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United States Court of Appeals for the Federal Circuit

04-1546

TRANSONIC SYSTEMS, INC.,

Plaintiff - Appellant,

v.

NON-INVASIVE MEDICAL TECHNOLOGIES CORPORATION (doing business as In-Line Diagnostics Corporation),

Defendant-Appellee.

DECIDED: July 25, 2005

Before SCHALL, GAJARSA, and PROST, Circuit Judges.

GAJARSA, Circuit Judge.

Transonic Systems, Inc. appeals from the district court's judgment of no infringement, in favor of Non-Invasive Medical Technologies Corporation, on claims 1, 9, 24, and 32 of U.S. Patent No. 5,685,989 (issued Nov. 11, 1997). <u>Transonic Sys., Inc.</u> <u>v. Non-Invasive Medical Techs. Corp.</u>, No. 1:99cv41 B, 1:00cv46 ST (D. Utah Aug. 9, 2004).

The district court erred in construing, and applying, the claim term "calculating". As set forth herein, the court reverses the district court's claim construction, vacates the judgment of no infringement, and remands for further proceedings concerning both the "Delta H" and "Go / No-Go" methods, and NMT products, at issue. The district court further determined that Transonic was estopped from asserting infringement under the doctrine of equivalents for all four claims. We vacate the district court's prosecution history estoppel ruling and remand for further proceedings.

Finally, we clarify that the "calculating means" in claims 24 and 32 require the function of "calculating" as defined in claims 1 and 9. On remand the district court should evaluate the means-plus-function terms in claims 24 and 32 for infringement using a section 112, paragraph 6 analysis, in light of the meaning of "calculating" as explained herein.

١.

Transonic Systems, Inc. ("Transonic") and Non-Invasive Medical Technologies Corporation ("NMT") make kidney dialysis equipment. Transonic owns U.S. Patent No. 5,685,989 ("the '989 patent") to a "Method and Apparatus to Measure Blood Flow and Recirculation In Hemodialysis Shunts."

A dialysis machine takes blood from a surgically implanted shunt, cleans it, and returns the blood to the body. The shunt eventually suffers from clotting or clogging; if allowed to progress past a certain point, the normal blood flow through the shunt is impaired and the dialysis is subject to "recirculation." Recirculation means that blood is drawn in multiple passes through the dialysis machine. The effect of recirculation is to reduce the machine's efficiency, because the recirculation displaces blood that needs dialysis. Eventually a new shunt must be implanted, but the number of times and places this can be done is limited.

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The '989 patent addresses this problem by teaching methods, and devices, for ascertaining the blood flow through the shunt. If reduced blood flow is identified early enough, doctors can intervene and address the reduced flow before a new shunt is required. The patent approaches this problem by a method termed "dilution," which relates the observable properties of volume, concentration, and measurable duration of an "indicator" to the shunt blood flow of interest. An indicator is a substance that alters a measurable property of blood, added during flow through the dialysis loop. The '989 patent describes eight equations setting forth specific relations between these observables – or measures derived from observable parameters – and the shunt blood flow of interest. Independent claims 1 and 9 are directed to processes for ascertaining the blood flow through a shunt, and independent claims 24 and 32 are directed to devices for doing the same.

NMT makes a "Crit-Line Monitor" that monitors patient's blood during dialysis. NMT further teaches two methods for ascertaining shunt blood flow. The first, "Delta H", relates to the hematocrit (red blood cell concentration) in dialyzed blood as a function of varying the dialysis filtration rate. The second, "Go / No-Go", calls for comparing one measured parameter, called "reverse-line recirculation" (the percentage of treated blood that recirculates through the dialyzer when blood flow through the dialyzer is reversed), to a reference (33%). If greater than 33%, the method teaches that shunt blood flow has fallen below 600 ml / min, indicating a problem.

Transonic sued NMT for infringing claims 1, 9, 24, and 32 of the '989 patent. The disputed claim term is "calculating." This court has, on two occasions, already addressed the meaning of "calculating." First, in <u>Transonic Sys., Inc. v. Non-Invasive</u>

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<u>Medical Techs. Corp.</u>, 10 Fed. Appx. 928 (Fed. Cir. 2001) ("<u>Transonic I</u>"), the court vacated and remanded the grant of preliminary injunction for Transonic. In <u>Transonic I</u>, the court explained that "calculating . . . must be construed as requiring the use of at least one of the equations set forth in the specification of the '989 patent." <u>Id.</u> at 934. Second, in <u>Transonic Sys., Inc. v. Non-Invasive Medical Techs. Corp.</u>, 75 Fed. Appx. 765 (Fed. Cir. 2003) ("<u>Transonic II</u>"), the court vacated and remanded the district court's summary judgment for NMT of non-infringement. <u>Id.</u> at 778. The court clarified its claim construction and further directed the district court to consider the doctrine of equivalents in view of the intervening Supreme Court decision in <u>Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.</u>, 535 U.S. 722 (2002). <u>Id.</u> at 775-79.

On remand the district court interpreted this court's clarification of "calculating" in <u>Transonic II</u> as meaning "requir[ing] calculation of a dilution curve." Turning to the "Delta H" method, the district court found no literal infringement of method claims 1 or 9. The court further determined that, as to "calculating means" under device claims 24 and 32, "NMT technology does not use the mathematical principles disclosed in the Transonic patent." The court understands this as a ruling that the accused devices lack an identical function, namely, "calculating" as defined in claims 1 and 9. Turning to the "Go / No-Go" method, the court found no evidence that the method "used" an equation relating to the teachings of the '989 patent, and implicated by the term "calculating." Finally, the district court determined that "the difference between [Delta H] and the '989 patent is substantial" and found Transonic barred from asserting infringement under the doctrine of equivalents.

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On August 6, 2004, the district court granted partial summary judgment of no infringement for Transonic on all four claims. Transonic filed its notice of appeal on August 17, 2004, asserting jurisdiction under 28 U.S.C. § 1292(c)(1). On March 18, 2005, the parties stipulated to final judgment in the trial court, <u>nunc pro tunc</u> to August 6, 2004. The court has jurisdiction under 28 U.S.C. § 1295(a)(1).

Π.

Α.

The court reviews <u>de novo</u> the district court's grant of partial summary judgment. The court will affirm the partial summary judgment of no infringement in favor of NMT if, drawing all reasonable factual inferences in favor of Transonic, the court concludes that the district court made the proper legal determinations and no genuine issue of fact prevented the determination of no infringement. Fed. R. Civ. P. 56(d); <u>Anderson v.</u> <u>Liberty Lobby, Inc.</u>, 477 U.S. 242, 255 (1986).

The infringement analysis follows two well-traveled steps. First, the court must review the district court's reading of "calculating". <u>See Cybor Corp. v. FAS Techs., Inc.,</u> 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc). This is a legal issue reviewed <u>de novo</u>. <u>Id.</u> Second, the court reviews the district court's application of the properly construed claims to the accused product. The comparison is a factual issue. <u>See Teleflex, Inc. v.</u> <u>Ficosa North America Corp.</u>, 299 F.3d 1313, 1323 (Fed. Cir. 2002). Reviewing partial summary judgment of literal infringement this court assesses, <u>de novo</u>, whether the district court correctly found no genuine issue of material fact precluding the judgment of no infringement.

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In <u>Transonic II</u> this court examined the relation between the "dilution principles" discussed in the '989 patent specification, the equations set forth in that specification, and the meaning of "calculating" and "determining" in the asserted claims. Rejecting the notion that infringement lay only in solving for shunt blood flow using the "exact equations" in the '989 patent specification, this court recognized that the specific arguments of the various equations might vary depending on the choice of indicator and the properties inspected to ascertain indicator density at any given time. As the court explained,

[T]he specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." <u>Vitronics Corp. v. Conceptronic, Inc.</u>, 90 F.3d 1576, 1582 (Fed. Cir. 1996). In this case, the patentee's statements made in the SUMMARY OF THE INVENTION, and reproduced in pertinent part below, are instructive:

Blood flow, Q, measured by the dilution method (A.C. Guyton Textbook of Medical Physiology, Sixth Edition, p. 287, 1981) is given by:

Q=V/S (Eq.1)

where V is the amount of injected indicator and S is the area under a dilution curve and is equal to the average concentration of indicator in the blood for the duration of the curve, multiplied by the duration of the curve.

* * *

The change of characteristics is measured by known sensors, such as sound velocity sensors, electrical impedance sensors, optical sensors, thermal sensors, isotope sensors, or the like, and the blood flow relationships are calculated in accordance with the foregoing equations. '989 patent, col. 1, II. 56-61 & col. 4, II. 26-27. . . . [T]he specification [of the '989 patent] does not disclose "calculating" or "determining" without the use of one of the disclosed relationships.

* * *

During prosecution of the '989 patent, in response to an Office Action rejecting the pending claims, Transonic identified several "primary features of the invention." Included in these features was "the calculation of shunt blood flow (line blood flow) from the sample via dilution principles as is taught in the present application." As discussed above, the only "calculation . . . via dilution principles" taught in the specification of the '989 patent revolves around the disclosed equations. In the same response, Transonic argued that the disclosed equations are critical to achieving the purpose of the invention and are novel over the prior art. It stated in pertinent part as follows:

The purpose of the invention is to measure shunt (blood line) blood flow, and for this purpose the application sets out the flow relationships which permit calculation of the line blood flow from other measurements. These relationships are not taught in the prior art...

Moreover, Transonic distinguished a prior art reference during prosecution by explaining that, "in the present invention[,] shunt flow is calculated from a dialysis flow and a concentration curve measurement." Based upon the claim, the specification, and the prosecution history, we again conclude that Transonic "disclaimed any interpretations of the terms 'calculating' and 'determining' that do not reflect the stated significance of the disclosed equations to the invention as a whole."

Transonic II, 75 Fed. Appx. at 775-76.

The court concluded:

[T]he terms "calculating" and "determining" must use at least one of the equations set forth in the specification of the '989 patent, <u>i.e.</u>, "Q = V/S", but that the claims also cover the use of indicators other than saline. In other words, the elements of the equation, "V" and "S", may be altered to account for the characteristics of different indicators, such as saline, temperature, etc., so long as the relationships set forth in the equations in the specification are still expressed.

<u>ld.</u> at 776-77.

Although the court explained that "calculating" or "determining" required the "use of at least one equation" set forth in the '989 patent specification, it did not delve into what it meant to "use" an equation or relation. Based on the '989 patent specification's frequent reference to dilution curves, on remand following <u>Transonic II</u> the trial court concluded that "calculating" means that the accused infringer has to "calculate a dilution curve."

Transonic contends that the trial court erred in this claim construction. In particular, Transonic contends that the construction is not required by the plain language of the claims, and, indeed, violates the canon of claim differentiation by making superfluous the specific reference to dilution curves in claim 18. Nor is the trial court's reading compelled by the '989 patent's written description, which discusses dilution curves in the context of explaining various mathematical relations but does not suggest that a curve must actually be drawn, or the area under a curve must be measured from a graph, in order to make use of the relations set forth in the specification. Finally, Transonic maintains that the trial court erred in ignoring the effect of a broadening amendment during prosecution, in which specific reliance on dilution curves was moved to issued claim 18 as a special case of the asserted claims. As set forth below, we agree with Transonic.

3.

For this analysis the court focuses on language, and prosecution history, of issued claims 1, 9, and 18. See <u>Vitronics Corp. v. Conceptronic, Inc.</u>, 90 F.3d 1576,

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1582 (Fed. Cir. 1996); <u>Bell Communications Research, Inc. v. Vitalink Communications</u> <u>Corp.</u>, 55 F.3d 615, 619-20 (Fed. Cir. 1995).

As originally filed, claim 1 required:

[1] <u>measuring</u> the [a] <u>amount</u> and [b] <u>duration</u> of said changed physical property in said arterial line and [2] <u>producing a dilution curve</u> from said measurement; and

[3] <u>determining from the area of said dilution curve the blood flow</u> in said arterio-venous shunt.

(II. 21-25).

Responding to a June 19, 1996 Office Action (and examiner interview), the inventors cancelled original claim 1 and added new independent claims (43 and 52) that issued as independent claims 1 and 9. The inventors explained that the new independent claim 43 was "revised to more clearly highlight the features of the invention which distinguish it over the prior art of record[.]" Arguing that new independent claims 43 and 52 (issued as 1 and 9) "define the primary features of the invention," the inventors defined those features as:

- "The sampling of the mixture downstream in the shunt using the intake of the hemodialysis circulating system;" and

- "The calculation of shunt blood flow (line blood flow) from the sample via dilution principles as is taught in the present application."

As issued, claim one requires:

measuring the amount of distinguishable blood characteristic in said removed portion of mixed blood; and

<u>calculating the rate of flow</u> of said shunt blood flow in said arterio-venous shunt <u>from said measured amount</u> of distinguishable blood characteristic.

'989 patent, col. 8, Il. 51-55 (emphases added). For this analysis, claim 9 differs only by

reciting "determining" instead of "calculating."

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The district court, Transonic argues, limited "calculating" in a manner consistent with the originally filed claim, but inconsistent with the broadened language that actually issued in claims 1 and 9.

By comparison, Transonic points to issued claim 18. It reads:

18. The process of claim 9, further including:

[1] <u>producing</u> from the changed parameter measurement <u>an indicator</u> <u>dilution curve</u> representing said distinguishable blood characteristic; and

[2] <u>determining from said indicator dilution curve said blood flow rate</u> in said shunt.

'989 patent, col. 10, II. 9-13 (emphases added). As Transonic argues, issued claim 18 basically appends to claim 9 (which, with issued claim 1, replaced original claim 1) the limitations from original claim 1.

In view of this record, two long-standing principles of claim construction support the view that "calculating" is not limited to "producing a dilution curve," nor to "calculating a dilution curve." First, this court's case law precludes a reading that restricts "calculating" to the limitations removed by broadening amendment. <u>See United States v. Telectronics, Inc.</u>, 857 F.2d 778, 783 (Fed. Cir. 1988) ("[C]ourts are not permitted to read back into the claims limitations which were originally there and were removed during prosecution of the application through the Patent Office." [cit. omitted]); <u>Kistler Instrumente AG v. United States</u>, 628 F.2d 1303, 1308 (Ct. Cl. 1980) ("It is significant that none of the claims in the patent which ultimately issued contain the narrow limitation of original claim It must be concluded that the Patent Office did not feel that this was a critical limitation. Thus, defendant's insistence upon this court's reading back into the claims limitations which were originally there and were removed during prosecution of the application through the Patent Office cannot be permitted."). Thus, "calculating" in issued claim 1 is broader than "calculating" in originally filed claim 1. The district court's construction is consistent with the plain language of the originally filed claim, but not the issued claim.

Second, by the doctrine of claim differentiation the court presumes that "determining" in claim 9 must have a different scope from the narrow limitations set forth in claim 18. See Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 910 (Fed. Cir.), cert. denied, 125 S. Ct. 316 (2004) ("[T]he presence of a dependent claim that adds a particular limitation raises a presumption that the limitation in question is not found in the independent claim."). "There is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims. To the extent that the absence of such difference in meaning and scope would make a claim superfluous, the doctrine of claim differentiation states the presumption that the difference between claims is significant." Tandon Corp. v. United States Int'l Trade Comm'n, 831 F.2d 1017, 1023 (Fed. Cir. 1987). Claim 18 plainly requires "producing ... an indicator dilution curve" and "determining" the shunt blood flow from it. By straightforward application of this doctrine, "determining" in claim 9 (and "calculating") has broader scope; it does not require "producing an indicator dilution curve." Although claim differentiation is only an interpretative presumption, NMT identifies no substantive reason to foreclose its application here. Cf. Comark Communications, Inc. v. Harris <u>Corp.</u>, 156 F.3d 1182, 1187 (Fed. Cir. 1998).

The '989 patent specification is fully consistent with a reading of "calculating" or "determining" that does not require creating a dilution curve or measuring the area

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underneath it. In the Summary of Invention, Transonic introduces its use of dilution methods to ascertain shunt blood flow. Discussing blood flow Q as a function of indicator volume V and defined variable "S", the specification explains:

S is the area under a dilution curve and is equal to the average concentration of indicator in the blood for the duration of the curve, multiplied by the duration of the curve.

'989 patent, col. 1, II. 62-65. As this passage explains, the area under a dilution curve can be ascertained without actually drawing such a curve and measuring the area under it. Put differently, the parameter relevant to the claims at bar, "S", represents the product of average indicator concentration over a specific interval, and the duration of that interval. In short, although "S" may have meaning as an area in the context of a dilution curve, charting indicator concentration over time, the fact that S may be graphically illustrated does not require that an infringer actually plot the curve. Aside from claim 18, which specifically requires "producing ... an indicator dilution curve," the claims at bar do not so require. The '989 patent specification, both at claim 18 and the written description explaining dilution principles, thus does not support the district court's analysis. The trial court erred in reading "calculating" and "determining" to mean "calculation of a dilution curve."

As this court explained in <u>Transonic II</u>, an infringer "calculates" or "determines" shunt flood blow within the meaning of the asserted claims by "using" at least one equation set forth in the '989 patent. A method or device "calculates" shunt blood flow within the meaning of the asserted claims if it solves for the flow as a function of the parameters set forth in the relevant question.

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For example, the '989 patent expresses the basic relation between shunt blood flow (Q) and 'dilution' as a ratio of indicator volume (V) and the product of a measuring interval and the average indicator concentration over that interval (S). I.e., Q = V / S. This expression captures an intuitive relationship in which a high blood flow rate suggests a briefer interval over which indicator can be detected, or a lower average concentration as the indicator rapidly dissipates in the presence of a high blood flow rate (and vice versa). A method or device that solves for shunt blood flow by measuring or deriving indicator volume, identifying a measuring interval over which the indicator is detectable, and obtaining the average indicator concentration over that interval, and combining this information according to a relation described in the '989 patent, therefore "uses" that relation. A method that obtains S by plotting a dilution curve and measuring the area beneath it provides one way of "using" this relation or equation, but the asserted claims are not limited to that approach.

The court further reaffirms the analysis in <u>Transonic II</u>, where the court held that such "use" of an equation set forth in the '989 patent includes varying the specific parameters at issue to account for different indicators or different indicator or blood properties that are inspected to ascertain indicator density. That is, "the elements of the equation, 'V' and 'S', may be altered to account for the characteristics of different indicators . . . so long as the relationships set forth in the equations in the specification are still expressed." 75 Fed. Appx. at 777. The elements of the equation may be altered to account for use of a different indicator, a different way of introducing that indicator to the bloodstream at the upstream location, and a different changed blood characteristic measured at the downstream location, so long as the resulting equation

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utilizes indicator dilution principles to estimate shunt blood flow. Thus, so long as an equation that embodies indicator dilution principles is used to estimate shunt blood flow, use of a different indicator, a different way of introducing the indicator to the blood, and a different changed blood characteristic do not mean that shunt blood flow is not "determined" or "calculated."

In sum, the court reverses the trial court's claim construction. The asserted claims do not require "producing a dilution curve." Instead, "calculating" in claim 1, and "determining" in claim 9, means solving or estimating shunt blood flow, using at least one of the equations set forth in the '989 patent. A method or device "uses" an equation in the '989 patent when it solves for shunt blood flow by combining measured parameters according to a particular relation specified in a relevant equation from the '989 patent.

C.

The court next considers whether, under the proper claim construction, the district court properly granted judgment of no infringement. The partial summary judgment is proper only when no reasonable trier of fact could find that every limitation recited in a properly construed claim is found in the accused device or method either literally or under the doctrine of equivalents. <u>See Bai v. L & L Wings, Inc.</u>, 160 F.3d 1350, 1353-54 (Fed. Cir. 1998).

1.

The district court stated that "[b]ecause indicator dilution equations are not the relationship contemplated by the Federal Circuit, the court need not consider whether ΔH equations are indicator dilution equations." Under this court's construction of

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"calculating" and "determining," however, the fact-finder must consider whether the Delta H method utilizes an equation that embodies indicator dilution principles. Upon review of the evidence, we conclude that a summary judgment was improper. With this record a reasonable fact-finder could find that determining shunt blood flow using the Delta H method is "calculating" or "determining" shunt blood flow within the meaning of the asserting claims.

As noted above, the Delta H method calls for assessing shunt blood flow by analyzing hematocrit as a function of a dialysis ultrafiltration rate. One of Transonic's experts, Dr. Spergel, explained in more detail how Delta H method works:

[I]n order to measure [shunt] blood flow, the clinician sets the ultrafiltration rate in the dialyzer first at a minimum speed, then at a maximum speed, and then at a minimum speed at very precise time intervals. It is my understanding that changing the ultrafiltration rate changes the hematocrit (i.e., the percentage of red blood cell mass in the blood). The CRIT-LINE reads the hematocrit at each speed. Then the clinician reverses the lines, and repeats the same procedure with the lines in the reversed position. From these various hematocrit levels, [shunt] blood flow would be manually calculated using a complicated formula provided by NMT in its literature.

(J.A. at 936). This "complicated formula" appears in one of NMT's Technical Notes: ABF = (UFR_{max} x R_{max}) / (Δ H_R – Δ H_N), where Δ H_R = R_{max} – [(R₁ + R₂) / 2)] and Δ H_N = N_{max} – [(N₁ + N₂) / 2)].

Importantly, the NMT Technical Note defines ΔH_R in terms of three measurements of hematocrit when the lines of the dialyzer are reversed: (1) R_{max} , which is a measurement of hematocrit at maximum ultrafiltration speed; (2) R_1 , which is a first measurement of hematocrit at minimum ultrafiltration speed; and R_2 , which is a second measurement of hematocrit at the minimum ultrafiltration speed. By comparing R_{max} to the average of R_1 and R_2 , the formula appears to take into account the change in

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hematocrit when the lines of the dialyzer are reversed. Moreover, according to the Technical Note, these measurements of hematocrit are made at four minute intervals, which seemingly correspond to the "very precise time intervals" referred to by Dr. Spergel. In light of this evidence, we cannot say that a reasonable jury could not conclude that the Delta H method measures a changed blood characteristic over time and utilizes a formula that mathematically relates particular variables according to indicator dilution principles.

Thus, the question of whether the Delta H method infringes the claims of the '989 patent must be remanded for further proceedings consistent with this court's claim construction.

2.

The district court also granted judgment that NMT's "Go / No-Go" method does not infringe the asserted claims of the '989 patent. The trial court relied on an absence of any genuine issue of fact concerning whether the NMT method "uses" a specific equation from the '989 patent relating reverse-line recirculation to shunt blood flow. In particular, Transonic argued that NMT's "Go / No-Go" method relies on the relation $Q_a =$ Q_b (1 / $R_{rev} - 1$), the relation between shunt blood flow (Q_a), dialyzer blood flow (Q_b), and reversed-line recirculation or percentage of recirculation with reversed lines (R_{rev}), that NMT discloses in material describing its "saline dilution" method. Transonic further argued that this relation is "mathematically equivalent" to "the equations disclosed" in the '989 patent. The trial court focused on equation 5 from the '989 patent. That equation provides:

$$Q_{shunt} = Q_{dial} (V_{ven} / V_{cal} * S_{cal} / S_{art} - 1)$$

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'989 patent, col. 2, I. 67. The equation expresses shunt blood flow (Q_{shunt}) as a function of dialyzer blood flow (Q_{dial}), the volume of indicator injected into the venous line (V_{ven}), the quantity of indicator used in a calibration injection (V_{cal}), the area under the diluation curve generated by a calibration (S_{cal}), and the "absolute concentration of indicator in the arterial blood line" (S_{art}). Id. at II. 18-64. The district court characterized Transonic's infringement argument as resting on mere "assumption" that the latter equation restates equation 5 in the '989 patent, and further determined that Transonic "has not established the use of this equation in the 'Go-No Go method'." Finding no genuine issue of fact, the trial court granted summary judgment for NMT.

Transonic argues that the trial court misread the record and ignored genuine issues of fact supporting infringement. We agree. First, there is no genuine dispute that NMT's "Go / No-Go" method is a special case of NMT's "saline dilution" method in which the dialyzer blood flow (Q_b) is simply fixed at 300 ml / min, and the calculated shunt blood flow is simply compared to a reference point of 600 ml / min. NMT's own documents indicate that NMT drew its shunt blood flow relation, for the saline dilution method, from a 1995 article by Krivitski. In a tech note describing its "Go / No-Go" screening criteria, NMT explained that

Review of published data proves that at a dialyzer blood flow rate of 300 ml / min, a reversed-line recirculation $[R_{\rm rev}]$ of approximately 33% is equivalent to an Access Blood Flow [shunt blood flow] of 600 ml / min.

Using the tech note as a starting point, Transonic's expert opined that the only "published data" establishing a "quantitative relationship between access blood flow, dialyzer blood flow rate, and reversed-line recirculation" was the "formula recited" in NMT's literature concerning its "saline dilution" method. In view of this evidence, NMT's argument that "the [saline dilution] equation cited by Transonic never appears in any literature describing or promoting the Go/No Go method" is misplaced.

Second, Transonic's expert further opined that NMT's reversed-line recirculation equation, for the "saline" method, and the relations set forth in the '989 patent, were "equivalent." Notwithstanding the trial court's characterizing this evidence on equivalence as a mere "assumption," we find the expert testimony sufficient to raise a genuine issue of material fact resisting summary judgment.

In short, a reasonable fact-finder could find that NMT's "Go / No-Go" method infringes the asserted claims by "calculating" or "determining" shunt blood flow on the basis of relations set forth in the '989 patent. The trial court erred in granting judgment of no infringement on NMT's "Go / No-Go" method.

D.

The court further notes that claims 24 and 32 both include limitations subject to the requirements of 35 U.S.C. § 112, ¶ 6 that are affected by our construction of the term "calculating." "Literal infringement of a § 112, ¶ 6 limitation requires that the relevant structure in the accused device perform the identical function recited in the claim and be identical or equivalent to the corresponding structure in the specification." <u>Odetics, Inc. v. Storage Tech. Corp.</u>, 185 F.3d 1259, 1267 (Fed. Cir. 1999). As the court explained in <u>Transonic II</u>, the functions of both "means for calculating" in claim 24 and "calculator means" in claim 32 require "calculating." 75 Fed. Appx. at 778. Therefore, on remand the district court should reassess infringement of claims 24 and 32 under the construction of "calculating", as clarified above. If the district court finds that the accused devices perform the identical function of "calculating" shunt blood flow,

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then the district court must ascertain whether the structures of those devices are identical or equivalent to the corresponding structure disclosed in the '989 patent. <u>See Odetics</u>, 185 F.3d at 1267.

Ε.

Finally, the district court determined that Transonic was estopped from asserting infringement under the doctrine of equivalents. We find this determination unsupported by the analysis in the district court's opinion. As explained by the Supreme Court in Festo, a narrowing amendment made to satisfy any requirement of the Patent Act invokes a presumption that the patentee surrendered all subject matter between the broader and the narrower claim language. 535 U.S. at 740. To overcome the presumption of surrender, the patentee bears the burden of proving whether an exception applies. See id. at 740-41 ("The equivalent may have been unforeseeable at the time of the application; the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question; or there may be some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question."). From the district court's partial summary judgment order we are unable to ascertain: (1) what amendment is at issue; (2) what claim scope was deemed to be surrendered; (3) what arguments Transonic made to overcome any presumption of surrender; and (4) why any such arguments were insufficient. Accordingly, we vacate the ruling on prosecution history estoppel and remand for analysis under Festo.

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The district court's construction of "calculating" was in error. The court reverses the district court's claim construction, and construes the claim as set forth in this opinion. The infringement analysis depending on this claim construction is flawed, and must be undertaken anew. Furthermore, the district court failed to conduct a proper <u>Festo</u> analysis. Therefore, we vacate the judgment of no infringement, and the ruling on prosecution history estoppel, and remand for proceedings consistent with this opinion.

Each side shall bear its own costs.

REVERSED-IN-PART, VACATED AND REMANDED.