UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ST. JUDE MEDICAL, CARDIOLOGY DIVISION, INC.
Petitioner

v.

VOLCANO CORPORATION
Patent Owner

Case IPR2013-00258
Patent 7,134,994

MULTIPURPOSE HOST SYSTEM FOR INVASIVE CARDIOVASCULAR DIAGNOSTIC MEASUREMENT ACQUISTION AND DISPLAY

PATENT OWNER VOLCANO CORPORATION'S PRELIMINARY RESPONSE

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EXHIBITS

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2001	157 Cong. Rec. S5429 (daily ed. Sept. 8, 2011) ("AIA Legislative History I")
2002	157 Cong. Rec. S1375 (daily ed. Mar. 8, 2011) ("AIA Legislative History II")
2003	H.R. REP. NO. 112-98 (2011) ("AIA Legislative History III")
2004	157 Cong. Rec. S1174 (daily ed. Mar. 3, 2011) ("AIA Legislative History IV")
2005	157 Cong. Rec. S1326 (daily ed. March 7, 2011) ("AIA Legislative History V")
2006	Notice of Electronic Filing, *St. Jude Medical et al. v. Volcano Corp.*, 1:10-cv-00631-SLR, No. 8, U.S. Dist. Ct., D. Del. (Sept. 20, 2010) ("Notice of Electronic Filing")
2007	Order re: Electronic Case Filing Policies and Procedures, U.S. Dist. Ct., D. Del. (April 2013), *available at* http://www.ded.uscourts.gov/sites/default/files/cm-ecf/CMECF-DEAdminProc_rev-4-13.pdf ("Order re: Electronic Case Filing Policies and Procedures")
2008	Local Rules of Civil Practice and Procedure of the United States District Court for the District of Delaware, Rule 5.2, U.S. Dist. Ct., D. Del (April 30, 2010), *available at* http://www.ded.uscourts.gov/sites/default/files/local_rules/LocalRulesCivil_4-30-10.pdf ("Local Rules of Civil Practice and Procedure, Rule 5.2")

I. INTRODUCTION

St. Jude Medical, Cardiology Division, Inc. ("St. Jude") seeks *inter partes* review of the '994 patent upon which St. Jude was sued for infringement more than two and half years before its petition was filed. As such, it is clear that St. Jude lacks standing to petition for *inter partes* review pursuant to the bar provision of 35 U.S.C. § 315(b), and its petition must be denied for that reason, without the Board even needing to reach the merits.

In support of its position that it has standing, St. Jude tries to create a loophole in the *inter partes* review bar provision of § 315(b) by advancing an incorrect narrow statutory interpretation of the term "complaint" used in § 315(b). But, the plain language of "complaint alleging infringement" used in § 315(b) is broader than that, and covers any claim for relief of patent infringement regardless of the pleading in which that claim for relief is presented. Importantly, the bar provision of § 315(b) – namely, the bar provision based on patent owner's action – has no provision that excludes counterclaims from the scope of the bar provision. By contrast, for the other *inter partes* review bar provision, § 315(a) – the bar provision based on petitioner's action – there is a specific provision that excludes counterclaims, § 315(a)(3). Given that Congress chose not to draw such a distinction in the § 315(b) bar provision, it would be improper for this Board to incorporate that distinction into § 315(b) when no such distinction is there.

Moreover, the clear legislative purpose behind the bar provision of § 315(b) would be undermined by the loophole that St. Jude is trying to create in § 315(b). Congress made

clear that the purpose behind the *inter partes* review bar provision of § 315(b) was to cut off an accused infringer's second bite at the apple to invalidate the patent using *inter partes* review after some reasonable time after being sued in Federal Court for infringement. It would make no sense – and St. Jude does not even attempt to argue it makes sense – to cut off the *inter partes* review option for one class of accused infringers (those accused by way of an initial pleading in a civil action), but arbitrarily not do that for another similarly situated class of accused infringers (those accused by way of counterclaim in an already pending litigation). Indeed, if St. Jude is allowed to create the loophole it is asking to be created in § 315(b), the result of that would be that those patent owners that bring a suit for infringement by way of counterclaim, even after prosecuting the infringement suit to a successful result through all appeals resulting in a valid and infringed patent, may still be faced with a petition from the infringer seeking *inter partes* review. This Board must not allow such an absurd result to be possible, and therefore must reject the improper statutory interpretation that St. Jude is advancing in support of its position on the standing issue.

The merits of St. Jude's petition are also lacking. Indeed, St. Jude does not assert that the claims of the '994 patent are anticipated by the prior art. Instead, St. Jude pieces together multiple-reference obviousness combinations. Specifically, for the sole independent claim (claim 1), St. Jude's petition advances two grounds for invalidity – Ground 1, which is a combination of four references, and Ground 3, which is a combination of three references. Ground 2 relates to dependent claims and extends from Ground 1;

Grounds 4-12 relate to dependent claims and extend from Ground 3. Although St. Jude's petition is deficient on several grounds, the merits discussion of this preliminary response focuses on one fundamental and critical deficiency: St. Jude fails to cite a reference or combination that discloses the claimed plurality of invasive sensor measurement processing components that process sensor data from multiple different invasive sensor types. As such, St. Jude fails to show that a material limitation of the sole independent claim 1 is present in the prior art upon which it relies, and thus there is no reasonable likelihood of St. Jude prevailing on any challenged claim of the '994 patent and the Board must reject all of Grounds 1-12.

In addition, Grounds 1-2 improperly rely on a GE Medical Systems operator's manual (the "Prucka Manual," Ex. 1003) that, although bearing a date of August 9, 2001, has not been shown to be a prior art printed publication as of that date or as of any date prior to the filing of the '994 patent on May 20, 2002. Similarly, Ground 4 improperly relies on another operator's manual from a company named Florence Medical Ltd. (the "SmartFlow Manual," Ex. 1027) that, although bearing a date of April 2001, has also not been shown to be a prior art printed publication as of that date or as of any date prior to the filing of the '994 patent on May 20, 2002. The information that St. Jude proffers as evidence of the printed publication status of these manual documents fails to address the critical point, whether the manual was available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it.

Finally, St. Jude attempts to mask the deficiencies of its alleged "printed publication" prior art by improperly supplementing them with alleged "public use" prior art evidence that is indisputably barred from consideration in *inter partes* review proceedings. *See* Petition, at pp. 14-15 (alleging that "market trends" and "independent invention" show the obviousness of the '994 claims, and citing the Mason Declaration, Ex. 1002, at ¶¶ 335-581, pages 137-305). These 169 pages of the Mason Declaration advance three additional invalidity grounds based on alleged "prior use" prior art, which in addition to being impermissible grounds for *inter partes* review, are ***not even identified in St. Jude's petition***, let alone substantively discussed. Accordingly, even if the Board institutes *inter partes* review of the '994 patent, the Board must limit the issues to only the patent and printed publication prior art invalidity grounds, and not force the Board and the Patent Owner to address a plethora of additional issues that are not properly raised in IPR.

II. BACKGROUND OF THE '994 PATENT INVENTIONS

The '994 patent claims a "multi-purpose host system" used in a medical facility (e.g., operating room or cardiovascular catheter lab) in which sophisticated invasive sensors are being used to obtain information from inside a patient. The '994 patented system facilitates measuring, processing, and displaying data obtained from different types of invasive diagnostic sensors, for example, pressure, flow, imaging, and temperature sensors. Previously, each specially designed invasive sensor type in a cardiovascular catheterization laboratory had its own dedicated processing and display device. *See* '994 Patent, Ex. 1001,

at 3:3-8. Thus, for example, if the cardiologist was using a pressure-sensing guidewire, she would use a dedicated pressure processing and display device; if she employed a flow-sensing guidewire, she would need a separate flow processing and display device. These monitoring devices displayed only a single set of parameters corresponding exclusively to the particular measurements obtained by the sensor. *Id.* at 2:49-59. And as new types of sensors were introduced, new monitoring devices would have to accompany them, increasing the risk of error as the lab staff was required to operate ever more devices. *Id.* at 2:60-66.

The ’994 patent addressed the need for a single, flexible system that could process and display signals from multiple invasive sensor types. *Id.* at 3:25-27. An example of the system architecture disclosed by the ’994 patent is illustrated in FIGS. 1 and 2:

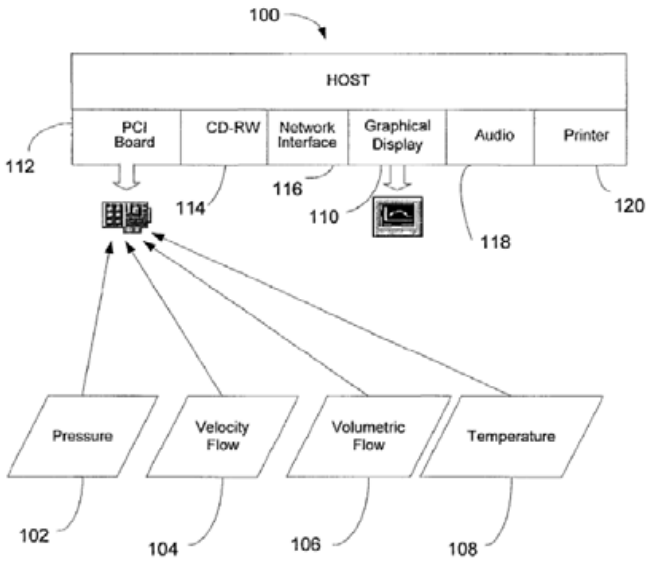

FIG. 1

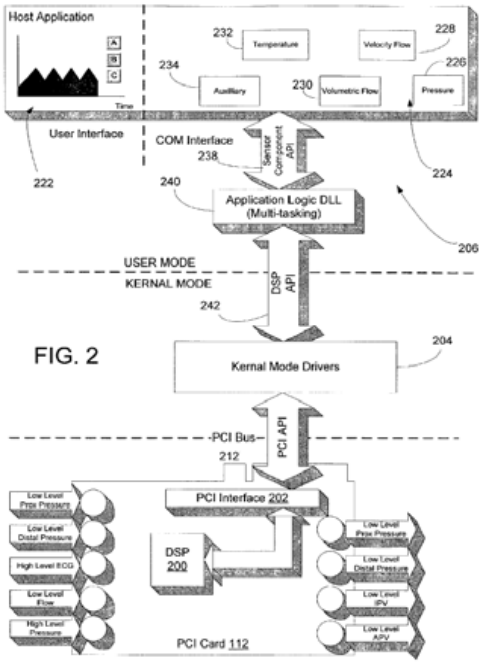

FIG. 2

The ’994 patent claims a “multi-mode graphical user interface host comprising diagnostic measurement user interfaces including display components corresponding to data output rendered by specified ones of the plurality of measurement processing components.” The claimed “multi-mode graphical user interface,” therefore, presents at least two visual displays for the user to choose from that correspond to and present data from at least two different types of diagnostic sensors. The “measurement processing components” process diagnostic data measured by multiple sensors, and “render” (transform) the data into forms that enable a practitioner to make use of the measured data. The user can choose among the various “diagnostic measurement user interfaces” with each interface presenting a different set of diagnostic data. Thus, for example, the system can process data from both flow and pressure sensors and enable the user to interact with corresponding separate flow and pressure displays. *Id.* at FIGS. 9-12e.

Indeed, the ’994 specification states: “A multifunctional invasive cardiovascular diagnostic measurement host is disclosed that interfaces a variety of sensor devices, such as guide wire-mounted pressure sensors, flow sensors, temperature sensors, etc., and provides a multi-mode graphical user interface providing a ***plurality of displays in accordance with the various types of sensors*** and measurements rendered by the sensors.” *Id.* at Abstract. In addition, Figure 3 (copied below) shows an exemplary multi-mode graphical user interface. *See id.* at 9:16-10:6. “A third region 304, by way of example, is reserved to display parameters and input/output data fields according to a

current mode of operation of the host 100 and display mode of the host application 222. The third region 304 is not persistent. Rather, the content of the third region 304 is determined by a particular use mode within which the host application is operating. In an embodiment of the invention, the third region 304 operates in one or more of the following modes: System, Pressure, Flow, and Combo (Combination)." *Id.* at 9:57-65.

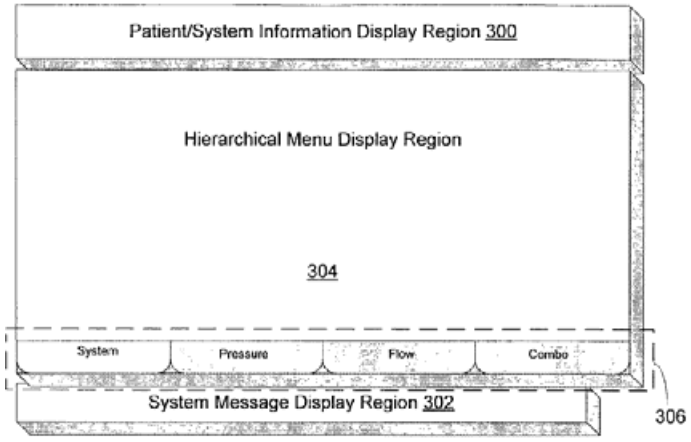

FIG. 3

The '994 specification explains the system's "ability to present multiple user display interfaces" and makes clear that "[e]ach of the display interfaces corresponds to a particular purpose for which the multipurpose host is currently configured based, for example, upon one or more sensor devices communicatively coupled to its external signal interface." *Id*. at 4:53-60; 5:25-30. Finally, the specification points to "a set of diagnostic modes of operation of the host system 100, and more particularly the display interfaces associated with illustrative pressure, flow and combination modes of operation." *Id*. at 11:21-27.

III. STANDARD FOR GRANTING *INTER PARTES* REVIEW

The Board may only grant a petition for *inter partes* review where "the information presented in the petition . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a); 37 C.F.R. § 42.108(c). St. Jude bears the burden of showing that this statutory threshold has been met. *See* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,756 (Aug. 14, 2012) [hereinafter "Practice Guide"] ("The Board . . . may institute a trial where the petitioner establishes that the standards for instituting the requested trial are met . . . ."). If *inter partes* review is granted, St. Jude also bears the burden of proving unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e).

A party challenging a claim as obvious under 35 U.S.C. § 103 must show where each claimed limitation is found in the prior art. *See, e.g.*, *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1361 (Fed. Cir. 2012). Failure to do so defeats a claim of obviousness. *Id.* The Office Patent Trial Practice Guide specifies that among the many responses a patent owner can submit to a petition is that the "prior art lacks a material limitation in all of the independent claims." 77 Fed. Reg. at 48,764. Because St. Jude fails to cite any prior art that discloses "a plurality of measurement processing components," as recited in the sole independent claim of the '994 patent – i.e., a material limitation in every claim of the '994 patent. Accordingly, St. Jude's Petition should be denied. However, the Board need not even reach the merits of the grounds of the Petition, because at the threshold, St. Jude lacks standing to have an *inter partes* review proceeding of the '994

patent instituted. *See id.* at 48,764 (providing that patent owner preliminary responses may include reasons why "[t]he petitioner is statutorily barred from pursuing a review").

IV. ST. JUDE LACKS STANDING UNDER 35 U.S.C. § 315(b) TO CONTEST THE '994 PATENT THROUGH *INTER PARTES* REVIEW

St. Jude lacks standing under 35 U.S.C. § 315(b) to maintain this proceeding. Section 315(b) bars an *inter partes* review where the petitioner has previously been "served with a complaint alleging infringement of the [challenged] patent" more than one year prior to filing an *inter partes* review petition. *Id.* But it is undisputed that St. Jude was served with a complaint for infringement of the '994 patent, by way of a counterclaim, ***more than two and a half years*** before the filing of its Petition. *See* Petition, at 1-3; Volcano's Answer and Counterclaims, Ex. 1007. St. Jude's attempt to create a loophole in the bar provision of § 315(b) must be denied, as St. Jude's contention that it has standing is contrary to the plain language of the statute and its legislative history.

Volcano's answer and counterclaim, in which Volcano made its complaint for infringement of the '994 patent against St. Jude, was served on St. Jude on Sep. 20, 2010. *See* Ex. 1007. Service of this pleading was accomplished pursuant to FRCP 5(b)(2)(E) using the District Court's case management / electronic court filing (CM/ECF) system, as authorized by FRCP 5(b)(3). Using the CM/ECF system, Volcano electronically filed its answer and counterclaim with the Court on September 20, 2010, and in turn the Court immediately made an automatic transmission of a notice of electronic filing (NEF) by e-mail

(blind copied) to several recipients including St. Jude's counsel of record, providing a link to the document that Volcano had filed so that it may be downloaded. The transmission of the NEF to St. Jude's counsel of record constituted service of the answer and counterclaims, as well as the complaint of infringement included in the counterclaims. *See* Notice of Electronic Filing (NEF), Sep. 20, 2010, Ex. 2006 (indicating the NEF was e-mailed to Mr. Steven Fineman, one of St. Jude's attorneys of record, as shown on Ex. 1006); *see also* U.S. Dist. Ct., Dist. Delaware, Order re: Electronic Case Filing Policies and Procedures, Para. (E)(2) (Ex. 2007) (providing that transmission of the NEF shall constitute service of the filed document and shall be deemed to satisfy the requirements of Fed.R.Civ.P. 5(b)(2)(D) [sic: 5(b)(2)(E)] and D. Del. LR 5.2); U.S. Dist. Ct., Dist. Delaware, Local Rules of Civil Practice and Procedure, Rule 5.2 (Ex. 2008) (providing that the District Court's NEF shall serve as the certificate of service). Volcano's infringement case under the '994 patent continued for over two years until October 22, 2012, when the parties stipulated to the dismissal of Volcano's claim under the '994 patent with prejudice, although only as to the St. Jude products that were at issue in that case. *See* Stipulation, Ex. 1009.

St. Jude tries to create a loophole in 315(b) by advancing an incorrect narrow statutory interpretation of the term "complaint" used in § 315(b). *See* Petition, at 1-3. St. Jude is on the wrong side of this statutory interpretation issue. The plain language of "complaint alleging infringement" used in § 315(b), which also furthers the provision's clear legislative purpose as will be discussed below, is broader than that, and covers any claim

for relief of patent infringement regardless of the pleading in which that claim for relief is presented. Indeed, the generally understood meaning of the term "complaint" goes beyond a particular pleading document, and includes any claim for which relief is requested, regardless of the pleading in which the claim for relief is sought. *See, e.g.*, *U.S. Philips Corp. v. Sears Roebuck & Co.*, 55 F.3d 592, 593 (Fed. Cir. 1995) ("Philips *complained of patent infringement* . . . ." (emphasis added)); *First Union Discount Brokerage Servs. v. Milos*, 997 F.2d 835, 844 n.14 (11th Cir. 1993) ("Count four of the amended *counterclaim complained* only of [the plaintiff's] negligent provision of printout information." (emphasis added)).

Indeed, the bar provision based on patent owner action under § 315(b) has no provision that excludes counterclaims from the scope of the bar provision. This is in stark contrast to the other *inter partes* review bar provision based on the third party's action set forth in § 315(a), where § 315(a)(3) specifically excludes from the scope of the § 315(a) bar provision an invalidity claim that is made by way of counterclaim. In particular, § 315(a)(1) provides that there is a bar to *inter partes* review when the third party has filed a civil action alleging invalidity of the patent, but § 315(a)(3) explicitly states that a "counterclaim" is outside the scope of a "civil action" for purposes of that subsection. Indeed, the exception of § 315(a)(3) applies only to that subsection of § 315(a), and not to all of § 315. Given that Congress chose not to draw such a distinction in the § 315(b) bar provision, it would be

improper for this Board to incorporate that distinction into § 315(b) when no such distinction is there.

Moreover, the clear legislative purpose behind the bar provision of § 315(b) would be undermined by the loophole that St. Jude is trying to put in § 315(b). Congress made clear that the purpose behind the *inter partes* review bar provisions of § 315(b) was to cut off an accused infringer's second bite at the apple to invalidate the patent using *inter partes* review after some reasonable time after being sued in Federal Court for infringement.[1] *See* 157 Cong. Rec. S1326 (daily ed. March 7, 2011) (statement of Sen. Sessions) ("AIA Legislative History V," VOLCANO Ex. 2005) ("The bill also includes many protections that were long sought by inventors and patent owners. . . . It imposes time limits on starting an *inter partes*

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[1] The fact that in this case St. Jude never had an option to pursue *inter partes* review, given that Volcano's complaint of infringement came more than a year before the option of *inter partes* review became available on September 16, 2012, is of no moment to the controlling issue the Board must address here. The statutory interpretation underlying St. Jude's position, namely, that the bar provision of Section 315(b) does not apply to a complaint of infringement made in a counterclaim, would apply to all cases, even those where the *inter partes* review option would been available before the one year bar period lapsed.

or post-grant review when litigation is pending" in order to ensure proceedings that "operate[] fairly and [are] not used for purposes of harassment or delay."). It would make no sense – and St. Jude does not even attempt to argue it makes sense – to cut off the *inter partes* review option for one class of accused infringers (those accused by way of an initial pleading in a civil action), but arbitrarily not do that for another similarly situated class of accused infringers (those accused by way of counterclaim in an already pending litigation). Indeed, during debate over the precise formulation of the § 315(b) statutory bar period, Congress never drew any distinction between these classes of accused infringers, but rather broadly and repeatedly referred to the law's applicability to "accused infringers." For example, in Senate debate concerning the statutory bar period, Senator Jon Kyl noted that "[t]he House bill also extends the deadline for allowing an *accused infringer* to seek *inter partes* review after he has been *sued for infringement*." 157 Cong. Rec. S5429 (daily ed. Sept. 8, 2011) (statement of Sen. Kyl) (emphasis added) ("AIA Legislative History I," VOLCANO Ex. 2001); *see also* 157 Cong. Rec. S1375 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl) (referring again, during legislative debate, to an *accused infringer* in relation to § 315(b)) ("AIA Legislative History II," VOLCANO Ex. 2002). Congress's recurring references to "accused infringer[s]" demonstrate that it carefully crafted the language of §

315(b) to provide all parties against which a "complaint alleging infringement" has been made, including both defendants *and* counterclaim-defendants, with a limited period to evaluate a complainant's claims and to choose a forum for challenging an asserted patent.[2] Indeed, there is *nothing* in the legislative history to suggest that Congress intended to differentiate in § 315(b) between various parties based on the form of pleading with which they were served.

By contrast, it also makes sense that the bar provision of § 315(a) draws an explicit distinction between initial pleadings and counterclaims. Indeed, § 315(a) addresses the scenario where a third party (under the threat of an infringement claim, but not a pending case) brings a declaratory judgment invalidity action in Federal Court. In that case, Congress deemed it appropriate to honor that third party's voluntary choice of forum (Federal Court) for addressing the invalidity claim, but immediately bar that third party from also pursuing *inter partes* review in the Patent Office. *See* H.R. REP. NO. 112-98, at 75 (2011) ("AIA Legislative History III," VOLCANO Ex. 2003). Of course, that choice of forum

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[2] The party accused of infringement is entitled to the full one-year period for evaluating the alleged claim, as Congress structured this grace period to begin from the time that the accused party received notice of the claim for infringement, which is presumed to occur through service, rather than from the filing date of such claim.

is not present if the third party is responding to an infringement lawsuit filed against it, and in response advances a counterclaim of invalidity. In such a case, the third party has not chosen Federal Court as the forum for the invalidity question, and hence Congress included § 315(a)(3) to exclude counterclaims from the scope of the § 315(a) bar provision. Of course, the third party must still file an *inter partes* review petition within one year of service of the infringement case, or be barred under § 315(b) from doing so. In any event, while distinguishing between initial pleadings and counterclaims would frustrate the legislative purpose if applied to § 315(b), it furthers the legislative purpose for § 315(a).

In support of the loophole St. Jude is trying to create in § 315(b), St. Jude asks the Board to interpret the term "complaint" narrowly in accordance with what St. Jude incorrectly asserts is a "definition" of the term "complaint" in the Federal Rules of Civil Procedure. In particular, St. Jude contends that the term "complaint" is defined by Rule 3 as the filing that commences a civil action. To be clear though, Rule 3 simply provides: "A civil action is commenced by filing a complaint with the court." This is not a definition of the term "complaint," as St. Jude contends, let alone a definition of the term "complaint" as that term is used in § 315(b). To the contrary, the Federal Rules of Civil Procedure, and Rule 3 in particular, sets forth an example of one thing that is a complaint, namely, the pleading document by which a civil action is initiated. Rule 3 is not a definition of anything and everything that is a "complaint." Nowhere else in the Federal Rules of Civil Procedure is

there a definition of the term "complaint" either. As such, the entire premise behind St. Jude's argument is flawed.

Moreover, even if the Federal Rules of Civil Procedure did provide a narrow definition of the term "complaint," that definition cannot trump the clear meaning of the term as it is used in § 315(b) and the legislative purpose behind § 315(b). *See* AIA Legislative History V, VOLCANO Ex. 2005. Indeed, the Board is not bound, as St. Jude would have it, by a definition of terms from the Federal Rules of Civil Procedure. In other instances where, as here, borrowing definitions of similar terms from the Federal Rules would frustrate the statutory framework or the Board's ability to properly implement these proceedings, the Board has rejected such definitions. *See* Practice Guide, 77 Fed. Reg. 157, 48,756, 48,759 (Aug. 14, 2012) ("The typical common-law expression of the 'real party-in-interest' . . . does not fit directly into the AIA trial context."); *see also Intellectual Ventures Mgmt. v. Xilinx, Inc.*, IPR2012-00018, Paper No. 12, Decision – Real Party in Interest (Jan. 24, 2013), at 3 (explaining that Patent Owner failed to show whether the "considerations of whether a non-party is a real party in interest for an *inter partes* review proceeding are the same or even similar to those considerations or requirements of . . . Federal Rule of Civil Procedure 7.1"). In this regard, St. Jude's reliance on *Ariosa Diagnostics v. Isis Innovation, Ltd.*, IPR 2012-00022, Paper No. 20, Decision – Institution of *Inter Partes* Review (Feb. 12, 2013) is of no moment. While the Board may certainly use the Federal Rules of Civil Procedure as an interpretive "guide," that does not mean that the Board is bound by a definition set forth in

the Federal Rules, especially when using that definition would create a loophole in the statute that would undermine the legislative purpose of the statute. Also, the *Ariosa* decision relates to the bar provision of § 315(a), which again, explicitly distinguishes between claims brought with the filing of a civil action and claims brought by way of counterclaim. That again is not the case with the § 315(b) bar provision.

Indeed, interpreting § 315(b) in the narrow fashion that St. Jude has proposed will likely unnecessarily complicate District Court proceedings for no reason. For example, those defendants wanting to counterclaim for patent infringement on their own patents will likely end up filing a new infringement case as opposed to bringing their case as a counterclaim, just so the loophole that St. Jude is trying to create in § 315(b) is not exploited. That patent owner bringing that new case, instead of the counterclaim, may then move the Court to combine its new infringement case with the other party's already pending infringement case, so that the net result is that both parties' infringement claims will be combined into a single case. But instead of this being done in a rational manner with the defendant filing its infringement complaint by way of counterclaim, it will have to be done through procedural maneuvers that will only serve to complicate and confuse District Court proceedings, without serving any beneficial purpose. For this additional reason, the statutory interpretation that St. Jude advances must be rejected.

Finally, St. Jude's reliance on the Board's decision in *Macauto U.S.A. v. BOS GmbH & KG*, IPR 2012-00004, Paper No. 18, Decision – Institution of *Inter Partes* Review (Jan. 24,

2013) is also of no help to St. Jude. *See* Petition, at 3. In *Macauto*, the Board determined that § 315(b) did not bar the petitioner from bringing an *inter partes* review petition because prior litigation between the parties had been dismissed *without prejudice*, thereby "leaving the parties as though the action had never been brought." *Id.* at 15. In contrast to *Macauto* and all the cases cited therein, all of the prior claims in district court litigation between Volcano and St. Jude over the '994 patent were dismissed *with prejudice*. Stipulation, Ex. 1009. As such, it cannot be said that the dismissal with prejudice leaves the parties "as though the action had never been brought." *See Macauto*, at 15. Indeed, Volcano can no longer bring an infringement claim against St. Jude over the products that were at issue in that case. Thus, *Macauto* has no applicability to the present case.

Accordingly, the Board should act consistently with the plain meaning of the statute and with congressional intent, and find that St. Jude lacks standing to petition for *inter partes* review.

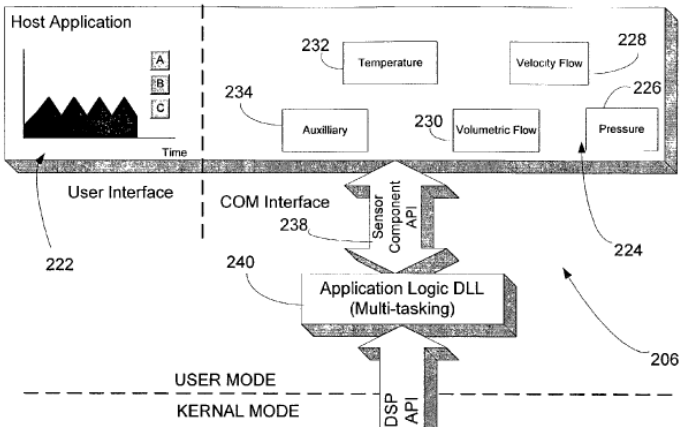
V. THE PRIOR ART CITED BY ST. JUDE UNDER ALL GROUNDS 1-12 FAILS TO DISCLOSE OR SUGGEST THE CLAIMED PLURALITY OF INVASIVE SENSOR MEASUREMENT PROCESSING COMPONENTS THAT FACILITATE RECEIPT OF DATA FROM MULTIPLE DIFFERENT INVASIVE SENSORS OF DIFFERENT SENSOR TYPES

St. Jude contends that the alleged prior art renders each claim of the '994 patent obvious over various combinations of references. While Volcano disputes St. Jude's interpretation of several of these references, these arguments need not be addressed in this paper because St. Jude fails to cite a single prior art reference, or any combination of

references, that disclose a "***plurality of measurement processing components***" as recited in independent claim 1 – the sole independent claim of the '994 patent. St. Jude's failure in this regard is dispositive, as the alleged prior art lacks disclosure of a material limitation of the one and only independent claim of the '994 patent. As such, the Board must deny *inter partes* review as to each ground of invalidity advanced in St. Jude's petition. *See* Practice Guide, 77 Fed. Reg. 48,756, 48,764 (Aug. 14, 2012).

By way of background, claim 1 of the '994 patent recites the limitation of a "plurality of measurement processing components" within a "multipurpose host system for *invasive* cardiovascular diagnostic measurement acquisition and display." According to the features of claim 1, the plurality of invasive sensor measurement processing components "facilitat[e] receiving data of particular sensor types." However, the alleged prior art fails to disclose or suggest such features of claim 1. Indeed, there is no discussion in any combination of the alleged prior art references that describes a plurality of invasive sensor measurement processing components that facilitate receipt of data from multiple different invasive sensors of different sensor types as recited in claim 1. Moreover, the plurality of measurement processing components in claim 1 is configured in a "component-based arrangement" such that respective ones of the "plurality of measurement processing components" correspond to the "particular sensor types."

FIG. 2 of the ’994 patent illustrates one example of a plurality of invasive sensor measurement processing components 226, 228, 230, 232, and 234 that are arranged to facilitate receiving data in the manner recited in claim 1:



’994 Patent Figure 2

As shown in the exemplary embodiment of FIG. 2, the system includes a plurality of invasive sensor measurement processing components 226, 228, 230, 232, and 234 that correspond to “particular sensor types,” and that are configured to facilitate receiving sensor data – for example, by interfacing with a sensor component API 238. *See* ’994 Patent, Ex. 1001, at 8:18-9:15. Such a configuration among the invasive sensor measurement processing components is beneficial because it allows for a modular system configuration, extensibility for adding new or different sensor types to the system, and can also isolate “malfunctions” that may occur in one component from affecting the others (critical for regulated medical devices such as those at issue in the ‘994 patent). *See id.* at 8:27-34.

This arrangement of invasive measurement processing components recited in independent claim 1 is not disclosed or suggested in any combination of the references asserted in either of grounds 1 or 3 of St. Jude's petition, which are the only grounds advanced against the sole independent claim of the '994 patent. Because neither ground 1, with the Prucka Manual (Ex. 1003) as the primary reference, nor ground 3, with the Degany patent (Ex. 1024) as the primary reference, assert any prior art that teach the claimed "plurality of measurement processing components" of claim 1, the Board should deny St. Jude's petition for *inter partes* review.

A. The references advanced in Ground 1, with the Prucka Manual as the primary reference, fail to disclose or suggest the claimed plurality of invasive sensor measurement processing components that facilitate receipt of data from multiple different invasive sensors of different sensor types, as required by independent claim 1.

Through ground 1 of its Petition, St. Jude contends that claim 1 of the '994 patent is unpatentable under 35 U.S.C. § 103 over a four-way combination of references, including the Prucka CardioLab® 2000/4000/7000 Operator's Manual, Software Version 5.1 ("Prucka Manual," Ex.1003); *Inside Windows NT Second Edition*, Microsoft Press, 1998 ("Inside Windows," Ex. 1004); *Inside COM*, Microsoft Press, 1997 ("Inside COM," Ex. 1018); and U.S. Patent 5,819,115 ("Hoese," Ex. 1005). St. Jude's arguments rely on the Prucka Manual, which is an operator's manual from GE Medical Systems for an electrophysiology system called "CardioLab." *See* Petition, at 22.

However, none of the references asserted in ground 1, whether alone or in any combination, disclose or suggest a system for invasive cardiovascular diagnostic measurement acquisition and display having the "plurality of measurement processing components" recited in claim 1. Indeed, St. Jude has failed to identify anything in the alleged prior art that discloses a plurality of invasive sensor measurement processing components that facilitate receiving data from multiple different invasive sensors of different sensor types, let alone that the measurement processing components correspond to "particular sensor types." Instead, St. Jude contends that various software "***functions***" from the Prucka Manual meet the specific limitations of claim 1. *See* Petition, at 29-30. In particular, St. Jude alleges that three such "functions" in the Prucka Manual teach these measurement processing components of claim 1: "measurement functions," "signal functions," and "macros." *Id.* However, these arguments overlook the specific features of the invasive sensor processing components recited in claim 1, and therefore do not actually meet a material limitation of the claim.

First, the "measurement functions" referenced in the Prucka Manual do not "***facilitat[e] receiving data***" of "***particular sensor types***." Indeed, rather than facilitating receipt of data from multiple different invasive sensors of different sensor types, the alleged "measurement functions" in the Prucka Manual merely process sensor data that has *already* been made available to the functions. *See* Prucka Manual, Ex. 1003, at 124-30. For instance, the Prucka Manual discusses a "Review window" that displays signals *before* the

alleged "measurement functions" process such signals. *See,* e.g. *id.*, at 128 (providing that a retrograde refractory periods measurement functions can perform measurements "on signals displayed in the Review window."). Each of the "measurement functions" in the Prucka Manual perform particular processing of data that the system has already received in order to determine values such as conduction intervals, sinus node recovery time, and antegrade and retrograde refractory periods. *See id.*, at 124-130. Thus, none of the "measurement functions" are described as facilitating receipt of data from various invasive sensors as recited in claim 1, let alone that the functions correspond to "particular sensor types." Instead, the Prucka Manual states that each of the various "measurement functions" performs analysis of a common set of "pressure signals." *Id.* at 124. Accordingly, the "measurement functions" fail to disclose or suggest the plurality of invasive sensor measurement processing components recited in claim 1.

Similarly, St. Jude's reliance on "signal functions" from the Prucka Manual is misplaced, as they also fail to teach the plurality of invasive sensor measurement processing components recited in claim 1. Like the "measurement functions," there is no suggestion from the Prucka Manual or the other references that respective ones of the "signal functions" have any role in *facilitating receipt* of data from particular sensor types. Instead, the Prucka Manual discusses that the "signal functions" can be used to apply various display and hardware settings according to user preferences. *See id.* at 74-83. Although the Manual includes several screenshots of user interfaces related to these "signal

functions," the reference is notably silent as to how they are implemented within the system. *See id.* Not only is there no description that the signal functions facilitate receiving data, but there is also no indication that particular ones of the signal functions actually correspond to particular types of invasive sensors, or that the functions operate on multiple different invasive sensors of different sensor types. *See id*.

The *Inside COM* reference does not cure the deficiencies of the Prucka Manual. St. Jude contends that the plurality of invasive sensor measurement processing components is rendered obvious by the "measurement functions" and "signal functions" of the Prucka Manual in view of a "programming standard" described in the *Inside COM* reference. *See* Petition at 23-24, 29-30. This argument has no merit. The *Inside COM* reference is nothing more than a programming handbook that lacks any connection to data acquisition and display systems, or invasive cardiovascular diagnostic systems. *See* Inside COM, Ex. 1018. Thus, *Inside COM*, even in combination with the Prucka Manual, lacks any disclosure or suggestion of invasive measurement processing components having the features recited in claim 1. For instance, St. Jude states that "it would have been obvious to implement each individual CardioLab function as a single COM component." Petition, at 24. Yet, even if individual ones of the "measurement functions" or "signal functions" were programmed as individual COM components as argued by St. Jude, they would still fail to include the features of the invasive sensor measurement processing components recited in claim 1. As noted above, neither the "measurement functions" or the "signal functions" facilitate receipt

of data from multiple different invasive sensors of different sensor types, and so modifying these functions according to *Inside COM's* "programming standard" would not cure these deficiencies. Regardless of the "programming standard" used to implement the CardioLab system, none of the references disclose or suggest the specific features of the invasive measurement processing components recited in claim 1.

Finally, the Prucka Manual's discussion of "macros" also fails to disclose or suggest the claimed invasive measurement processing components of the '994 patent. St. Jude admits that the macros merely "facilitate the execution of measurement and signal functions." Petition, at 30. Therefore, the deficiencies in the references pertaining to the "measurement functions" and "signal functions" are similarly applicable to "macros." Thus, neither the Prucka Manual, *Inside COM*, or the other references disclose or suggest that the "macros" can be made to facilitate receipt of data from multiple different invasive sensors of different sensor types, or that the "macros" correspond to "particular sensor types" as recited in claim 1. Instead, the Prucka Manual provides instructions that allow a user to manage and create macros through a user interface without any discussion of the specific features of claim 1. *See* Prucka Manual, Ex. 1003, at pp. 4-8–4-11.

In all, the alleged prior art references in Ground 1 fail to disclose or suggest "a plurality of measurement processing components," as required by claim 1 of the '994 patent. Because a material limitation of the sole independent claim of the patent is missing from the

prior art, the Board should deny St. Jude's petition for *inter partes* review of the '994 patent based on Ground 1, and on Ground 2, which extends from Ground 1.

B. The references advanced in Ground 3, with the Degany patent as the primary reference, fail to disclose or suggest the claimed plurality of invasive sensor measurement processing components that facilitate receipt of data from multiple different invasive sensors of different sensor types, as required by independent claim 1.

St. Jude's separate combination of references set forth in ground 3 of the Petition also fails to disclose the plurality of invasive sensor "measurement processing components" recited in claim 1 of the '994 patent. St. Jude provides a three-way combination of references in ground 3 in order to argue that claim 1 is unpatentable under 35 U.S.C. § 103. Petition, at 36-47. These alleged prior art references include U.S. Patent 6,193,669 ("Degany," Ex. 1024); Krauss, *et al*, "LabView™ for sensor data acquisition", Trends in Analyt. Chem., Vol. 18, No. 5, 1999 ("Kraus," Ex. 1025); and the *Inside Windows* reference, Ex. 1004, that was similarly used in ground 1, as discussed above. However, these references fail, whether taken separately or in combination, to disclose the "plurality of measurement processing components" claimed in the '994 patent.

By way of background, the Degany patent, which is the primary reference relied on in grounds 3-12 of St. Jude's Petition, describes systems and techniques that are fundamentally different from the system described in the '994 patent and recited in claim 1. Generally, the Degany patent discusses a "method and devices for detection, localization and characterization of occlusions, aneurysms, dissections, stent position, dissections, stent

mal-position, wall characteristics, and vascular bed." *Id.*, at Abstract. To this end, Degany discusses "introducing an artificial pressure signal in the blood vessel," and monitoring the response to the signal using **one or more sensors *of the same type***. *See id.* at 8:1-55. Figure 11 illustrates the system discussed in the Degany patent:

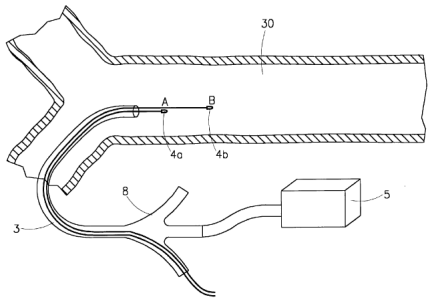


FIG.11

Figure 11 shows a catheter 3, inserted into a blood vessel 30 of a patient. *Id.* at 25:31-41. The catheter 3 delivers two pressure sensors, 4a and 4b, to the appropriate site within the patient's blood vessel. *Id.* A pulse generator 5 delivers a pressure pulse through the catheter 30 and into the blood vessel 30. *Id.* A computer system (not shown) connected to the sensors 4a and 4b is configured to capture information from the sensors 4a and 4b to determine information about the health of the vessel 30. *Id.*

However, the Degany patent fails to disclose or suggest the claimed plurality of invasive sensor measurement processing components that facilitate receipt of data from multiple different invasive sensors of different sensor types. Instead, Degany describes data acquisition techniques that use one or more sensors *of the same type* to collect signals from the patient's blood vessel. *See id.*, at 8:36-46, 18:15-27:5. Indeed, Degany actually

teaches away from the multiple different invasive sensors of different sensor types of claim 1, stating that multiple "simultaneous measurements" have "prove[n] impractical considering clinically available tools and methods." *Id.*, at 3:38-40. For example, as illustrated in Figure 11 above, Degany discusses a system that uses two *pressure* sensors 4a and 4b. *See id.* at 25:31-41. The Degany system does not include a pressure sensor in combination with a second, different type of invasive sensor. *See id.*

Moreover, the references in ground 3 fail to disclose or suggest the particular arrangement and features of the claimed invasive measurement processing components. Namely, the references do not disclose any such components that facilitate receiving data from "particular sensor types," as recited in claim 1. St. Jude's petition non-specifically alleges that Degany discloses "software and the processing of measurements," and "numerous ways of processing cardiovascular diagnostic measurements," including "pressure sensor signal analysis." Petition, at 44. Notably, these allegations lack any indication of how anything from Degany corresponds to the particular features of the invasive sensor measurement processing components recited in claim 1. *See id*.

The Kraus reference does not cure the deficiencies of Degany. St. Jude contends that Kraus discloses "the use of Labview software to perform measurement processing in software components," specifically noting Kraus's discussion of "virtual instruments and sub-virtual instruments." Petition, at 44. However, there is no indication in Kraus that anything, including the "virtual instruments and sub-virtual instruments," actually

corresponds to particular sensor types and that they facilitate receiving data from the particular types of sensors in the manner recited in claim 1. Instead, Kraus generally discusses a software system referred to as LabView™ that is produced by National Instruments™ as a "universal programming system." *See* Kraus, Ex. 1025, at 312. Kraus states that a "virtual instrument" is what a "program in LabView is called," and a "sub-virtual instrument" allows the "integration of program code" in order to condense the layout of "complex tasks." *See id.*, at 312, 315. There is no discussion in Kraus about components that facilitate receiving data from particular sensor types. Petition, at 44.

The third reference asserted in Ground 3 of the Petition (*Inside Windows*, Ex. 1004) also does not disclose or suggest the plurality of invasive measurement processing components recited in claim 1, and St. Jude does not rely on it this regard. Accordingly, because a material limitation of the sole independent claim of the patent is missing from the prior art of Ground 3, the Board should deny St. Jude's petition for *inter partes* review of the '994 patent based on Ground 3, and on Grounds 4-12, which extend from Ground 3.

In summary regarding Grounds 1-12, St. Jude has not established that any of the alleged prior art teaches "a plurality of measurement processing components," as recited in claim 1. Thus, a material limitation of the sole independent claim of the '994 patent is missing from the prior art. This alone is sufficient for the Board to deny instituting *inter partes* review, and is indeed dispositive. *See* Practice Guide, 77 Fed. Reg. 48,756, 48,764 (Aug. 14, 2012).

VI. GROUNDS 1 AND 2 SHOULD BE DENIED FOR NOT BEING BASED ON PRINTED PUBLICATION PRIOR ART

Grounds 1 and 2 of St. Jude's Petition should be denied from any *inter partes* review proceeding that the Board may institute. These grounds primarily and improperly rely on the Prucka Manual, Ex. 1003, which is an operator's manual from GE Medical Systems. Reliance on the Prucka Manual is improper for at least two reasons. First, St. Jude has failed to establish that the Prucka Manual is prior art under 35 U.S.C. § 102. Only patents and printed publications may be relied upon to allege anticipation or obviousness in *inter partes review* petitions. 35 U.S.C. § 311. Yet, there is nothing in the record presented by St. Jude that proves the Prucka Manual was in fact a printed publication as of May 20, 2002 – the filing date of the '994 patent. The declaration that St. Jude proffers for the purpose of establishing the Manual as a printed publication is lacking in several respects. Ex. 1037. Indeed, it fails to address the critical question of whether the Manual "was disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence, can locate it." *E.g.*, In re *NTP, Inc.*, 654 F.3d 1279, 1296 (Fed. Cir. 2011). St. Jude has not established that this is the case, and therefore has not established that the Manual is a prior art printed publication.

Second, the Prucka Manual includes serious deficiencies in its disclosure of the system that it describes (the CardioLab system). The impropriety stems from St. Jude's attempt to mask these deficiencies by relying on evidence of "prior uses" of the *CardioLab*

system to supplement the Manual's actual disclosure. *See infra* Section VII. By statute, patents and printed publications are the only types of prior art references that may be relied upon to allege invalidity in *inter partes* review. 35 U.S.C. § 311(b). St. Jude attempts to work around this limitation by importing alleged teachings from the CardioLab system itself, rather than the Manual, in order to compensate for the deficiencies in the Manual's actual disclosure.

As such, and as elaborated in the following sections, the Board should deny *inter partes* review of St. Jude's Grounds of invalidity 1 and 2.

A. St. Jude has failed to establish that the Prucka Manual is a prior art printed publication.

Grounds 1 and 2 should be denied because St. Jude has not shown that the Prucka Manual – the primary reference asserted in these grounds – is a printed publication that may be relied on as prior art under 35 U.S.C. § 311(b). St. Jude proffers the Vadodaria declaration, Ex. 1037, as evidence of the Manual's printed publication status, but it fails to prove the critical point of whether the manual was available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, could locate it as of May 20, 2002, when the '994 patent was filed. *See* In re *NTP, Inc.*, 654 F.3d at 1296. Quite simply, the evidence does not show that the Manual was available to the public at any particular date prior to the filing of the '994 patent, and thus the Prucka Manual cannot qualify as prior art.

Neither the Vadodaria declaration, nor any other evidence, establishes that anyone outside of GE Medical Systems did in fact have a copy of the Manual prior to May 20, 2002. Instead, both the Petition and the Vadodaria declaration begin by noting the August 9, 2001, initial "release" date provided in the text of the Manual on page 1-3. *See* Petition, at 20-21; Prucka Manual, Ex. 1037, at 3. Yet, there is no evidence that the Manual actually achieved printed publication status on the August 9, 2001 release date, or at any other time prior to the filing of the '994 patent. Indeed, the Vadodaria declaration fails to mention even one instance of when a particular person or entity was actually provided a copy of the Manual relied on in Grounds 1 and 2. Instead, the declaration, from former GE Medical Systems employee Sachin Vadodaria, includes many *general* statements about alleged practices at GE. For instance, Vadodaria states that "[i]t was the company's *practice* to *release* manuals as of the release date shown in the manual." Vadodaria IPR Declaration, Ex. 1037, at 3 (emphasis added). There is no explanation of what "release" actually means, such as whether it was published in a manner to make it accessible to members of the public as of the release date, or whether it was merely internally released from a publication department within GE. For example, the declaration identifies no particular date on which the Manual was allegedly made available for sale, and even lacks any indication of how long "*after the date* of [the Manual's] release" that it was supposedly made available for sale. *See id*. at 4 (emphasis added).

The declaration then states that "[i]t was our company's practice that, if we received a request from an interested party, we would send copies of relevant manuals," and that "most industry workers understood, that systems such as the Prucka CardioLab would have associated documentation that could be requested from the supplier by people interested in purchasing the system, and that the suppliers would provide this documentation to encourage sales of their products." *Id.* Again, the declaration only discusses general company "practice" and purported industry norms. *See id.* In this context, there is no indication that GE actually received any requests for the Manual, that GE provided the manual to any particular party, or that GE actually would have reliably produced the manuals upon request. *See id.*

Indeed, the only two particular sales of the CardioLab system that Vadodaria identifies as being specifically involved in were to Stanford University in 2000 and the Mayo Clinic in 2000 – *both prior to the August 9, 2001 "release" date* of the Prucka Manual. *See id.* at 2-3. Presumptively, the Manual would not have been provided before its release date, and the declaration does not suggest as much. Even regarding alleged sales that occurred after August 9, 2001, the declaration fails to identify even one specific purchaser that actually received a copy of the Manual. And although the declaration indicates that GE provided manuals to various unidentified purchasers in the August 2001 timeframe, there is no further evidence that corroborates Vadodaria's declaration more than a dozen years after the fact. *See id.* at 3.

Accordingly, St. Jude has failed to establish that the Prucka Manual, on which it primarily relies in its invalidity contentions in Grounds 1 and 2, is a prior art printed publication. For this fact alone, the Board should deny instituting *inter partes* review of these grounds. However, even if the Prucka Manual itself does constitute prior art, the Board should deny Grounds 1 and 2 for the separate reason that St. Jude improperly relies on inadmissible "prior use" evidence to mask deficiencies in the Prucka Manual's actual disclosure.

B. St. Jude relies on inadmissible evidence to mask deficiencies in the Prucka Manual's actual disclosure.

Grounds 1 and 2 should be denied due to St. Jude's impermissible reliance on evidence of prior public uses, which are prohibited from *inter partes* review, to overcome deficiencies in the Prucka Manual's actual disclosure. Unlike district court litigation, petitioners in *inter partes* review may only challenge the validity of a patent under 35 U.S.C. § 102 or § 103 based on "prior art consisting of patents or printed publications." 35 U.S.C. § 311(b). Other potential sources of prior art, such as proof that something was sold, offered for sale, or known in the United States before the challenged patent's date of priority – collectively, so-called "prior use" prior art references – are not available in *inter partes* review. Despite these restrictions of the forum in which it has chosen to litigate, St. Jude's petition augments information discussed in the Prucka Manual with information gathered from impermissible "prior use" references. In so doing, St. Jude attempts to mask

deficiencies in the Prucka Manual, which is a lengthy, but largely non-descriptive, document that leaves much to the reader's imagination and that teaches far less than what St. Jude argues it does.

St. Jude's Petition relies on evidence of "prior use" prior art by citation throughout grounds 1 and 2 to the declaration testimony of its expert witness, Mr. W. Anthony Mason. *See* Petition, at 19-36; Mason Declaration, Ex. 1002. However, well over half of the Mason declaration is directed to discussion of three "prior use" systems, including the CardioLab system that is the subject of the Prucka Manual reference. *See* Mason Declaration, Ex. 1002, at 138-221 (including 83 pages of discussion about the CardioLab system based on "prior use" evidence and not based on the Prucka Manual). For example, Mr. Mason admits that "[t]he Prucka Manual is an operator's manual, and as such, does not disclose the source code of the CardioLab software." *Id.* at 51. Yet, based on impermissible "prior use" evidence, the declaration contains multiple pages of source code from the software that is not present, and not even described, in the actual content of the Prucka Manual. *See, e.g.*, *id.* at 146-51.

Of course, St. Jude is careful not to tip off the Board to its improper reliance on material outside of the Prucka Manual. The claim charts and other descriptions provided in grounds 1 and 2 of the Petition generally cite to portions of the Mason declaration that are formally separated from the analysis of alleged "prior use" evidence. *See* Mason Declaration, Ex. 1002 (providing formal discussion of systems based on "prior use"

references starting at paragraph 335). In reality, though, there is cross-pollination between the sections that make even the cited portions impermissibly reliant on "prior use" grounds. *Id.* at 4:11, 47:119-49:122. Key portions of the declaration that are cited in the Petition and that are supposedly separate from the discussion of "prior uses," actually refer to these "prior uses" rather than or in addition to the Manual itself.

In one example, the Petition alleges in discussion of ground 1, that "[t]he Network Interface Cards can use the 'Peripheral Interface Connect' (PCI) or 'Industry Standard Architecture' (ISA) interfaces, which were available on 'most computers' at the time." Petition, at 25. The Petition further alleges that, "Because the Prucka Manual teaches a connection from a fiber optic network cable to a computer, and because Hoese and Exhibits 1056-1057 teach that such a connection can be achieved with a network interface card using standard interfaces, it would have been obvious to combine Hoese with the Prucka Manual." *Id.* at 26. Both of these quotations from the Petition include a citation to paragraph 131 of the Mason declaration, in which Mr. Mason "note[s] that the Prucka CardioLab was a real commercial product, and used a fiber-to-PC expansion card as well. . . ." Ex. 1002, at 55:131. Volcano does not concede the accuracy of this statement, and disputes Mr. Mason's characterizations in this regard. However, it is plainly improper for St. Jude to rely on "prior use" references as the basis for its obviousness argument in *inter partes* review. *See* 35 U.S.C. § 311(b).

In another example, the Mason declaration improperly relies on testimony about prior uses of the CardioLab system that are not described in the Prucka Manual. The Mason declaration includes multiple citations to the declaration of Sheri Prucka, who purports to be the Founding Partner and President of Prucka Engineering, the original CardioLab product developer. Prucka Declaration, Ex. 1053, at 1-2. These citations are used for more than just establishing the level of ordinary skill in the art or to determine an expert opinion on the basis of the alleged prior art references from the Petition. Instead, the Prucka declaration is specifically directed to discussion of technological aspects of the CardioLab system that could only be known through experience with the system itself, and not from the Manual. *See id.* at 3-9 (discussing alleged aspects of the particular design of the CardioLab system). For instance, the Mason declaration alleges, based on Ms. Prucka's declaration testimony, that "it would have been customary and obvious for one with ordinary skill in the art in 002 to have used kernel mode device drivers to extract information from a peripheral interface card." Mason Declaration, Ex. 1002, at 47. Because the Manual, on which St. Jude relies in its Petition, lacks any discussion of kernel mode drivers or peripheral interface cards, the reference to Ms. Prucka's testimony is really an improper attempt to establish unpatentability of the '994 patent claims on the basis of impermissible "prior use" evidence.

The Board should not allow St. Jude to work around the fundamental limitations of *inter partes* review by relying on "prior use" references to mask the shortcomings of the references it has actually asserted in its Petition. Accordingly, the Board should deny *inter*

partes review of grounds 1 and 2 due to St. Jude's introduction of non-statutory references to fill in gaps and deficiencies from the Prucka Manual's actual disclosure.

VII. GROUND 4 SHOULD BE DENIED FOR NOT BEING BASED ON PRINTED PUBLICATION PRIOR ART

The Board should deny St. Jude's petition for *inter partes* review of Ground 4. This ground heavily relies on an operator's manual from Florence Medical Ltd. that discusses the SmartFlow™ Integrated Lumen Physiology system. *See* Ex. 1027 (the "SmartFlow Manual"). As with the Prucka Manual, St. Jude has offered improper evidence in Ground 4 that cannot form the basis of an *inter partes* review under 35 U.S.C. § 311(b). To this end, St. Jude inappropriately relies on the SmartFlow Manual as a printed publication without offering sufficient evidence to establish that it was publicly available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, could locate it. *See* In re *NTP, Inc.*, 654 F.3d at 1296. Moreover, St. Jude improperly attempts to mask deficiencies in the SmartFlow Manual's actual disclosure by bringing in "prior use" evidence that is impermissible in *inter partes* review proceedings.

A. St. Jude has failed to establish that the SmartFlow Manual is a prior art printed publication.

St. Jude has not established that the SmartFlow Manual qualifies as a printed publication, and it therefore cannot be relied upon as prior art in any *inter partes* review proceedings that may be instituted. *See* 35 U.S.C. § 311(b) (2012). The SmartFlow Manual is referenced in every limitation of the claims challenged in ground 4 of the Petition,

and is therefore central to St. Jude's invalidity contentions. *See* Petition, at 48-51. Due to St. Jude's core reliance on such evidence, and concurrent failure to establish the Manual's printed publication status, St. Jude cannot show that there is a "reasonable likelihood" that it will prevail on ground 4. *See* 35 U.S.C. § 314(a); 37 C.F.R. § 42.108(c). As such, the Board should deny *inter partes* review of this ground due to St. Jude's failure to meet the requisite statutory standard. *Id.*; *see also* Practice Guide, 77 Fed. Reg. 48,756, 48,764 (Aug. 14, 2012) (indicating that preliminary responses may include notice to the Board that "[t]he references asserted to establish that the claims are unpatentable are not in fact prior art").

St. Jude offers the declaration of Dr. Chen Barak, who purports to be a former Vice President of Florence Medical Ltd., as evidence to establish the SmartFlow Manual as a printed publication prior art reference. Barak IPR Declaration, Ex. 1028, at 2; Petition, at 47. However, the Barak declaration fails to adequately address whether the SmartFlow Manual was sufficiently public for it to qualify as a printed publication prior art as of the '994 patent's May 20, 2002, filing date. In several respects, St. Jude has not shown that the Manual was accessible, through exercise of reasonable diligence, to persons of interest or ordinary skill in the art or subject matter of the '994 patent prior to May 20, 2002.

For example, Dr. Barak states that as of May 14, 2001, Florence Medical "began to promote the SmartFlow system to potential customers," and that "[i]t was the company's practice to supply copies of the [] SmartFlow Operator's Manual with all systems that

Florence Medical sold in 2001." Barak IPR Declaration, Ex. 1028, at 3. However, Dr. Barak provides no indication that Florence Medical actually did sell any SmartFlow systems during this period prior to the '994 patent's filing date. *See id.* It is thus unclear whether any customers actually received a copy of the SmartFlow Manual. Dr. Barak's statement does not preclude the possibility that no units were sold, and, therefore, that no customers were actually provided with copies of the Manual. Furthermore, the Barak declaration does not indicate whether any sales that may have occurred were subject to a non-disclosure agreement or other restrictions on the dissemination of information contained in the SmartFlow Manual.

Dr. Barak then testifies that "[a] copy of the attached SmartFlow Operator's Manual was also publicly available as an electronic file in SmartFlow systems that we had on public display at industry scientific meetings." *Id.* at 3-4. Yet, this statement again fails to establish that the Manual was actually accessible to one of ordinary skill in the art, exercising reasonable diligence, or that any person actually received or reviewed a copy of the Manual. Even assuming for the sake of argument that the SmartFlow *system* was on public display at conferences, the declaration provides no indication of whether there was a practical way for attendees to access the Manual's "electronic file" from the system, and provides no indication that anyone *did* access the Manual.

The declaration then includes testimony that Dr. Barak attended a cardiovascular industry conference in May 2001 in which Florence Medical "prominently displayed the

SmartFlow *system*," and the "*booth* was visible to thousands of conference attendees." *Id.* at 4. However, beyond the system and the presentation booth, the declaration is notably unspecific about the Manual. Dr. Barak states that the Manual was "openly available" at the booth, but he does not state whether it was actually displayed or whether anyone actually reviewed or even saw the Manual during the conference. *Id.*

The other statements testified to in the Barak declaration similarly fail to provide sufficient facts to prove that the SmartFlow Manual was adequately accessible as needed to establish it as a printed publication. For instance, according to the declaration, "[d]uring 2001, Florence Medical promoted the SmartFlow system by sending units to doctors," including in the United States. *Id.* at 5. Allegedly, "[i]t was the company's practice that the systems sent to physicians . . . were supplied with the attached SmartFlow Operator's Manual." *Id.* Yet, again, the declaration lacks specific information about the context and extent of the alleged distribution of the Manual. The declaration does not identify any particular physicians that received or reviewed the Manual. There is no discussion of how many units may have been sent to these doctors. And although the declaration states that "Florence Medical placed no restrictions on the SmartFlow Operator's Manual," *id.* at 5, the statement is vague, failing to indicate whether the Manual may have been subject to non-disclosure agreements.

In all, St. Jude has failed to carry its burden of proving that the SmartFlow Manual is a printed publication, and accordingly, whether the Manual may be relied on as prior art.

For this reason, the Board should deny *inter partes* review of ground 4 and any other ground in the Petition that may also rely on the SmartFlow Manual as allegedly teaching any limitations of the claims of the '994 patent.

B. St. Jude relies on inadmissible evidence to mask deficiencies in the Prucka Manual's actual disclosure.

The Board should deny the fourth ground of invalidity advanced in St. Jude's Petition for *inter partes* review. Contrary to the limitations imposed by 35 U.S.C. § 311(b), which restricts the scope of *inter partes* review petitions to grounds of invalidity that are based on prior art consisting only of patents and printed publications, St. Jude improperly advances invalidity contentions in Ground 4 that rely on evidence of "prior uses" of the SmartFlow system in order to supplement the actual disclosure of the SmartFlow Manual.

Through Ground 4 of its Petition, as in Grounds 1 and 2, St. Jude again relies on portions of its expert declaration that pertain to separate evidence of "prior uses" of a system, which goes beyond any information about the system that is actually described in the SmartFlow Manual, or the other references asserted in Ground 4. *See* Petition, at 47. For instance, St. Jude's petition introduces the SmartFlow Manual by stating, "Both the SmartFlow Manual and the '669 patent belonged to the same assignee (Florence Medical)." *Id.* In support of this statement, the Petition cites the declaration of its expert witness, Mr. W. Anthony Mason, Ex. 1002, at ¶ 240. Petition, at 47. But in fact, rather than discussing just the SmartFlow Manual and the '669 Patent as suggested by the Petition, this portion of

the Mason declaration actually ties independent and impermissible "prior use" evidence about the SmartFlow *system* to the teachings of both the SmartFlow Manual and the '669 patent. *See* Mason Declaration, Ex. 1002, at ¶ 240 (citing ¶¶ 190-93).

Indeed, this portion of the Mason declaration has very little connection to the SmartFlow Manual at all, but instead directs the reader to four paragraphs of discussion about "prior uses" of the SmartFlow system that is completely separate from and not disclosed in the SmartFlow Manual itself. *See id*. This "prior use" discussion alleges certain features about the system architecture, operating system, user display, and development information of the SmartFlow system that does not stem from the SmartFlow Manual. *See id.* at ¶¶ 190-93. Instead, the Mason declaration analyzes the "prior uses" of the system based on the declarations of Mr. Frank Martin and Dr. Chen Barak, who both purport to be former officers of Florence Medical Ltd., the company that developed the SmartFlow system. *See* Martin Declaration, Ex. 1058, at 1; Barak Lit. Declaration, Ex. 1134, at 1. These declarations contain substantial information about "prior uses" of the SmartFlow system based on their personal knowledge and experience working with the system, and not from the SmartFlow Manual that St. Jude's Petition purports to rely on. *See* Martin Declaration, Ex. 1058, at 2; Barak Lit. Declaration, Ex. 1134, at 3-7.

In summary, Ground 4 of St. Jude's Petition improperly relies on "prior use" evidence to supplement the actual disclosure of the SmartFlow Manual. Such "prior use" evidence is

plainly inadmissible in *inter partes* review petitions according to 35 U.S.C. § 311(b). Accordingly, the Board should deny *inter partes* review of Ground 4 of St. Jude's Petition.

VIII. THE 169 PAGES OF DECLARATION TESTIMONY AND 63 EXHIBITS SETTING FORTH THREE "PRIOR USE" GROUNDS FOR INVALIDITY, WHICH GROUNDS ARE NOT EVEN ADDRESSED IN ST. JUDE'S PETITION, MUST BE EXCLUDED FROM THE SCOPE OF ISSUES TO BE ADDRESSED IN ANY *INTER PARTES* REVIEW PROCEEDINGS THAT MAY BE ORDERED

St. Jude has attempted to mask the deficiencies of its alleged "printed publication" prior art by supplementing them with alleged "public use" prior art evidence that is indisputably barred from consideration in *inter partes* review proceedings. *See* 35 U.S.C. § 311(b) (2012) ("A petitioner in an *inter partes* review may request to cancel as unpatentable 1 or more claims . . . *only on the basis of prior art consisting of patents or printed publications*."). Indeed, the limited means of challenging patentability in *inter partes* review is one of the hallmarks of the proceedings that distinguish it from District Court litigation. *See* 157 Cong. Rec. S1174 (daily ed. Mar. 3, 2011) ("AIA Legislative History IV," VOLCANO Ex. 2004). Congress included these limitations as a means of reducing the number of issues and overall complexity of the proceedings, and to ensure that the Board could meet its statutory mandate to issue a final decision within twelve months of instituting proceedings. *See id.* St. Jude seeks to exempt itself from these limitations by introducing at least 169 pages of declaration testimony and 63 exhibits that are directed to evidence of prior "public uses," which are unquestionably improper and outside the bounds of *inter partes* review. In fact, through the Mason declaration, St. Jude advances three additional

invalidity contentions, which in addition to being impermissible grounds, ***are not even identified in St. Jude's petition***, let alone substantively discussed. *See* Mason Declaration, Ex. 1002, at 137-305. These grounds serve no legitimate purpose. Instead, St. Jude discreetly relies on them to bolster otherwise non-descriptive disclosures of the alleged printed publications that are purportedly relied on in its Petition. For example, two of the three additional invalidity contentions set forth in the Mason declaration pertain to public uses of the systems that are allegedly described in the Prucka Manual and the SmartFlow Manual, respectively. *Id.* The third contention relates to similarly impermissible public use evidence. *Id.*

These impermissible grounds, along with the abundance of exhibits that St. Jude submits to support them, cannot be maintained in any proceedings that the Board may institute. The plain language of the statute, which St. Jude ignores, makes clear that *inter partes* reviews are proceedings of intentionally limited scope. Moreover, the novel legal theory by which St. Jude attempts to raise these otherwise impermissible grounds – "secondary indicia of obviousness" – has no legal support. Specifically, St. Jude alleges that "market trends" and "simultaneous invention" justify inclusion of "prior use" grounds that are limited to neither patents or printed publications, and that, in some instances, even relate to uses that occurred *after* the filing date of the '994 patent. Petition, at 14-15; Ex. 1002, at 138. This theory is not only flawed in the abstract, but will also present significant burdens to the Board and to the Patent Owner that were not envisioned in *inter partes*

reviews. Each of the prior use grounds will increase the complexity and number of factual issues that must be the subject of discovery and the Board's attention in any proceedings that may be instituted. Finally, if the Board does not limit the scope of these proceedings to grounds stemming from patents and printed publications, then the prior use grounds must also fall within the scope of any estoppel that may attach to these proceedings such that St. Jude is not entitled to a second chance to raise these same invalidity grounds in any subsequent District Court litigation proceedings concerning the '994 patent.

A. There is no question the additional three grounds of invalidity set forth in St. Jude's expert declaration, but not in its petition, are impermissible grounds for *inter partes* review proceedings.

The three "prior use" grounds of invalidity that St. Jude attempts to backdoor into these *inter partes* review proceedings are categorically impermissible. Indeed, that *inter partes* review is limited to invalidity grounds based on "prior art consisting of patents or printed publications" is fundamental. *See* 35 U.S.C. § 311(b). The Board should not indulge St. Jude's attempts to expand the scope of proceedings beyond these clear statutory bounds.

St. Jude attempts to raise its impermissible prior use grounds through the declaration of its expert witness, Mr. W. Anthony Mason. *See* Mason Declaration, Ex. 1002. Notably, these grounds are not actually raised anywhere in its Petition and are not even discussed in the Petition. Instead, under the guise of "objective evidence" of obviousness, the Mason declaration includes 168 pages of testimony about three systems – the Prucka

CardioLab/Mac-Lab system, the SmartFlow system, and the EP-Workmate system – that St. Jude alleges render the claims of the '994 patent invalid. Not only is St. Jude wrong on the merits of its allegations, but more importantly, these grounds are completely inappropriate to raise in an *inter partes* review petition.

The basis for St. Jude's prior use invalidity grounds include a number of exhibits that would not qualify as prior art even in district court litigation, let alone in *inter partes* review. For example, among these 63 exhibits are a GE CardioLab flyer dated February 2011, and a National Instruments™ webpage from April 2013 that describes a data acquisition product being offered for sale over a decade after the filing date of the '994 patent. *See* CardioLab 2011 Flyer, Ex. 1076; NI 2013 Data Card, Ex. 1078. In support of St. Jude's "prior use" invalidity ground based on the Prucka CardioLab/Mac-Lab system, Mr. Mason's testimony heavily relies on the declaration of Sheri Prucka. *See, e.g.*, Mason Declaration Ex. 1002, at 139-40. The Prucka declaration, in turn, primarily discusses the CardioLab/Mac-Lab system on the basis of Ms. Prucka's purported personal knowledge as a founding partner and president of Prucka Engineering, Inc., which was the original developer of the CardioLab/Mac-Lab system, rather than from patents or printed publications. *See* Prucka Declaration, Ex. 1053, at ¶¶ 05-23.

The other two prior use grounds advanced by St. Jude rely on similarly impermissible evidence. For instance, the Mason declaration includes 47 pages of discussion about the SmartFlow *system*, with only one reference to the SmartFlow *Manual*

that is actually asserted in ground 4 of the Petition. *See* Ex. 1002, at 221-268; Petition, at 47-51. The overwhelming amount of the 47 pages discussing the SmartFlow system is not supported by the Manual at all, but instead relies on various sources of non-printed publications. *See* Mason Declaration, Ex. 1002, at 221-268. Indeed, the vast amount of Mr. Mason's discussion of the SmartFlow system is informed by evidence that St. Jude does not even try to establish as printed publications. For instance, Mr. Mason references the declaration of Dr. Chen Barak, the purported former Vice President of Operations at Florence Medical, to support Mr. Mason's analysis of the SmartFlow system. *See* Ex. 1002, at 221-268; Ex. 1134. Perhaps fittingly, St. Jude's shorthand for the declaration is the "Barak Lit. Decl.," as Dr. Barak's declaration was apparently originally prepared during the parties' prior district court litigation over the '994 patent. *See* Barak Lit Decl., Ex. 1134 (referenced as the "Barak Lit. Decl." as compared to Exhibit 1028, named the "Barak IPR Declaration"). Dr. Barak's testimony is directed to the SmartFlow *system*, and it relies on the personal knowledge of Dr. Barak as a Florence Medical officer, and also on other non-public information such as the "SmartFlow-Software Design Description" and the "SmartFlow Software Requirements Specification." *See* Barak Lit Decl., Ex. 1134, at 4-5. Mason uses such information, for example, to analyze the source code of the SmartFlow system, which was attached to the Barak Litigation Declaration and which is not described in any patents or printed publications. The plain impropriety of such analysis is captured in Mr. Mason's conclusion, which alleges:

> Accordingly, the SmartFlow ***system*** was in ***public use or on sale*** in the United States before May 20, 2011, and was ***known or used by others*** in the United States prior to May 20, 2002. ***Thus, the SmartFlow system was prior art*** under both 35 U.S.C. §§ 102(a) &(b). Because it practiced each limitation in claim 1 of the '994 patent, claim 1 of the '994 patent is invalid as anticipated under 35 U.S.C. § 102.

Mason Declaration, Ex. 1002, at 268. Volcano rejects the substance of the statement, which sounds much more like attorney argument than the conclusion of a technical expert. However, the statement does make it indisputably clear that St. Jude is advancing "prior use" invalidity contentions outside of its petition that are impermissible in *inter partes* review. Indeed, it also reveals that Mr. Mason's declaration is actually being recycled from prior litigation, and that St. Jude was apparently unable to tailor its invalidity contentions to the limited grounds available before this Board in *inter partes* review. For example, while Mr. Mason first argues that evidence of prior public uses is relevant to objective indicia of obviousness, his conclusion pertains to anticipation under 35 U.S.C. § 102. *See* Mason Declaration, Ex. 1002, at 221. Plainly, St. Jude is merely attempting to use "objective indicia of obviousness" as a means of circumventing the limitations imposed by 35 U.S.C. § 311(b) and to introduce impermissible evidence of prior public uses.

These attempts to circumvent the statute are especially relevant because they are being used to mask deficiencies in disclosures from both the Prucka and SmartFlow

Manuals that are used as primary references in grounds 1 and 2, and 4 of St. Jude's petition, respectively. These grounds effectively rely on alleged "prior use" information to supplement the Manuals, which is impermissible in *inter partes* review. *See supra* Sections VI.B and VII.B (explaining that the Board should exclude each of the grounds that rely on improperly supplemented disclosures from the Prucka and SmartFlow Manuals).

In all, there is no question that St. Jude is attempting to improperly advance three "prior use" grounds outside of its Petition. Moreover, as explained below, the legal theory that St. Jude uses to justify its actions is flawed and lacks a foundation in the law.

B. St. Jude's argument that that these three additional grounds of invalidity are "secondary indicia of obviousness" and therefore relevant to this *inter partes* review proceeding has no legal support.

The Board should reject St. Jude's dubious legal theory that it uses to justify its three "prior use" grounds advanced in the Mason declaration. The theory, which relies on "simultaneous invention" as an indicia of obviousness, is a narrow doctrine that is rarely applied in District Court litigation proceedings, and has even less applicability in *inter partes* review in view of the statutory limitations on proper grounds for invalidity set forth in 35 U.S.C. § 311(b). In any event, St. Jude's attempt to advance additional invalidity grounds and to submit substantial amounts of impermissible evidence into these proceedings on the basis of "simultaneous invention" stretches the narrow doctrine to new ends, and the Board should now allow it.

The introduction of St. Jude's legal theory begins in its Petition in a section benignly captioned, "Objective Evidence of Obviousness." Petition, at 14. Within this section, St. Jude includes just six lines about "secondary considerations" being relevant to an obviousness analysis, and specifically alleges that "market trends and prior invention indicate the obviousness of the '994 patent." Petition, at 15. No further explanation of relevance is provided, other than a citation to a decision of the Court of Appeals for the Federal Circuit for the alleged notion that "simultaneous invention" is relevant to obviousness. *Id.* (citing *Geo M. Martin Co. v. Alliance Machine Systems Intern. LLC*, 618 F.3d 1294, 1306 (Fed. Cir. 2010)). The Petition includes no additional discussion in this regard beyond these six lines, and no further explanation of how the secondary factors noted in the section are at all relevant to the '994 patent or to the Board's task in determining whether to institute *inter partes* review. However, its importance becomes evident in view of the 169 pages of declaration testimony and 63 exhibits that St. Jude has submitted to advance its three "prior use" grounds, and its attempts to use the impermissible evidence of "prior uses" to mask deficiencies in the alleged prior art references that are actually asserted in the Petition.

The crux of St. Jude's argument for advancing these "prior use" grounds is that they allegedly evidence "simultaneous invention" with the claimed inventions of the '994 patent. *See* Petition, at 15; Mason Declaration, Ex. 1002, at 137. The argument is flawed in at least two respects. First, it directly conflicts with 35 U.S.C. § 311(b), which states that *inter partes*

review proceedings are restricted to invalidity challenges that are based on "prior art consisting of patents or printed publications." *Id.* And second, even in other contexts such as district court litigation, "simultaneous invention" is a narrow, rarely applied doctrine that is inapplicable to the circumstances of this case.

To begin, St. Jude's "simultaneous invention" theory ignores the clear limitations that § 311(b) imposes on *inter partes* review proceedings. St. Jude asks the Board to consider a plethora of "prior use" references in support of the grounds for invalidity advanced in the Mason declaration, but not in its Petition. *See* Mason Declaration, Ex. 1002, at 137. Yet, as these grounds are based on neither "patents or printed publications" as required by § 311(b), the Board lacks any authority to consider them. Indeed, Congress specifically limited the scope of *inter partes* review in order to stay away from a "big discovery and legal process." *See* AIA Legislative History IV, VOLCANO Ex. 2004. If St. Jude desires to advance invalidity contentions premised on evidence of alleged "prior uses" outside the scope of § 311(b), then it has chosen the wrong forum to do so. St. Jude's expert states that "instances of simultaneous invention are not required to qualify as prior art." Mason Declaration, Ex. 1002, at 137. Regardless of whether this assertion has merit, or how evidence of "simultaneous invention" has been considered in obviousness analyses by the courts, it cannot be applied in the instant case because § 311(b) restricts the grounds and evidence that may be considered for purposes of *inter partes* review proceedings.

Moreover, even if the Board could reconcile the "simultaneous invention" theory with § 311(b), it has no role in the present case. Courts have indicated that evidence of "simultaneous invention" as a secondary consideration of obviousness has limited usefulness, and must be applied, if at all, with caution. *See Lindemann Maschinenfabrik GMBH v. Am. Hoist & Derrick Co.*, 730 F.2d 1452, 1460 (Fed. Cir. 1984). As of the '994 patent's May 2002 filing date, interference practice was a key component of the Patent Act, which awarded first inventors with a patent even over near-simultaneous inventions. *See* 35 U.S.C. §§ 102(g), 135 (2006). Thus, overreliance on St. Jude's theory seriously risks undermining this statutory framework that was in place at the time the '994 patent was filed. *See Lindemann Maschinenfabrik*, 730 F.2d at 1460 (finding that simultaneous invention was not an indication of obviousness); *Environmental Designs, Ltd. v. Union Oil Co. of California*, 713 F.2d 693, 698 n.7 (Fed. Cir. 1983) ("The virtually simultaneous making of the same invention does not in itself preclude patentability of that invention. Hence, the entirety of what is known as interference practice."). Accordingly, the courts have been especially circumspect about using simultaneous invention to find obviousness, even in District Court litigation where there are no restrictions on the types of prior art that may be asserted. If anything, in view of the prior art limitations imposed by § 311(b), the Board should be even more skeptical of any "simultaneous invention" argument made in *inter partes* review. It certainly provides no basis for St. Jude to advance three additional grounds of invalidity

through over 160 pages of declaration testimony and 63 exhibits that are not even mentioned in its Petition.

Additionally, the evidence that St. Jude presents to support its alleged "prior use" grounds of invalidity fall well outside the narrow scope of the "simultaneous invention" doctrine in the limited circumstances in which it has been applied. Evidence of simultaneous invention must be "contemporaneous" with the priority date of the challenged claims. *See Geo. M. Martin Co.*, 618 F.3d at 1305-06. The application from which the '994 patent issued was filed in May 2002. '994 Patent. Yet, St. Jude has submitted certain exhibits that are dated *years* after this filing date. For example, Exhibit 1078 shows sales and technical information for a data acquisition card being offered for sale in *April 2013*. Also, unlike the challenger in *Geo. M. Martin*, St. Jude has not established that the systems alleged in the three "prior use" grounds evidence "what constitutes the level of ordinary skill in the art" as of the filing date of the '994 patent. *See Geo. M. Martin Co.*, 618 F.3d at 1305-06 (finding an instance of "contemporaneous" invention relevant to obviousness only where the challenger identified two other prior art systems that were first sold "three and five years, respectively" before the patent's critical date). St. Jude has not identified prior systems comparable to those in *Geo. M. Martin*, and accordingly, it has not established that the Board can even consider evidence of "simultaneous invention."

In short, St. Jude has presented a flawed legal theory that directly conflicts with the limits of § 311(b). St. Jude then leverages its theory in an attempt to persuade the Board to

institute *inter partes* review on the basis of impermissible prior art references. By advancing three additional grounds of invalidity outside its Petition, and submitting a plethora of non-patent or printed publication evidence, St. Jude pushes the limits of the narrow legal doctrine into unchartered territory. The Board should reject this attempt according to the plain limitations of § 311(b).

C. Including these three additional alleged prior use grounds within the scope of issues for this *inter partes* review proceeding would be a significant burden to the Board and the Patent Owner.

These additional "prior use" grounds advanced by St. Jude will significantly increase the complexity and scope of any proceedings that may be instituted, presenting a significant burden to both the Board and the Patent Owner. The additional burden will be felt in several respects throughout the course of any proceedings that the Board may institute. For example, the scope of routine discovery will burgeon to potentially include cross-examination of each of St. Jude's declarants who testified in support of the additional "prior use" grounds, even where there may not be a direct connection between these declarants and any of the invalidity grounds that were expressly alleged in the Petition. *See* Practice Guide, 77 Fed. Reg. 48,756, 48,761 (Aug. 14, 2012). Additional discovery may also be required into information about each of the CardioLab, SmartFlow, and Workmate *systems*, so that Volcano is afforded the opportunity to identify potentially inconsistent positions to those advanced by St. Jude. *Id.* These possibilities present additional burdens to all parties, including the Board's responsibilities in overseeing discovery into these matters.

Moreover, the Board and the Patent Owner will be further burdened by consideration of additional factual issues surrounding each of these systems that would needlessly complicate the proceedings.

Indeed, in addition to the probability that these "prior use" grounds will swallow the prior art limitations set forth in § 311(b), they also will likely frustrate the objective of *inter partes* review to provide a simpler, efficient alternative to district court litigation. *See, e.g.*, 35 U.S.C. § 316(a)(11) (requiring a final determination in *inter partes* review within one year of notice of institution of proceedings); 37 C.F.R. § 42.100(c) ("An *inter partes* review proceeding shall be administered such that pendency before the Board after institution is normally no more than one year."); AIA Legislative History IV, VOLCANO Ex. 2004 (noting, in reference to the "entire post-grant review process," that "what [Congress] is trying to get away from" is a "big discovery and legal process."); *Berk-Tek LLC v. Belden Inc.*, IPR 2013-00058, Paper No. 13, Decision – Institution of *Inter Partes* Review (May 2, 2013), p. 32 (denying review of redundant invalidity grounds). Accordingly, should St. Jude's petition be granted in any part, the Board should focus the proceedings on those grounds that are actually set forth in St. Jude's Petition. In order to avoid needless complication and expansion of the issues, the three "prior use" grounds, and the 63 exhibits in support thereof, should be excluded from the scope of any proceedings that may be instituted.

D. If the Board includes these three additional alleged prior use grounds within the scope of issues for this *inter partes* review proceeding, then these invalidity grounds must fall within the scope of estoppel, thereby

preventing St. Jude from getting a second bite at the apple and raising these same invalidity grounds in any subsequent District Court litigation proceeding.

According to the provisions of 35 U.S.C. § 315(e), "[t]he petitioner in an *inter partes* review of a claim in a patent . . . that results in a final written decision . . . may not request or maintain a proceeding before the Office," and also "may not assert either in a civil action" before a district court or in the International Trade Commission, "any ground that the petitioner raised or reasonably could have raised during that *inter partes* review." *Id.* at § 315(e)(1)-(2). That is to say, a petitioner in *inter partes* review, and his privies and real parties in interest, are subject to estoppel upon issuance of a final written decision of the Board. As such, if the Board does not deny the three additional "prior use" grounds that St. Jude advances, and does not exclude the exhibits related thereto, then St. Jude must be subject to estoppel on these grounds pursuant to § 315(e). Once St. Jude chose to litigate these alleged invalidity grounds before the Board in *inter partes* review, it effectively elected to risk waiving any future invalidity challenges of the '994 patent on these grounds, and any other "prior use" grounds that it reasonably could have raised, in any subsequent proceedings in various forums. St. Jude is entitled to just one bite at the apple, and estoppel is a consideration that any petitioner must consider when pursuing *inter partes*

review. If the Board determines that St. Jude's alleged "prior use" grounds will be considered, then such grounds must fall within the scope of statutory estoppel.[3]

IX. CONCLUSION

For the reasons set forth above, the Board should decline to institute *inter partes* review of claims 1-20 of the '994 patent.

Respectfully submitted,

Date: Aug. 6, 2013

/Stephen R. Schaefer, Reg. No. 37,927/
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[3] If the Board does not exclude St. Jude's "prior use" grounds from these proceedings, one question that follows is whether all prior use grounds that could have been raised under the guise of secondary considerations of obviousness would also fall within the scope of estoppel under 35 U.S.C. § 315(e), thereby requiring all petitioners to raise such grounds in *inter partes* review, lest they forever lose the opportunity to litigate them in subsequent district court proceedings.

CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.6(e)(4)(i) *et seq.* and 42.105(b), the undersigned certifies that on August 6, 2013, a complete and entire copy of this Patent Owner's Preliminary Response, and all supporting exhibits, were provided via email to the Petitioner by serving the correspondence email address of record as follows:

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