim, including all of its components together. A party that makes the components of a claimed invention but does not combine them together does not make a patented invention."). Thus, Dr. Sasso was unable to prove Medtronic owed any unpaid royalties, and the Court should amend the judgment in Medtronic's favor. At the very least, because a contrary finding is against the weight of the evidence, a new trial on the point is required.

IV. BECAUSE THE '313 AND '046 PATENTS ARE INVALID, DR. SASSO'S CLAIM UNDER THE 1999 AGREEMENT COULD NOT BE PROVEN, AND THE VERDICT SHOULD BE SET ASIDE

By its terms, the 1999 Agreement expired after seven years if there was no "patent having valid claim coverage of the Medical Device." PX3 § 7. Thus, even if Dr. Sasso had been able to prove coverage by claims 26 or 34 of the '313 patent (which he failed to do, *see supra* Section III.B), the agreement still expired after seven years if those claims were ***invalid***. Since sales of

the Medical Device began in 2002, the seven years ended in 2009. PX3 § 7; PX1000AA (including royalty letter evidencing sales under the 1999 Agreement in Q4 2002). Thus, to assert any breach that took place after 2009, a claim covering the Medical Device must be ***valid***.

The United States Patent and Trademark Office ("Patent Office") has reexamined the only claims Dr. Sasso put at issue in this case—claims 26 and 34 of the '313 patent. Offer of Proof on Invalidity Evidence at 6, 9, 11, 14 (Nov. 27, 2018); DX1618, DX1620, DX1622, DX1624 (attachments to Offer of Proof on Invalidity Evidence through Cross-Examination (Nov. 19, 2018)). After completing the reexamination process, the Patent Office issued Final Office Actions followed by Notices of Intent to Issue Ex Parte Reexamination Certificates, cancelling claims 26 and 34 among other claims. Offer of Proof on Invalidity Evidence at 9-11, 13-15 & Exs. 3-4, 6-8, 11 (Nov. 27, 2018); *see also* 35 U.S.C. § 307(a).

With the patent claims invalidated by the Patent Office, Dr. Sasso could no longer demonstrate that a "valid" patent claim covered a Medtronic product.[7] Indeed, a claim's cancellation means the plaintiff "loses any cause of action based on that claim, and any pending litigation in which the claims are asserted becomes moot." *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 721 F.3d 1330, 1340 (Fed. Cir. 2013); *id.* at 1347 ("In light of the cancellation of Baxter's remaining claims, Baxter no longer has a viable cause of action against Fresenius. Therefore, the pending litigation is moot. We vacate the district court's judgment and remand with instructions to dismiss."). Indeed, claims cancelled in reexamination proceedings are void *ab initio*, as if the patent had never issued at all. *Id.* at 1346; *see also ePlus, Inc. v. Lawson Software, Inc.*, 789

[7] Medtronic properly and timely denied this allegation in the Third Amended Complaint, and as explained below, no affirmative defense was required. *See infra* Section VI.A.

F.3d 1349, 1358 (Fed. Cir. 2015) ("[U]nless [the patent] exists, and is in force at the time of trial and judgment, the suits fail.").

As a matter of law (and not just as a matter of evidence), as of November 20, 2018, Dr. Sasso should not have been able to rely on the invalidated claims of the '313 or '046 patents to support his claim for breach. Without those patent claims, the 1999 Agreement expired in 2009, and Dr. Sasso had no cause of action to assert. The verdict should therefore be vacated and the claim under the 1999 Agreement dismissed.

V. THE JURY'S AWARD OF $79.8 MILLION IN DAMAGES UNDER THE 1999 AGREEMENT SHOULD BE VACATED OR REDUCED TO ZERO

The jury awarded the full $79.8 million in damages that Dr. Sasso requested. Yet that damages figure was based on unreliable principles and invalid assumptions directly contradicted by the evidence, and it should be reduced or vacated.

Dr. Sasso's damages expert, Mr .Pellegrino, calculated royalties he believed Medtronic owed under the 1999 Agreement by essentially performing the following:

1. Adding up the "Net Sales" of the Disputed Products
2. Reducing those Net Sales by some percentage to account for his assumption that some, but not all, of the Disputed Products Medtronic sold were used by surgeons to perform the surgical technique that Dr. Sasso allegedly invented.

Regarding step one, as explained above, none of the Disputed Products was a "Medical Device" under the 1999 Agreement and therefore none were royalty-bearing. Mr. Pellegrino simply assumed the Disputed Products were royalty-bearing based on the incorrect supposition that some of the Disputed Products were implanted into patients using the five-component kit Dr. Sasso allegedly invented. As described above, that assumption is incorrect. There was simply no evidence that any Disputed Product was ever implanted during a surgery (other than by Dr.

Sasso) using the five-component kit or in fact any using any other surgical technique allegedly invented by Dr. Sasso.

Regarding step two, Mr. Pellegrino sought to estimate the percentage of times that surgeons might have implanted the Disputed Products using the five-component kit and a surgical technique Dr. Sasso says he invented. In so doing, Mr. Pellegrino resorted to pure speculation, unsupported by credible evidence. Mr. Pellegrino began by ***equating*** Dr. Sasso's allegedly inventive surgical technique with ***all*** minimally invasive spine surgery techniques, and then estimated the adoption rate of minimally invasive spine surgery as a stand-in for Dr. Sasso's invention. This assumption was flatly contradicted by the evidence, and resulted in a fatal flaw in Mr. Pellegrino's analysis. Moreover, even if the overall adoption rate for minimally invasive surgery were somehow relevant to the royalty calculation, Mr. Pellegrino's assumed adoption rate was unreliable because it was artificially inflated by an unsupported "outer cannula adoption rate," which in fact was no such thing, and which has no bearing on the use of Dr. Sasso's alleged technique.

In the end, the jury accepted Mr. Pellegrino's theory in its entirety and awarded $79.8 million. But damages for breach of contract cannot be based on speculation and uncertainty, and cannot stand if unsupported by the evidence. *See, e.g., Western Sizzlin, Inc. v. Harris*, 741 S.W.2d 334, 336 (Tenn. Ct. App. 1987) ("uncertain, contingent, or speculative damages should not be awarded"); 11/28/2018 Tr. 120:16-17 (final jury instructions) ("Base your decision on the evidence and not on guess or speculation."). As such, the damages verdict should be vacated or reduced to zero.

A. Dr. Sasso's Claim For Damages Is Untethered To His Contractual Right To Royalties

Mr. Pellegrino utterly failed to tie his royalty calculation to the scope of the 1999 Agreement. The 1999 agreement grants Dr. Sasso royalties exclusively on "Net Sales of the Medical Device." PX3 § 4(B). As explained above, a "Medical Device" must be listed in Schedule B by catalog number and must "includ[e] the Invention"—yet, as described above (*see* Section III.A), none of the Disputed Products meets each of these requirements.[8]

To the extent Dr. Sasso demands royalties based on third-party surgeons' use of the Disputed Products during certain surgical "methods" allegedly invented by Dr. Sasso, the payment provision and definitions of the 1999 Agreement do not entitle him to those.[9] Nowhere does the agreement permit a non-royalty-bearing product to be transformed to a royalty-bearing Medical Device through its use by a third party. *See* PX3 § 1(C) (defining Medical Device); § 4(B) (providing for royalty payments). And even if use of an instrument in combination with other instruments during a specified procedure ***could*** suddenly make it royalty-bearing, no evidence suggests that any surgeon other than Dr. Sasso (for whose usage no royalties are due) ***ever*** used the surgical technique Dr. Sasso claims to have invented. Therefore, the Court should amend the judgment in Medtronic's favor. At the very least, because the damages verdict is against the weight of the evidence, a new trial on the point is required.

[8] Further, to the extent Dr. Sasso relies on the Navigated Guide Wireless MAST TLIF technique to allege breach, he failed to tie any "Net Sales" as defined by the 1999 Agreement or any revenues whatsoever to any such technique or related product.

[9] Indeed, Dr. Sasso transferred all techniques and know-how to Medtronic for the consideration enumerated in the agreement. PX3 §§ 1(A), 1(B), 4(A).

B. Dr. Sasso's Claim For Damages Is Untethered To His Theory Of Liability And Unsupported By Evidence

As explained above, Dr. Sasso believed that he was entitled to damages for "the value of putting in implants, screws and cages, through a technique that is described in the '313 patent." 11/9/2018 Tr. 122:11-19 (Sasso); 11/9/2018 Tr. 115:15-18 (Sasso) ("Q But you were to be paid for those as something that is included in the invention? A As long as they're used in the method that the patent describes."); *see also* 11/16/2018 Tr. 37:9-11 (Pellegrino) (royalty based includes "all devices that would be planted in accordance with Dr. Sasso's inventions in certain surgeries"); 11/16/2018 Tr. 70:4-11 (Pellegrino) (invention on which damages sought includes the five elements of Dr. Sasso's "kit," however packaged).

Thus, to calculate his royalty demand, Mr. Pellegrino sought to estimate the percentage of times that surgeons implanted Disputed Products using Dr. Sasso's allegedly inventive five-component technique. Mr. Pellegrino, however, was thwarted by the fact that there is no evidence whatsoever as to when—if ever—surgeons used this technique, as Mr. Pellegrino readily admitted. 11/16/2018 Tr. 62:16-19 (Pellegrino) ("Well, we don't have an exact measurement. We asked – we'd love to just know exactly how many screws were placed and we

don't know how many screws were placed."). Indeed, there is no evidence that any surgeon ever used Dr. Sasso's alleged technique, much less did so frequently.[10]

As an improper substitute, therefore, Mr. Pellegrino simply equated Dr. Sasso's purported technique with ***all*** minimally invasive spine surgery techniques, and then further inflated this number. As discussed below his reasoning and assumptions were fatally flawed and unsupported by the evidence. The Court should amend the judgment to so reflect, or at the very least, order a new trial.

1. Mr. Pellegrino's Damages Theory Erroneously Equated Dr. Sasso's Supposed Technique With Minimally-Invasive Surgery

To perform the second step of his analysis—reducing the Net Sales of the Disputed Products to account for Dr. Sasso's theory that only some of the Disputed Products were used to perform the allegedly inventive surgical technique—Mr. Pellegrino first assumed that the ***percentage*** of sales subject to royalties corresponded to the percentage of ***all*** spine surgeries performed in ***any*** minimally invasive manner. In other words, Mr. Pellegrino ***equated*** Dr. Sasso's allegedly inventive surgical technique with minimally invasive spine surgery:

> Q … ***You took all of surgery and you reduced it to what you regard as a rate percentage of minimally invasive surgery?***
>
> A Yes, that's correct.

[10] Mr. Pellegrino essentially presumed without evidence (other than what Dr. Sasso told him) that whenever a doctor performs a minimally-invasive surgery to implant any of Medtronic's devices, the doctor must necessarily use all five of the devices required by claim 26 of the '313 patent. He sought to justify that speculative leap by stating that the "standard of care as I'm aware is to use an outer cannula and the other elements to place that screw," asserted that "the products that I'm looking at are not guide wire products," and claimed to be "unable to find anything that said there was another way" to perform minimally-invasive surgery. 11/27/2018 Tr. 97:22-98:11 (Pellegrino). But there was no evidence of this "standard of care" beyond the self-serving testimony of Mr. Pellegrino and Dr. Sasso (*id.*; 11/27/2018 Tr. 115:8-19 (Sasso)), and indeed, Dr. Sasso's own testimony about the other minimally invasive surgeries surgeons may perform undermines the idea that every single minimally invasive surgery must have been by Dr. Sasso's methods. *See* 11/13/2018 Tr. 13:16-16:4 (Sasso).

> Q … ***The reduction you made for minimally invasive surgery assumes, does it not, the use of Dr. Sasso's method throughout?***
>
> ***A Yes, that's correct.***

11/27/2018 Tr. 97:6-21 (Pellegrino) (emphasis added); *see also* 11/16/2018 Tr. 43:10-17 (Pellegrino) ("So I reduced that amount to account for only those products that would be placed in an MIS form that might use the inventions that Dr. Sasso transferred."); 11/16/2018 Tr. 46:10-15 (Pellegrino) ("Q So can you tell us in one, maybe two sentences what you mean when you say utilization or utilization rate? A Sure. If a surgeon performs 100 operations, how many of them were done in MIS, minimally invasive form.").

This assumption—that the rate of minimally-invasive spine surgeries versus open spine surgeries was an accurate stand-in for the adoption rate of Dr. Sasso's purported five-component technique—was flatly contradicted by the evidence. The evidence repeatedly showed that minimally invasive surgery can be performed in any number of ways, including many independent of anything having to do with Dr. Sasso.

Indeed, Dr. Sasso never claimed to have invented minimally invasive spine surgery, but instead claimed to have invented a way of using five separate components—including an "outer cannula"—to perform spine surgery less invasively. For example, Dr. Sasso testified that the "big difference" "between what was taught earlier and what my patent was" was "[w]hen you separate the outer cannula from the drilling and aiming"—or, in short, "[m]y patent, my intellectual property teaches the outer cannula," or tube. 11/14/2018 Tr. 61:5-62:10 (Sasso). But Dr. Sasso conceded that minimally invasive surgery can be performed with tubes (as his supposed technique requires), ***or without***. 11/13/2018 Tr. 12:15-23 (Sasso) ("Q With regard to minimally invasive surgery, that's the use of an outer cannula or a tube, right? A It can. Q So some are with tubes, right, some minimally invasive surgery is done with tubes? A It can. Q And

some is done or can be done without tubes, right? A It may."); *see also id.* at 13:15-18 (Sasso) ("Q Okay. But in all events, minimally invasive surgery can be done with tubes, as we discussed, and without? A Sure."). Dr. Sasso also conceded that minimally invasive surgery can be performed where screws or implants are ***not*** used, and that those surgeries are not the subject of his "claims in this case with regard to the '313 patent." *Id.* at 13:24-14:7 ("Q And another way is to do spine surgery, minimally invasive with tubes, but where no screws or implants are used, correct? A Sure. Q And your claims in this case with regard to the '313 patent don't involve spine surgery done minimally invasively with tubes, but where there are no screws or implants placed? A Correct."); *see also id.* at 14:10-16:4 (discussing types of minimally invasive surgeries where no screws or implants are used).

Further, Dr. Kevin Foley testified he had been performing minimally invasive surgery since the 1980s—long before Dr. Sasso—and the evidence demonstrated that Dr. Foley's minimally invasive surgical techniques and patents predated any technique invented by Dr. Sasso or described in the '313 patent. 11/16/2018 Tr. 148:9-150:1 (Foley) (Dr. Foley explaining his interest in minimally invasive surgery beginning in the 1980s); 11/16/2018 Tr. 150:2-157:6 (Foley) (Dr. Foley testifying regarding 1995 article he co-authored describing minimally invasive procedure); DX1637 (U.S. Patent 5,792,044 to Dr. Foley and others describing minimally invasive surgery as of 1996 application date); DX1342 (1997 brochure for MED MicroEndoscopic Discectomy System disclosing minimally invasive procedure); *see also* 11/16/2018 Tr. 146:7-17 (Foley) (describing MED as minimally invasive).

In sum, the evidence plainly refuted Mr. Pellegrino's assumption that each and every time a surgeon used minimally-invasive surgical techniques to implant a Disputed Product, that Disputed Product was necessarily implanted using Dr. Sasso's alleged technique. This is but one

of several reasons Mr. Pellegrino's damages calculations were unreliable, speculative, and contrary to the facts.

2. Mr. Pellegrino's Minimally-Invasive Surgery Adoption Rate Was Improper

Even if the minimally invasive surgery adoption rate were a proper substitute for the percentage of times surgeons implanted the Disputed Products using Dr. Sasso's alleged technique (it is not), Mr. Pellegrino's estimate of that adoption rate was fatally flawed.

Mr. Pellegrino improperly relied on a single, unreliable editorial to estimate the adoption rate of minimally-invasive spine surgery over time.[11] But he did not stop there. Instead, he ***increased*** that assumed starting point by further assuming that Medtronic is "a market leader in this space" and "is bringing the average up." 11/16/2018 Tr. 59:7-60:10 (Pellegrino). He did this by multiplying the minimally-invasive surgery adoption rate by what he called "Medtronic's outer cannula market adoption rate" between 2008 and 2016. 11/16/2018 Tr. 59:7-60:10; 61:21-62:13 (Pellegrino). That unsupported methodology increased his damages calculation (and thus the verdict) ***by approximately 50%*** overall. *See* 11/26/2018 Tr. 149:7-157:11 (VanderVeen). This methodology was unsupported by ***any evidence whatsoever*** that his ultimate calculation reflected the percentage of times surgeons actually implanted the Disputed Products using the

[11] This estimate was based on an article never entered into evidence, , which was unreliable and unconnected to the facts of this case. 11/16/2018 Tr. 43:19-44:2 (Pellegrino) ("And we found an academic research article that was published in the Spine journal in 2016 that shows that instrumented surgeries in 2000. … By 2010, one in six surgeries are instrumented and in an MIS form and by 2016 it's now one in three."); *id.* at 79:11-80:8 (Pellegrino). This was speculative and unhelpful, and the jury should not have heard it. *See Western Sizzlin*, 741 S.W.2d at 336 (damages calculations must not be based on speculation, but on reasonable certainty); *Connersville Wagon Co. v. McFarlan Carriage Co.*, 76 N.E. 294, 297 (Ind. 1905) (damages must be shown with "reasonable certainty required by law"); *Armstrong v. Cerestar USA, Inc.*, 775 N.E.2d 360, 366 (Ind. Ct. App. 2002) (expert testimony requires more than subjective belief or unsupported speculation to be admissible); *Whedon v. State*, 900 N.E.2d 498, 506 (Ind. Ct. App. 2009) ("To be admissible under Indiana Evidence Rule 702(a), an expert witness's opinion testimony must be helpful to the trier of fact.").

five-component surgical technique or any other surgical technique purportedly invented by Dr. Sasso in connection with the 1999 Agreement.

First, there was absolutely no evidence in the record beyond Mr. Pellegrino's conclusory statement that, even if Medtronic were a "market leader in the space," it would somehow "bring[] that average up." 11/16/2018 Tr. 59:7-60:10 (Pellegrino). It was nothing but bare assertion by Mr. Pellegrino and thus insufficient to support a verdict.

Second, Mr. Pellegrino's "outer cannula market adoption rate" was an improper proxy for usage of Dr. Sasso's purported invention. Mr. Pellegrino assumed that Medtronic's METRx and Quadrant products were the "outer cannula" used by third-party surgeons to perform the five-component surgical technique allegedly invented in connection with the 1999 Agreement. Then, he assumed that the sales of these devices were an indication of the rate of third-party surgeons' use of that technique. This was fallacy.

As an initial matter, there is no dispute that these devices can be used in techniques ***other than*** Dr. Sasso's allegedly inventive technique. Indeed, Dr. Sasso himself conceded that METRx can be used with minimally-invasive procedures where ***no*** screws or implants are used, and therefore would be outside his "method." *See* 11/13/2018 Tr. 19:13-21:24 (Sasso); PX766 at 6. Further, METRx can be used with non-Medtronic screws and implants, so counting every instance of METRx use leads to an inflated number. *See* Dep. Ex. 10 (Patterson Tr.) 17:14-19. Thus, Mr. Pellegrino's assumption that Medtronic's sales of METRx and Quadrant is a viable indication of surgeons' use of Dr. Sasso's alleged five-component technique is simply wrong.

Moreover, even if the adoption rate of METRx or Quadrant were somehow relevant, Mr. Pellegrino did not actually calculate their usage rate. Instead of measuring a "rate" of adoption of METRx and Quadrant—such as a measurement of their share of the overall market over time,

or the percentage of surgeries performed using these devices—he simply illustrated the self-evident proposition that METRx and Quadrant revenues ***grew*** between 2000 and 2016 (from 0% of their 2016 total in 2000 to 100% of that 2016 total in 2016). 11/16/2018 Tr. 60:11-61:18; 11/26/2018 Tr. 150:9-151:20. This is unremarkable; when all that is being measured is cumulative revenue as a percentage of overall revenue, it is always 0% in the beginning and 100% at the end. Then, even though he did not measure any "adoption rate" for Medtronic's outer cannulas in the market at all, Mr. Pellegrino purported to compare this so-called "rate of adoption" of Medtronic's METRx and Quadrant products to the adoption rate of minimally-invasive surgery according to the *Spine* editorial. 11/16/2018 Tr. 61:19- 62:10 (Pellegrino). But these "rates" were apples and oranges; they measure completely different things. The former measures the accumulated sales of METRx and Quadrant ***against Medtronic's own sales forecast***, whereas the latter measures the adoption of minimally-invasive surgeries as a share of ***all spine surgeries performed***. Comparing them serves no purpose; all it shows is that both increased over time, but the comparison does not show any correlation or other relationship. *See* 11/26/2018 Tr. 150:9-155:12 (VanderVeen). Thus, it was improper for Mr. Pellegrino to assume that the relationship between these numbers had any bearing whatsoever on whether (and with what frequency) surgeons implanted Medtronic's Disputed Products using Dr. Sasso's allegedly inventive five-component technique. This was yet another fatal flaw in Mr. Pellegrino's unreliable opinion.

* * *

Even if Medtronic owed royalties for products implanted by surgeons using a technique Dr. Sasso allegedly invented in connection with the 1999 Agreement—Medtronic does not—Mr. Pellegrino relied on wrong assumptions, flawed methods, and bad data, and the damages award

should be set aside. Mr. Pellegrino improperly assumed an "outer cannula adoption rate" (which in fact was no such thing) to estimate the percentage of time Medtronic's products were implanted using Dr. Sasso's alleged technique. He also improperly assumed that the industry-wide adoption rate for minimally invasive spine surgery represented the use of Dr. Sasso's technique. However, there was no evidence that any surgeon ever used any Disputed Product in such a manner, let alone at the rates claimed by Mr. Pellegrino. Because the jury awarded every dollar that Mr. Pellegrino demanded, it is clear that it swallowed his unreliable speculation completely. The Court should enter judgment of no damages or, at a minimum, order a new trial.

VI. MEDTRONIC IS ENTITLED TO A NEW TRIAL REGARDING THE 1999 AGREEMENT DUE TO THE EXCLUSION OF EVIDENCE THAT THE ASSERTED PATENT CLAIMS ARE INVALID

A new trial may be granted where evidence is excluded in a way that violates a party's substantial rights, including where a party's defense and ability to cross-examine witnesses is unduly limited. *See Armstrong v. Gordon*, 871 N.E.2d 287, 293-297 (Ind. Ct. App. 2007) (ordering new trial where exclusion of evidence and cabining of cross-examination affected party's substantial rights); *see also State Farm Mut. Auto. Ins. Co. v. Woodgett*, 59 N.E.3d 1090, 1093 (Ind. Ct. App. 2016) (ordering new trial based on improper exclusion of evidence); *Arlton v. Schraut*, 936 N.E.2d 831, 842 (Ind. Ct. App. 2010) (ordering new trial in part based on exclusion of evidence); Ind. Tr. R. 61. Because the exclusion of invalidity evidence affected both Medtronic's ability to argue that it was not liable for breach of the 1999 Agreement and the amount of damages it owed if liability was found, this exclusion went to "the heart of the matter the jury was asked to decide" (*Armstrong*, 871 N.E.2d at 297): the existence and scope of a breach of the 1999 Agreement. Consequently, Medtronic's substantial rights were violated

based on the improper exclusion of invalidity evidence and the testimony of its expert, Dr. John Liu. *Id.* A new trial should be ordered at which that evidence may be presented.

A. Because The 1999 Agreement Requires Coverage By A "Valid" Patent Claim, Medtronic Should Have Been Allowed To Present Evidence that the Asserted Patent Claims Are *Not* "Valid" As Well As Dr. John Liu's Timely-Disclosed Testimony Regarding Patent Coverage

The Court excluded from trial Medtronic's evidence that the relevant patent claims were invalid. The Court's ruling was premised primarily on the fact that no affirmative defense of invalidity had been pled and that Medtronic's expert disclosure was untimely. *See* Order Excluding Witnesses and Striking Affirmative Defense of Patent Invalidity (Sept. 13, 2018); *see also* Order Granting Summary Judgment to Plaintiff on Term of the Screw Delivery Agreement and on Validity as a Defense to Payment (Sept. 13, 2018) at 2 ("Invalidity of the '313 and '046 patents was required to be pleaded as affirmative defenses by the Defendants and was not."). Medtronic maintained its objection to the exclusion at trial, and made written offers of proof. *See* Offer of Proof on Invalidity Evidence through Cross-Examination (Nov. 19, 2018); Offer of Proof on Invalidity Evidence (Nov. 27, 2018).

Respectfully, that exclusion was error. Medtronic was not raising invalidity as an affirmative defense, but to "controvert[] an element of a plaintiff's prima facie case." *Willis v. Westerfield*, 839 N.E.2d 1179, 1185 (Ind. 2006) ("Whether a defense is affirmative 'depends upon whether it controverts an element of a plaintiff's prima facie case or raises matters outside the scope of the prima facie case.'"); *see also Rice v. Grant Cty. Bd. of Comm'rs*, 472 N.E.2d 213, 214 (Ind. Ct. App. 1984) (quoting 2A J. Moore, Moore's Federal Practice, ¶ 8.19[1] (2d ed. 1984)); *Hodge v. Jones Holding Co.*, No. M1998-00955-COA-R3-CV, 2001 WL 873458, at *4-5 (Tenn. Ct. App. Aug. 3, 2001). Evidence of patent invalidity was proffered to controvert an element of Dr. Sasso's alleged entitlement to royalties, namely the contractual requirement that a

valid patent claim cover a Medtronic product to extend the life of the agreement past seven years. *Paint Shuttle, Inc. v. Cont'l Cas. Co.*, 733 N.E.2d 513, 524 (Ind. Ct. App. 2000); PX3 § 7; *see also* Section IV.

Moreover, Medtronic's identification of Dr. Liu was not untimely. Medtronic's disclosure of trial witnesses on January 3, 2017—timely served long before trial—disclosed that it would put forward a "medical expert." Order Granting Defendants' Motion with Regard to Witness List (Nov. 10, 2016). Dr. Liu is a practicing spine surgeon, and is therefore a "medical expert." And Medtronic timely disclosed Dr. Liu's identity, background, and opinions on May 22 and June 22, 2018, the dates during the expert discovery window when the parties mutually agreed to exchange expert opinions. Sixth Case Management Order at 1; Defs' Opp. to Plf's Mot. to Exclude Witnesses and Evidence of Patent Invalidity (Aug. 31, 2018) at 4-5. Dr. Sasso was not prejudiced by these disclosures. Dr. Sasso received Dr. Liu's opinions and background pursuant to the expert disclosure deadlines, with ample time for his experts Dr. Parnell and Mr. Rappaport to serve expert reports in rebuttal, which they did. And Medtronic timely offered Dr. Liu for deposition during the expert discovery period—a deposition Dr. Sasso refused to take. Defs' Opp. to Plf's Mot. to Exclude Witnesses and Evidence of Patent Invalidity (Aug. 31, 2018) at 8. Because there was no prejudice to Dr. Sasso, Dr. Liu's timely opinions should not have been excluded at trial. *See, e.g.*, *Wright v. Miller*, 989 N.E.2d 324, 331 (Ind. 2013) (reversing motion to strike never-disclosed expert witness based on minimal prejudice); *see also Dumont v. Davis*, 992 N.E.2d 795, 808 (Ind. Ct. App. 2013).

Moreover, Dr. Liu would have testified that Medtronic has never had a five-part kit including the claimed components of claim 26 of the '313 patent, and the extent to which Dr. Sasso's purported techniques were used—if ever. *See* Offer of Proof Regarding the Expert

Testimony of John Liu, MD as to Claim Coverage (Nov. 27, 2018). Without this testimony, Medtronic was prejudiced from countering Dr. Sasso's arguments regarding claim coverage as put forward by Dr. Parnell—a void Dr. Sasso's lawyers exploited in closing argument. *See* 11/28/2018 Tr. 42:2-19 (Sasso closing argument) ("With access to all these doctors, Medtronic has produced no doctor whatsoever to counter the broad application of Dr. Sasso's invention, not a single one. They found Dr. Theiss in Alabama and taught him their principles of patent law to argue the '491 patent. Dr. Theiss is a spine surgeon, why didn't he tell us anything about Dr. Sasso's minimally invasive surgery.").

Depriving Medtronic of the opportunity to adduce evidence of invalidity and no claim coverage forced Medtronic to try this case with one arm tied behind its back, and warrants a new trial.

B. Dr. Sasso Opened The Door To Evidence Regarding Reexaminations Of The '313 And '046 Patents

At trial, Medtronic was prevented from putting forward any evidence that the '313 or '046 patents were invalid—even though the Patent Office had already issued final office actions invalidating the relevant claims. *See supra* Section IV; Offer of Proof on Invalidity Evidence through Cross-Examination (Nov. 19, 2018); Offer of Proof on Invalidity Evidence (Nov. 27, 2018); Oct. 25, 2018 Order (granting Dr. Sasso's motion in limine preliminarily excluding invalidity evidence); 11/14/2018 Tr. 11:23-12:16 (denying Medtronic's motion to introduce invalidity evidence). Emboldened by the knowledge that Medtronic would be unable to cross-examine him on the validity of the patent claims, Dr. Sasso repeatedly misled the jury by testifying that the claims of the '313 patent were very broad (so broad that it was surprising they were ever granted) and that their breadth vastly increased the value of the invention he transferred to Medtronic. 11/9/2018 Tr. 47:17-48:5, 51:2-51:25; 59:24, 63:23, 82:4-14 (Sasso);

see also id. (Sasso) 50:15-18 (testifying that the patent application that became the '313 patent "became … the '046 patent as well"). Moreover, Dr. Sasso specifically tied the value of the invention of the '313 patent to the amount of damages he was allegedly owed. *Id.* at 122:11-19 ("Q Okay. ***What does Medtronic owe you on your screw delivery system agreement?*** A Well, we have an expert that's looked at all and he's going to come and tell us. Q And what has he done an analysis of? A He's done an analysis of this, ***what's the value of putting in implants, screws and cages, through a technique that is described in the '313 patent***." (emphasis added)).

Hearing this unrebutted testimony, the jury was left to believe that the Patent Office allowed the '313 patent to issue (followed by its child, the '046 patent) because it represented a broad, valuable new invention—an invention so broad that "[t]hey thought that maybe it wasn't going to get through" because the Patent Office would "narrow [the] claims and say that claim is too broad." *Id.* at 51:14-16, 82:8-10 (Sasso). The truth, which Dr. Sasso did not reveal, is that the Patent Office had already reexamined the claims and found them ***invalid***. Exs. 6 & 7, Motion to Introduce Invalidity Evidence (Nov. 13, 2018) (final office actions); Exs. 4 & 8, Offer of Proof on Invalidity Evidence (Nov. 27, 2018) (notices of intent to file reexamination certificate). An invalid patent is not valuable, and even if the Patent Office had not invalidated the claims, any attempt by Medtronic to enforce it would have triggered a validity challenge. *See* Note, Recasting the U.S. International Trade Commission's Role In the Patent System, 126 Harv. L. Rev. 2337, 2346 (2013) ("[A]n invalid patent is worthless since it prevents a patentee from ever again suing anyone for patent infringement, thereby relieving all potential infringers from having to bear the risk of litigation or having to pay license fees"); *Coupled Prods., LLC v. Nobel Auto. Mexico LLC*, No. CIV.A. 09-0323, 2011 WL 4499344, at *4 (W.D. La. Sept. 27, 2011) (noting that invalidity counterclaims are asserted in "nearly every patent infringement case").

Because Dr. Sasso presented only half the story on the breadth and value of the ’313 and ’046 patents, he opened the door to the evidence that completes the story—namely evidence that the patents are in fact valueless and cover nothing at all. Medtronic should have been permitted to cross-examine him to “explore the subject fully” and mitigate the “false or misleading impression of the facts related” by presenting evidence of *ex parte* reexaminations of those patents—and the results thereof—on cross-examination. *See Stokes v. State*, 908 N.E.2d 295, 302 (Ind. Ct. App. 2009); *see also Hall v. State*, 36 N.E.3d 459, 471 (Ind. 2015) (“Indiana courts have long recognized that otherwise inadmissible evidence may become admissible if a party ‘opens the door’ to questioning on that evidence in order to correct a ‘deceptively incomplete disclosure.’”); *Singh v. Lyday*, 889 N.E.2d 342, 350 (Ind. Ct. App. 2008) (noting in a civil context that “[a] party may ‘open the door’ to otherwise inadmissible evidence by presenting similar evidence that leaves the trier of fact with a false or misleading impression of the facts related.”). The contrary result misled the jury, deprived Medtronic of its right to a fair trial, and subjected it to improperly inflated damages.

Perhaps most egregiously, Dr. Sasso’s counsel relied on the validity of the ’313 patent in his closing and proclaimed (after its final cancellation) that “[t]hat patent is in force today.” 11/28/2018 Tr. 39:23-40:3 (Sasso closing argument). Protected by the exclusion of invalidity evidence, this knowingly untrue statement misled the jury. Given this and all of the above, Medtronic’s substantial rights were prejudiced, and a new trial should be granted in which such evidence may be admitted. *See* Mot. to Introduce Invalidity Evidence (Nov. 13, 2018); Offer of Proof on Invalidity Evidence through Cross-Examination (Nov. 19, 2018); Offer of Proof on Invalidity Evidence (Nov. 27, 2018); *Armstrong*, 871 N.E.2d at 293-297; *State Farm*, 59 N.E.3d at 1093; *Arlton*, 936 N.E.2d at 842.

VII. DR. SASSO'S CLAIM FOR BREACH OF THE 1999 AGREEMENT IS BARRED BY THE STATUTE OF LIMITATIONS AND THE DOCTRINE OF LACHES

A. Dr. Sasso's Claim Is Barred By Tennessee's Statute Of Limitations

Dr. Sasso first asserted a claim for breach of the 1999 Agreement in his First Amended Complaint, dated June 6, 2014. Compl.; First Amended Compl. Under Tennessee law, which governs his claim for breach, the applicable limitations period is six years. Tenn. Code Ann. § 28–3–109; 11/28/2018 Tr. 114-115 (final jury instructions). Accordingly, Dr. Sasso's claim is time-barred if, before June 6, 2008, Dr. Sasso knew, or in the exercise of reasonable care should have known, that Medtronic was marketing products for which he now claims he is entitled to royalties under the 1999 Agreement. *Pero's Steak & Spaghetti House v. Lee*, 90 S.W.3d 614, 621 (Tenn. 2002). Notice "includes knowledge of sufficient facts and circumstances that enable a reasonably cautious person to investigate and ascertain the facts." *Bailey v. Shelby County*, No. W2012-01498-COA-R3-CV, 2013 Tenn. App. LEXIS 333, at *35 (May 16, 2013) (citing *Blevins v. Johnson County*, 746 S.W.2d 678, 683 (Tenn. 1988)); *see also* 11/28/18 Tr. 114-115 (final jury instructions).

The evidence supports only one conclusion on this point: Dr. Sasso's claims under the 1999 Agreement are time-barred. To the extent Dr. Sasso argues the products on which he sought royalties—and was awarded damages—"includ[e] the Invention," he could have known that through reasonable care long prior to June 6, 2008, since each product was already released before 2008, and Dr. Sasso would have been aware of that release. Dr. Sasso knew well before 2008 that Medtronic was selling, but not paying him royalties on, the Disputed Products for which he now demands payment. The royalty reports he received under the December 1999 Agreement were all paid on facet screws only. 11/9/2018 Tr. 142:3-25 (Sasso) (agreeing he has been paid royalties for facet screws); 11/9/2018 Tr. 103:18-104:2 (Sasso) (testifying he received

facet royalty payments beginning in 2002); PX1000AA (royalty letters from Medtronic to Dr. Sasso showing royalties on "Facet Screw Products" beginning in fourth quarter of 2002 with letter dated January 20, 2003). Thus, Dr. Sasso was on notice well before 2008 that Medtronic was not paying him royalties on any of the Disputed Products, even though they were approved for use in minimally-invasive surgery. Indeed, Dr. Sasso testified that the first sales of products that he claims used his invention took place ***as early as 2002***. 11/9/2018 Tr. 120:19-24 (Sasso).

More specifically, Dr. Sasso's damages expert, Mr. Pellegrino, calculated damages on CD Horizon screws and Perimeter, Capstone, and Clydesdale cages. 11/16/2018 Tr. 37:4-38:19 (Pellegrino). Those products were being sold, without royalties to Dr. Sasso, no later than 2005. Versions of the CD Horizon screw on which Dr. Sasso seeks royalties were approved for use years before: Medtronic's CD Horizon M8 screw was launched in 1998 and the M10 screw in 1999. Dep. Ex. 10 (Patterson Tr.) 24:24-26:6; DX1731A. Another of the screws for which Dr. Sasso seeks damages, Legacy, was introduced in 2003. Dep. Ex. 10 (Patterson Tr.) 29:20-30:5; DX1731A; DX1366 (CD Horizon Legacy 5.5 Spinal System-Deformity Surgical Technique) (2004).[12] Likewise, the interbody implants on which Dr. Sasso sought damages, Capstone, Clydesdale, and Perimeter, were launched in 2004 and 2005. Dep. Ex. 10 (Patterson Tr.) 42:9-45:25; DX1732. Moreover, interbody implants generally, as claimed in claim 34, were available

[12] That Dr. Sasso also seeks damages on products (Solera, Voyager) released during the statutory period does not mean he could not have discovered his claim prior to the statutory period—for example, after the release of M8 in 1998, the M10 in 1999, or Legacy in 2003. Dep. Ex. 10 (Patterson Tr.) 24:24-26:6, 31:11-33:8; DX1731A; DX1731B. Nor can the fact that Dr. Sasso does not seek damages before 2008 avoid a time-bar. The law does not permit a discovery date to be moved simply because a plaintiff voluntarily constricts a damages period. *See, e.g., Scates v. State*, 383 N.E.2d 491, 493 (Ind. Ct. App. 1978) ("A person who has it in his power to make his cause of action complete must do so within a reasonable time, and the statute of limitations will not await the pleasure or convenience of the plaintiff.").

before 1999, and Dr. Sasso was aware of them no later than 2002. 11/20/2018 Tr. 55:13-15 (Melkent); 11/9/18 Tr. 77:7-19; 79:21-80:19 (Sasso) (Dr. Sasso testifying that Michael DeMane wrote him in 2002 that "interbody cage [implants] sales were going to go through the roof," which Dr. Sasso took as referring to an expanded use of Dr. Sasso's screw delivery technique); PX211.

Additionally, Mr. Pellegrino relied on other Medtronic products that Dr. Sasso asserts are used as part of his "invention" (the five-part kit of claim 26 of the '313 patent)—METRx and Quadrant—to calculate his "outer cannula adoption rate." 11/16/2018 Tr. 60:11-24 (Pellegrino). But Medtronic began selling the MED cannula, METRx's predecessor, for minimally invasive spine surgery in 1996—several years before Dr. Sasso entered into the 1999 Agreement, and eighteen years before the complaint regarding the alleged breach. *See* DX1342 (MED MicroEndoscopic Discectomy System Surgical Technique) (1997); DX1367 (METRx System Surgical Technique) (2004); DX1344 (Sofamor Danek Product Catalog) at C-2 (1997); Dep. Ex. 10 (Patterson Tr.) 10:2-7; 11/16/18 Tr. 191:4-16, 196:22-199:19 (Foley). The Quadrant retractor system, another product identified by Mr. Pellegrino as the "cannula" of claim 26 (11/16/2018 Tr. 60:11-24 (Pellegrino)), was launched by 2006—eight years before Dr. Sasso alleged a breach of the 1999 Agreement. DX1379 (MAST Quadrant Medial Lateral Blades Procedural Solutions Technique) (2006).

Other elements of the five-part product recited in claim 26 of the '313 patent (the basis for Dr. Sasso's demand under the 1999 Agreement), such as the trocar, the means for drilling an opening in a bone at the surgical site, and the means for screwing a screw into the opening in the bone, were available beginning at least by 1996 and 1997. *See* PX713 (Universal Cannulated Screw Set brochure) (1997); DX1344 (Sofamor Danek Product Catalog at A-126 (1997));

DX1339 (1996); 11/20/2018 Tr. 48:11-50:13 (Melkent). Finally, the Universal Drill Guide (the means for aiming said means for drilling) has been available since at least July 1, 1998. 11/20/2018 Tr. 47:6-48:3 (Melkent); DX1368 (1998).

Dr. Sasso has not suggested any reason that prevented him from investigating his claims under the 1999 Agreement in the years before June 2008, or from bringing them earlier than this date when he learned that Medtronic was not paying him royalties on these products. There is no question that Dr. Sasso knew, or in the exercise of reasonable diligence should have known, about Medtronic's screws and implants and their approval for use. Nor is there any question that Dr. Sasso would have known how these products operate.

Besides the Disputed Products being widely available and marketed, Dr. Sasso regularly attended yearly spine society and medical device conferences at which Medtronic's new products were launched and promoted. 11/9/18 Tr. 166:3-168:2 (Sasso); 11/16/18 Tr. 108:9-111:8 (Wilson); 11/7/18 Tr. 82:12-85:21 (McAdoo). Dr. Sasso often presented papers or research at these conferences, participated in continuing medical education labs where doctors practice procedures on cadavers or fake bones, and visited the trade show floor. 11/7/18 Tr. 84:13-22 (McAdoo). Nor is there any question that Dr. Sasso paid close attention to the status of his product development and royalty agreements and was not hesitant to seek information from Medtronic.[13] Given the evidence, Dr. Sasso should have discovered his claim long before June

[13] *See* 11/5/2018 Tr. 102:14-103:11 (Coates); DX1065 (Dr. Sasso's July 2004 letter complaining about the incomplete Vantage agreement as well as "the two patents you own but haven't paid me for," and numerous other topics); 11/14/2018 Tr. 39:12-51:7 (Sasso); DX1205 (2003 letter requesting that payments on facet products be made directly to his company rather than to himself); DX1231 (2004 email requesting sales info for Vantage); DX1235 (2004 letter requesting Vertex sales information); DX 1254 (2005 email providing Vertex sales information); PX448 (2009 email exchange regarding Vertex royalties); Dep. Ex. 8 (Jones Tr.) 172:16-174:8; DX1267.1 (2007 request for domestic and international sales data for all his purchase agreements).

6, 2008.[14] Yet Dr. Sasso admitted that prior to his First Amended Complaint, he never demanded that Medtronic pay him royalties on any of the Disputed Products, including CD Horizon screws and Capstone, Clydesdale, and Perimeter interbody implants. 11/13/2018 Tr. 97:21-101:22 (Sasso). Therefore, his claim is time-barred.

In sum, Dr. Sasso asserted breach of the 1999 Agreement for the first time on June 6, 2014, which is far more than six years after he was on notice of the facts he needed to bring the claim he has brought. The Court should accordingly enter judgment for Medtronic that Dr. Sasso's claim under the 1999 Agreement is time-barred. At the very least, because a contrary finding is against the weight of the evidence, a new trial on the point is required.

B. Dr. Sasso's Claim Is Barred By The Doctrine Of Laches

For similar reasons, Dr. Sasso's claim is barred by laches, which prevents a court's intervention "when the original transaction has become obscured by time and the evidence lost," based on the "public policy to allow claims and titles long acquiesced in to remain in repose." *John P. Saad & Sons, Inc. v. Nashville Thermal Transfer Corp.*, 715 S.W.2d 41, 46 (Tenn. 1986); *see also Huber v. Hamilton*, 33 N.E.3d 1116, 1120 n.4 (Ind. Ct. App. 2015) ("'Independently of any statute of limitation, courts of equity uniformly decline to assist a person

[14] To the extent Dr. Sasso asserts that the first time his invention was commercialized by Medtronic was in 2010 when he asserts the navigated wireless TLIF procedure was released (see 11/27/2018 Tr. 112:18-23 (Sasso)), his own evidence belies this. First of all, his expert Mr. Pellegrino seeks damages back through 2008. 11/27/218 Tr. 95:19-23 (Pellegrino). If Dr. Sasso believes he was entitled to damages from 2008, he must believe there was a breach before 2010. Further, Dr. Sasso also asserts that he complained about Medtronic's breach to Dr. Stephen Oesterle at Medtronic in 2008 specifically regarding the December 1999 Purchase Agreement. 11/9/2018 Tr. 98:7-101:19 (Sasso); PX411; PX414. By fall of 2008 when Dr. Sasso was complaining to Dr. Oesterle, he testified that "we finally have the device." 11/9/2018 Tr. 98:7-101:19 (Sasso). There is nothing that occurred in the intervening time between the beginning of the statutory period in June 2008 and these emails would trigger Dr. Sasso's discovery of his claim; he ought to have known about it long before, when the accused products launched and Dr. Sasso was not paid royalties on them.

who has slept upon his rights and shows no excuse for his laches in asserting them.'" (quoting *SMDfund, Inc. v. Fort Wayne-Allen Cnty. Airport Auth.*, 831 N.E.2d 725, 729 (Ind. 2005))); 11/28/2018 Tr. 115:13-19 (final jury instructions) ("Laches is a defense that bars a claim if with full knowledge of the facts, the plaintiff unreasonably delays in pursuing his rights. To demonstrate that Dr. Sasso's claim is barred, Medtronic must prove that Dr. Sasso unreasonably delayed in filing this lawsuit and that the delay prejudiced Medtronic.").

Here, Dr. Sasso waited as many as eleven years after the release of products on which he seeks royalties and at least six years after he concedes he complained to Medtronic regarding its payments the 1999 Agreement. 11/9/2018 Tr. 98:7-101:19 (Sasso); Dep. Ex. 10 (Patterson Tr.) 29:20-30:5; DX1731A. That delay is unreasonable and triggers the laches doctrine. *See, e.g,, Saad & Sons*, 715 S.W.2d at 46 (affirming application of laches where notice of breach came four years after breach). Further, there is prejudice to Medtronic resulting from Dr. Sasso's delay: the loss of memory from trial witnesses, including Brad Coates and Michael DeMane, and the financial burden of increased prejudgment interest—here, millions of dollars. *See* 11/28/2018 Tr. 78:23-79:10; *see also* 11/5/2018 Tr. 85:18-86:10 (Coates) (explaining he no longer recalls negotiation of the 2001 Agreement); Dep. Ex. 7 (DeMane Tr.) 14:23-15:2, 22:12-24:9, 24:20-26:5, 31:4-31:11, 38:7-25, 42:11-15, 58:1-59:3 (explaining he no longer remembers meeting Dr. Sasso, the 1999 Agreement, Dr. Sasso's role in the facet screw program, or the '313 patent). Dr. Sasso's claim is therefore barred by the doctrine of laches. If the judgment is not amended, because a contrary finding is against the weight of the evidence, a new trial on the point is required.

VIII. THE $32.7 MILLION VERDICT UNDER THE 2001 AGREEMENT IS CLEARLY ERRONEOUS AS CONTRARY TO OR NOT SUPPORTED BY THE EVIDENCE, AND AT A MINIMUM AGAINST THE WEIGHT OF THE EVIDENCE

Like the 1999 Agreement, the 2001 Agreement provided for life-of-patent royalties only if a valid patent claim covered a Medtronic product. PX1 § 4(A). Because the jury awarded every dollar Dr. Sasso requested for his Vertex claim and decided Medtronic's counterclaim of mistake in Dr. Sasso's favor, it is clear that the jury found that life-of-patent royalties were awardable. *See* Judgment (Nov. 29, 2018). That verdict was not supported by the evidence. The Court should thus amend the judgment to reflect that Dr. Sasso is not owed life-of-patent royalties and that Medtronic has not breached the 2001 Agreement by ending payments after the eight-year term, or in the alternative that Dr. Sasso is owed at the very most the underpayment Dr. Sasso's damages expert Mr. Stover calculated through the third quarter of 2009, when the 2001 Agreement expired. *See* PX100F, PX100G (Stover charts calculating damages owed by quarter). At the very least, because the verdict was against the weight of the evidence, a new trial should be granted on Dr. Sasso's 2001 Agreement claim.

A. Any Finding That The Vertex System Is Covered By The Asserted Claims Of The '491 Patent Is Contrary To The Evidence

To prove that Medtronic's Vertex system is covered by U.S. Patent No. 6,485,491 ("the '491 patent"), Dr. Sasso was required to show that a Vertex component was covered by one or more claims of the '491 patent. *Frank's Casing Crew*, 389 F.3d at 1378; *Jang*, 532 F.3d at 1332; PX1 § 4(B). Dr. Sasso relied only on independent claims 21 and 48 of the '491 patent, but there was not sufficient evidence to show that a Vertex component met every requirement of either of those claims. Accordingly, the Court should enter judgment that the '491 patent does not cover Vertex, or at the very least grant a new trial on the issue.

1. No Vertex Component Contains The "Coupling Member Extending From Said Body Through Said Transverse Hole In Said Upright Portions" Of Claim 21

Claim 21 of the '491 patent requires, among other things, an "offset member" that includes a "coupling member" that extends through a transverse hole of the saddle members. PX7, cl. 21. No Vertex components satisfied this requirement; the evidence showed that the Vertex coupling member was too large to fit through the transverse hole.

Claim 21 requires a "transverse hole" that is "defined through" "a plurality of upright portions" and "that is transverse with respect to said channel." PX7 at 13:23-27. This claim language means that the transverse hole goes through two or more (i.e., both) upright sections of the saddle member. Both experts agreed that there was indeed a hole through both upright portions of the saddle member of the Vertex product. 11/7/2018 Tr. 236:24-237:6 (Parnell); 11/26/2018 Tr. 58:25-60:2 (Theiss). The claim further requires a coupling member extending through that transverse hole. PX7 at 13:32-34 ("a coupling member extending from said body through said transverse hole in said upright portions"). Both experts agreed that there was indeed a coupling member in the Vertex system. 11/7/2018 Tr. 177:21-178:8; 180:9-181:13 (Parnell) (describing the "offset member"); 11/26/2018 Tr. 57:6-58:13 (Theiss) (referring to the "offset member"). There was no dispute as to the existence or size of the coupling member, and importantly, both experts further agreed that ***the coupling member was too large to extend through the hole*** that went through both upright sections of the saddle member. 11/7/2018 Tr. 237:24-238:3 (Parnell); *see also* 11/26/2018 Tr. 57:6-58:24 (Theiss) (explaining that, when the Court's construction is properly applied, "the offset connector is too big to fit through the transverse hole"); DX1751 (Vertex multiaxial screw and offset connector). This should dispose of claim 21.

Dr. Parnell, however, found a result-oriented way to interpret the claim to find coverage by claim 21. Dr. Parnell nonsensically called the hole through the upright portions the "channel" (instead of the "transverse hole") and call the U-shaped opening between the saddle members a "transverse hole" (instead of the "channel"). *See, e.g.*, 11/7/2018 Tr. 237:24-238:23 (Parnell). This opinion, however, violated the Court's claim construction. This Court construed "channel" to mean "a generally U-shaped opening, specifically a void that is open on two opposite ends and open on one of its sides." Order Granting Defendants' Motion to Resolve Disputes Over the Scope of Patent Claims as a Matter of Law (Sept. 13, 2018) ("Claim Construction Order"). Presumably this is why Dr. Parnell eventually admitted on cross-examination that the U-shaped opening could indeed be called a "channel," undermining his insistence that the U-shaped opening was instead the transverse hole. 11/7/2018 Tr. 235:10-236:2 (Parnell) (agreeing U-shaped opening between upright portions is a channel). And importantly, Dr. Parnell agreed that the coupling member cannot fit through the transverse hole—demonstrating that not every element of claim 21 is met by the Vertex system. 11/7/2018 Tr. 237:17-238:6, 238:24-239:5 (Parnell) ("Q And so Medtronic's multi-axial screw does not allow a rod to go in two different directions, right. It can go in the channel, correct? A Yes. Q It can't go through a transverse hole, right? A Yes."); 11/26/2018 Tr. 60:17-23 (Theiss) ("[T]he Vertex screws do not have any saddle member that has both a U-shaped channel and a transverse hole to define upright portions with the coupling member extends through said transverse hole. So as a result of that, my conclusion and my assessment of the patent is that Vertex lacks the necessary claim requirements of Claim 21.").

In short, no credible evidence supported a finding that a Vertex component contains a "coupling member extending from said body through said transverse hole in said upright portions" as required by claim 21.

2. No Vertex Component Contains The "Cross-Shaped Member" Of Claim 48 Under The Court's Claim Constructions

Claim 48 of the '491 patent requires, among other things, a "cross-shaped member having a longitudinal axis connecting first and second longitudinal ends and a transverse axis connecting first and second transverse ends." PX7, cl. 48. This Court construed this phrase to mean "a member having two axes intersecting at right angles with four arms." Claim Construction Order at 2. No evidence permits a finding that Medtronic's Vertex system includes the claimed cross-shaped member, because Medtronic's M-plates and Keel plates lack two axes intersecting at right angles with four arms.

First, no reasonable jury could find that Medtronic's M-Plates have four arms. Dr. Parnell opined that the M-Plates, which are shaped like the letter "M," have three vertical arms and one horizonal arm that overlaps with the horizontal axis. 11/7/2018 Tr. 187:24-188:24 (Parnell). But Dr. Parnell acknowledged that the patent specification repeatedly used the words "arms" and "ends" interchangeably, and that arms exist at the *end* of each axis in Figure 19—the only embodiment disclosed by the '491 patent. 11/8/2018 Tr. 8:25-9:6, 9:12-14, 11:24-12:9 (Parnell). Given the Court's claim construction and when viewed in light of the specification, no evidence supports a finding that Medtronic's M-plates have four arms with an arm at each end of each axis. Because the purported horizontal arm is not at the end of an axis, and because the two outside vertical arms are not on an axis, the M-plates do not have four arms. With fewer than four arms, the M-plates cannot satisfy the Court's construction, and therefore, claim 48 does not cover the M-plates. *See* 11/8/2018 Tr. 28:17-22 (Parnell).

Second, there is no evidence that Medtronic's Keel plates are covered by claim 48, because they lack two axes intersecting at right angles with four arms. Dr. Parnell's opinion was based not on how the Keel plates were actually designed, but on arbitrarily drawing axes on top of the Keel plates to achieve a desired outcome. For example, Dr. Parnell argued that two axes can be drawn on the Keel plate vertically and horizontally such that the horizontal axis connects the saddle members and the vertical axis traverses the middle two apertures without touching two upper arms. 11/8/2018 Tr. 29:23-30:6 (Parnell). This theory ignored that the '491 patent—and the claim language itself— requires each axis to connect two ends. PX7 at 7:48-54. Specifically, the claim requires "a longitudinal axis ***connecting first and second longitudinal ends*** and a transverse axis ***connecting first and second transverse ends***." PX7, cl. 1. Dr. Sasso and his experts sought to interpret the word "axis," found in the claim and the claim construction, in a manner that directly ***contradicted*** this claim language. This was improper. A term—such as the term "axis" here, which the Court did not construe—cannot be interpreted in a manner that contradicts the claim language. *Cf. AgroFresh Inc. v. Essentiv LLC*, No. 16-662-MN-SRF, 2018 WL 5342449, at *4 (D. Del. Oct. 18, 2018). Here, the axes on the accused occipital plates must be identified in a manner consistent with the claim, namely each axis ***must*** each "connect[]" two "ends." PX7, cl. 48. To draw an axis in a manner that does not connect its ends—as Dr. Sasso and his experts sought to do—would be contrary to the claim language and would therefore not satisfy the claim requirements. 11/26/2018 Tr. 113:7-114:7 (Theiss). Importantly, ***both*** sides' experts agreed that when the axes are drawn to connect the ends of the Keel plates—as the claim plainly requires—the axes are not at "right angles," as the claim construction requires, and therefore cannot satisfy claim 48. 11/8/2018 Tr. 30:18-31:14 (Parnell) (admitting that when drawing axes "from one end diagonally to the other end" and [t]hrough the centers of the hole"

on the Keel plate, "those axes would not be perpendicular"); *see also* 11/26/2018 Tr. 114:8-115:2 (Theiss). Thus, Dr. Sasso's theory did not provide sufficient evidence to support a verdict.

Dr. Parnell alternatively opined that the axes could be drawn in the shape of an "X" over the Keel plates; however, even these axes do not connect the ends of the plate and are therefore incorrectly drawn. 11/7/2018 Tr. 185:10-15 (Parnell). Instead of connecting the ends of the plate, Dr. Parnell admitted that he simply drew the axes in an "arbitrary" fashion. *See* 11/8/2018 Tr. 33:6-10 (Parnell); *see also id.* at 31:25-32:2 (Parnell) ("Q But you found a way to draw axes on this plate that were at right angles, right? A Several ways, actually, yes."). Again, this "arbitrary" interpretation is contrary to the claim language, which requires that each axis connect its two ends, and was therefore an improper interpretation of "axis."[15]

B. No Evidence Supports A Finding That Any Other Patent Extends The Term Of The 2001 Agreement

The 2001 Agreement expires "eight (8) years from the date of first commercial sale of Medical Devices or upon the last to expire of any U.S. issued patent included in the Intellectual Property Rights, whichever is longer." PX1 § 8. There is only one entry on Exhibit A, which defines the Intellectual Property Rights—the '638 application that issued as the '491 patent. *Id.* § 1(B), Exhibit A; PX7 (showing "Appl. No.: 09/663,638"). The ***only*** patent Dr. Sasso put at issue in this case that issued from the '638 application was the '491 patent.

[15] There is no evidence to support a verdict based on the dependent claims of the '491 patent, first because the independent claims do not cover Vertex, and second because Dr. Parnell did not distinguish between the dependent claims' requirements or explain where in the Vertex system the particular requirements of each claim are found. 11/7/2018 Tr. 191:5-193:6, 193:22-194:8 (Parnell). Instead, his testimony was utterly conclusory: he said that he had made a determination of claim coverage and invited the jury to simply trust him. Such *ipse dixit* expert testimony is insufficient to support a jury verdict. *See, e.g.*, *Wendler & Ezra, P.C. v. Am. Int'l Grp., Inc.*, 521 F.3d 790, 791 (7th Cir. 2008) ("'An expert who supplies nothing but a bottom line supplies nothing of value to the judicial process.'").

At trial, Dr. Sasso demanded life-of-patent royalties based on coverage of Vertex by four other patents: the '621, '277, '359, and '714 patents. *See* PX14; PX27; PX29; PX30; 11/13/2018 Tr. 75:10-76:5 (Sasso). None of these patents issued from or is related to the '638 application listed on Exhibit A. 11/5/2018 Tr. 209:5-210:2 (Rappaport); 11/20/2018 Tr. 161:15-165:7 (Hedges). And the applications that did give rise to these patents were never added to Exhibit A. PX1, Exhibit A. Nor did Dr. Sasso ever request that they be added to Exhibit A. 11/14/2018 Tr. 33:25-34:25 (Sasso). Moreover, these patents are not in the same family as the '491 patent. *See* PX14; PX27; PX29; PX30 (none claiming priority to '491 patent); *see also* 11/5/2018 Tr. 209:10-210:9 (Rappaport) (agreeing that '621 patent is not in the same family as '491 patent). Dr. Sasso is not even a named inventor on these patents, nor has he ever claimed that he should be. 11/13/2018 Tr. 75:18-76:5 (Sasso). These patents therefore are not "Intellectual Property Rights," and under Section 8, cannot give rise to life-of-patent royalty obligations. This alone disposes of Dr. Sasso's argument that these four patents require royalties past the eight-year term.

Dr. Sasso, nonetheless, argues that these four patents "aris[e] out of the Intellectual Property Rights," thereby warranting royalty payments through their respective expiration dates. *See* PX1 § 4(B). This interpretation would lead to absurd results. ***First***, it would reward Dr. Sasso for the inventions of others. Dr. Sasso argues that he need not be an inventor of a patent for it to give rise to royalties. But the 2001 Agreement expressly states that Dr. Sasso is a "co-inventor" on the only on the patent application listed in Exhibit A, and does not contemplate royalties on other patents or patent application on which he is ***not*** a co-inventor. PX1 § 4(B). Likewise, Dr. Sasso's other agreements with Medtronic, including the consulting agreement that directly led to this purchase agreement, consistently required him to be a named inventor. *See*

DX1002.2 (2001 consulting agreement); DX1008 (Vantage); DX1009 (Atlantis); DX1011 (SiLo); DX1012 (OnePin); DX1013 (Bryan); *Phenix Square Ltd. v. Wright*, 682 S.W.2d 518, 521 (Tenn. 1984) (under Tennessee law, documents that refer to each other and have incorporated conditions must be interpreted together as the agreement of the parties). Indeed, a 2005 communication from Medtronic to Dr. Sasso listed his current agreements and stated "'Life of Patent' means that if the royalty product is covered by a valid claim of an issued US patent ***naming Physician as an inventor***, then royalties will be paid for the life of such US patent." DX1241.1 at Ex. D (emphasis added). Furthermore, it was error to instruct the jury that those consulting agreements were not at issue in the case, because they were relevant to corroborate Medtronic's interpretation of the July 2001 Agreement's requirement that Dr. Sasso be a named inventor. 11/27/2018 Tr. 179:25-180:12, 181:9-25, 183:2-184:1 (objections and colloquy regarding instructions). Because this instruction misled the jury as to the law, the instruction prejudiced Medtronic's substantial rights, and Medtronic is entitled to a new trial. *See, e.g.*, *LaPorte Cmty. Sch. Corp. v. Rosales*, 963 N.E.2d 520, 525-526 (Ind. 2012) (Indiana courts "presume that such an [erroneous] instruction 'influenced the verdict and will reverse unless the verdict would have been the same under a proper instruction'") (internal citation omitted).

Second, interpreting the 2001 Agreement to require life-of-patent royalties on patents Dr. Sasso did not invent and that are unrelated to the only patent application listed in the agreement could potentially lead to ***perpetual*** royalties for Dr. Sasso based on inventions of others without any written consent by Medtronic and without written agreement by the parties—clearly not what Medtronic intended. 11/9/2018 Tr. 19:14-25 (Sasso); 11/14/2018 Tr. 93:15-25 (Sasso) (noting that, under Dr. Sasso's interpretation, for a patent giving rise to life of patent royalties under the 2001 Agreement, "[t]here's no time limit on when it has to be filed or when it has to be

issued").[16] Such an unreasonable interpretation of the contract cannot stand under Tennessee law; Medtronic's interpretation that only patents related to the application listed in Exhibit A (which defines the Intellectual Property Rights) can set the term of the contract—which is exactly what Section 8 provides—is the only reasonable one. *See, e.g.*, *Minor v. Nichols*, No. W2012-01720-COA-R3-CV, 2014 WL 356508, at *7 (Tenn. Ct. App. Jan. 31, 2014). Further, none of the other four patents arose out of the Intellectual Property Rights; however, even if they did, this would not change the term of the patent under Section 8. This is consistent with the Court of Appeals' holding in the prior interlocutory appeal that a schedule to the agreement cannot be implicitly amended; rather, the parties must agree to the material terms, such as the list of Intellectual Property Rights and patents that extend the term of the agreement. *Sasso*, 45 N.E.3d at 840-841. Therefore, no reasonable jury could find that the 2001 Agreement extends through the life of any patent unrelated to the '638 patent application listed on Exhibit A—and certainly not one on which Dr. Sasso is not even a named inventor. To find otherwise would extend the term of the agreement far beyond the term that the parties expressly agreed to.

Nor has Dr. Sasso shown patent coverage of a Medtronic product by the '621, '359, '714, and '277 patents. Dr. Parnell merely enumerated the claims Dr. Sasso asserts cover the products, without explaining ***what*** the claims' requirements were or ***how*** those particular limitations were present in the product in any way. No evidence supports a finding of patent coverage on any of

[16] Further, there is insufficient evidence to show that Dr. Sasso contributed to the '621 patent in any way. Bob Farris, an inventor on the '621 patent, testified that Dr. Sasso did not give any feedback on the placement of the notches on the Vertex multiaxial screw, and Dr. Sasso offered no other contribution he might have made. *See* 11/21/2018 Tr. 69:14-70:4, 79:22-81:2 (Farris); PX293, PX294, PX299, PX301 (emails regarding notch placement showing no feedback from Dr. Sasso).

these grounds. 11/7/2018 Tr. 194:19-195:10; 195:23-196:20, 198:3-15, 199:11-23 (Parnell).[17] As Dr. Parnell conceded, "[e]very claim has a different scope than the other claims, for different coverage." *Id.* at 208:14-17 (Parnell); *see also Application of Cole*, 326 F.2d 769, 775 (C.C.P.A. 1964) (noting the "well established view that each claim of a patent is in theory a separate patent"). Dr. Parnell utterly failed to provide meaningful testimony as to whether or how those claims allegedly covered the Vertex system. *Alexsam, Inc. v. IDT Corp.*, 715 F.3d 1336, 1341-1342 (Fed. Cir. 2013) (reversing denial of judgment as a matter of law regarding infringement where expert testified "without elaboration" and in a "cursory manner" as to a particular claim limitation, leading to a lack of substantial evidence).

IX. THE COURT SHOULD GRANT A NEW TRIAL ON THE 2001 AGREEMENT CLAIM DUE TO THE ADMISSION OF IMPROPER EVIDENCE REGARDING THE '491 PATENT

Prior to trial, the Court granted Medtronic's motion *in limine* to exclude testimony and opinions that disregard or contradict the Court's claim construction order. Orders on Motions *In Limine* at 4 (Oct. 23, 2018). Yet at trial, Dr. Sasso's counsel introduced dictionary definitions of an unconstrued claim term that were contrary to the meaning given by the Court, contrary to the claims themselves and contrary to the specification, as well as irrelevant, prejudicial statements of the inventor's intent, which disregarded and contradicted the Court's construction.

First, Dr. Sasso introduced PX788B, labeled only as "Figure 3. The axes of the human body," which shows a person with vectors labeled "[t]ransverse axis," "[l]ongitudinal axis," and "[f]rontal axis," the first two of which are claim terms. PX788B; 11/26/2018 Tr. 81:21-83:4 (Theiss). Medtronic objected at sidebar, but the evidence was admitted. 11/26/2018 Tr. 81:21-

[17] Dr. Sasso's single conclusory word of testimony announcing his view that the patents cover the relevant products does not alter this result. 11/9/2018 Tr. 20:1-6 (Sasso) ("Q Have you reviewed each of the patents that are on this board, '491, '621, '359, '714, '277. A Yes. Q Do each of the patents on the board that cover the Vertex patent? A Yes.").

82:2. Such extrinsic evidence was inappropriate, because it conflicts with the claim language itself, since the "longitudinal axis" and "transverse axis" in PX788B are not shown to be connecting two ends. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005); *GPNE Corp. v. Apple Inc.*, 830 F.3d 1365, 1370 (Fed. Cir. 2016). Second, Dr. Sasso introduced PX788A, dictionary definitions for the word "axis," again over Medtronic's objection. PX788A; 11/26/2018 Tr. 83:5-84:20 (Theiss). These definitions include "the line about which a rotating body, such as the earth, turns"; "a central line that bisects a two-dimensional body or figure"; and "a central or principal structure about which something turns or is arranged." PX788A. These definitions are inconsistent with the language in the '491 patent, which does not discuss rotation or turning at all, and instead repeatedly states that the axes must connect the ends of the cross-shaped member. *See, e.g.*, PX7 at 2:39-42, 7:48-54. Admission of this evidence was improper. Where a dictionary definition might represent an ordinary usage of a term—but one inconsistent with the patent's specification and claims—it must be rejected. *See, e.g., Nystrom v. TREX Co.*, 424 F.3d 1136, 1145 (Fed. Cir. 2005).

These irrelevant and prejudicial exhibits misled the jury in their task of determining claim coverage, because they led the jury to believe that the axes might be drawn in a manner that contradicts the claims and patent. *Cf. Key Mfg. Grp., Inc. v. Microdot, Inc.*, 925 F.2d 1444, 1448 (Fed. Cir. 1991) (reliance on an "[i]mproper claim construction can distort the entire infringement analysis"). Admission of this evidence that encouraged interpretation in a manner that contradicts the claim language was legal error. *See, e.g., Ruckus Wireless, Inc. v. Innovative Wireless Sols., LLC*, 824 F.3d 999, 1003 (Fed. Cir. 2016) ("Legal error arises when a court relies on extrinsic evidence that contradicts the intrinsic record."); *cf. Phillips*, 415 F.3d at 1318-1319.

Additionally, Dr. Sasso's counsel showed the jury a portion of the '491 patent specification with boilerplate language that discusses the "spirit of the invention." *See* 11/26/2018 Tr. 96:15-97:2 (Theiss) (Dr. Sasso's counsel reading from '491 patent); PX7 at 12:7-13. This testimony and evidence as to the inventors' intent is irrelevant, confusing, unfairly prejudicial, and should be have been excluded. Ind. R. Evid. 402, 403. Statements of an inventor's subjective intent cannot change the scope of a patent's claims, since only the claim itself defines the scope of the invention. *See, e.g.*, *Howmedica Osteonics Corp. v. Wright Med. Tech., Inc.*, 540 F.3d 1337, 1346 (Fed. Cir. 2008); *Intellectual Ventures I LLC v. T-Mobile USA, Inc.*, 902 F.3d 1372, 1378 (Fed. Cir. 2018); 11/28/2018 Tr. 124:9-11 (final jury instruction); 11/5/2018 Tr. 180:21-181:1, 213:6-8 (Rappaport); 11/20/2018 Tr. 143:13-145:21 (Hedges).

Because this evidence was irrelevant and prejudicial, the Court should grant Medtronic a new trial on the 2001 Agreement claim. *See, e.g.*, *Lepucki v. Lake Cty. Sheriff's Dep't*, 801 N.E.2d 636, 640 (Ind. Ct. App. 2003), *as corrected* (Jan. 7, 2004) (ordering new trial where "we cannot conclude that [the party's] substantial rights were not affected by the admission of the evidence"); *Crenshaw v. McMinds*, 456 N.E.2d 433, 434 (Ind. Ct. App. 1983) (holding that admission of irrelevant and highly prejudicial evidence was reversible error and granting new trial).

X. THIS COURT SHOULD DISMISS THE CASE FOR LACK OF SUBJECT MATTER JURISDICTION

For at least the reasons stated in Medtronic's Trial Brief supporting its Motion for Judgment on the Evidence at the Close of Plaintiff's Evidence under Trial Rule 50 (Nov. 19, 2018) and Medtronic's Memorandum in Support of its Motion to Dismiss (Oct. 3, 2016), this Court should dismiss this case because at all times it lacked subject matter jurisdiction, due to the fact that Dr. Sasso's claims necessarily raised substantial issues of patent law, over which the

federal courts have exclusive jurisdiction. Medtronic's Trial Brief at 42-46; 28 U.S.C. § 1338(a); *Gunn v. Minton*, 568 U.S. 251, 257 (2013); *Jang*, 767 F.3d at 1337-1338.

XI. CONCLUSION

For the foregoing reasons, the Court should grant Medtronic's motion to correct error, and amend the judgment accordingly, grant a new trial, and/or dismiss the case.

December 28, 2018

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