United States Court of Appeals for the Federal Circuit

PHARMA TECH SOLUTIONS, INC., DECISION IT CORP.,
Plaintiffs-Appellants

v.

LIFESCAN, INC., LIFESCAN SCOTLAND, LTD., JOHNSON AND JOHNSON,
Defendants-Appellees

2019-1163

Appeal from the United States District Court for the District of Nevada in No. 2:16-cv-00564-RFB-PAL, Judge Richard F. Boulware, II.

Decided: November 22, 2019

JOHN J. SHAEFFER, Fox Rothschild LLP, Los Angeles, CA, argued for plaintiffs-appellants. Also represented by JEFFREY H. GRANT; WILLIAM A. RUDY, Denver, CO.

EUGENE M. GELERNTER, Patterson Belknap Webb & Tyler LLP, New York, NY, argued for defendants-appellees. Also represented by GREGORY DISKANT; CHARLES DAVISON HOFFMANN, SEAN REEVES MARSHALL, Hoffmann Marshall Strong LLP, New York, NY.

Before MOORE, REYNA, and STOLL, *Circuit Judges.*

STOLL, *Circuit Judge.*

This is an appeal from the district court's summary judgment of noninfringement under the doctrine of equivalents. Because prosecution history estoppel bars the claims for infringement under the doctrine of equivalents, we affirm.

BACKGROUND

I

Pharma Tech Solutions, Inc. sued LifeScan, Inc. for infringement of its U.S. Patent Nos. 6,153,069 and 6,413,411, which concern blood glucose monitoring systems for home use by individuals with diabetes. To test blood glucose, an individual typically draws blood by pricking a finger, placing the blood on the end of a test strip, and placing the test strip into a meter. The test strip contains a pair of electrodes, including a working electrode and a second electrode. The working electrode is coated with an enzyme that oxidizes glucose in the blood sample. Following an incubation period, the meter (1) applies a known electric potential across the electrodes, creating a diffusion limiting electric current (referred to as the "Cottrell current") through the sample; and (2) measures Cottrell current. A proportional relationship exists between the measured current and blood glucose concentration. Based on this proportional relationship, a microprocessor in the meter converts the measured electric current to a blood glucose level and then reports the blood glucose level to the user.

The shared specification of Pharma Tech's '069 and '411 patents states that the claimed inventions improve on these prior art blood glucose monitoring systems by "eliminat[ing] several of the critical operator depend[e]nt variables that adversely affect the accuracy and reliability" of these systems. '069 patent col. 4 l. 66–col. 5 l. 3. The

specification explains that the invention accomplishes this objective by performing multiple Cottrell current measurements and comparing the results. "In a system that is operating correctly, the results should agree within reasonable limits." *Id.* at col. 4 ll. 51–52. Results outside of a prescribed percentage of each other, however, generally indicate a system error, and the system will alert the user of a potential measurement error.

With emphasis added to highlight the claim limitation at issue on appeal, illustrative claim 1 of the '069 patent recites:

> 1. An apparatus for measuring compounds in a sample fluid, comprising:
>
> a) a housing having an access opening therethrough;
>
> b) a sample cell receivable into said access opening of said housing, said sample cell being composed of;
>
> (i) a first electrode which acts as a working electrode;
>
> (ii) a second electrode which acts to fix the system potential and provide opposing current flow with respect to said first electrode, said second electrode being made of the same electrically conducting material as said first electrode, and being operatively associated with said first electrode, the ratio of the surface area of said second electrode to the surface area of said first electrode being 1:1 or less;
>
> (iii) at least one non-conducting layer member having an opening therethrough, said at least one non-conducting layer member being disposed in contact with at least one of said first and second electrodes and being sealed against at least one of said first and second electrodes to

> form a known electrode area within said opening such that said opening forms a well to receive the sample fluid and to allow a user of said apparatus to place the sample fluid in said known electrode area in contact with said first electrode and said second electrode;
>
> c) means for applying an electrical potential to both said first electrode and said second electrode;
>
> d) means for creating an electrical circuit between said first electrode and said second electrode through the sample fluid;
>
> e) means for measuring a first Cottrell current reading through the sample fluid at a first predetermined time after the electrical potential is applied and for obtaining at least one additional Cottrell current reading through the sample fluid, the at least one additional Cottrell current reading occurring at a second predetermined time following the first predetermined time;
>
> f) microprocessor means for *converting the first Cottrell current reading into a first analyte concentration measurement using a calibration slope and an intercept specific for the first Cottrell current measurement, for converting the at least one additional Cottrell current reading into an additional analyte concentration using a calibration slope and an intercept specific for the at least one additional Cottrell current measurement, and for comparing the first analyte concentration measurement with the at least one additional concentration measurement to confirm that they are within a prescribed percentage of each other*; and
>
> g) means for visually displaying the results of said analyte concentration measurements.

Id. at col. 13 ll. 10–61.

II

The product accused of infringing under the doctrine of equivalents is LifeScan's OneTouch® Ultra® system, a blood glucose meter for home use. When blood is detected on a test strip inserted into LifeScan's meter, the meter measures current from two working electrodes during a five-second countdown period. LifeScan's meter obtains final current measurements from the first and second working electrodes at "5 seconds + 40 milliseconds (±25ms) after the measurement period begins" and "5 seconds + 340 ms (±25ms) after the measurement period begins." J.A. 57.

LifeScan's meter then conducts a "Current Difference Test" to ensure that the difference between the recorded currents is within a defined limit. J.A. 57. "If the Current Difference Test passes, then the total final current (combining both working electrodes) is calculated." J.A. 58. "[A] single glucose result is calculated from the total final current using a strip slope and intercept based on the strip's calibration code." J.A. 58.

It is undisputed that LifeScan's meters neither convert multiple Cottrell current readings to analyte concentration measurements nor compare multiple analyte concentration measurements. Pharma Tech agrees that the accused products therefore do not literally infringe the claim. But Pharma Tech asserts that "an analyte measurement can be expressed as a current at a given time or as a concentration" and, thus, the accused device infringes under the doctrine of equivalents. Appellant's Br. 40.

III

Because this appeal involves prosecution history estoppel, a discussion of the relevant prosecution history is helpful. Pharma Tech agrees that any prosecution history estoppel determined to apply to the '069 patent extends to the related '411 patent, so we focus on the prosecution history of the '069 patent.

As originally filed, claim 4 of the patent application that ultimately issued as the '069 patent (application claim 4) read as follows:

> 4. An apparatus for measuring compounds in a sample fluid, comprising
>
> a) a housing having an access opening therethrough[,]
>
> b) a sample cell receivable into said access opening of said housing, said sample cell being composed of
>
> a first electrode which acts as a working electrode,
>
> a second electrode which acts to fix the system potential and provide opposing current flow with respect to said first electrode, said second electrode being of substantially the same size as said first electrode and being made of the same electrically conducting material as said first electrode, said second electrode being operatively associated with said first electrode,
>
> at least one non-conducting layer member having an opening therethrough said layer member being disposed in contact with at least one of said electrodes and said layer member being sealed against at least one of said first and second electrode to form a known electrode area within said opening such that said opening forms a well to receive said sample fluid and to place said fluid in said known electrode area in contact with said first electrode and said second electrode,
>
> (c) means for applying an electrical potential to said first electrode and said second electrode,

> (d) means for creating an electrical circuit between said first electrode and said second electrode through said sample,
>
> (e) means for measuring Cottrell current through said sample and
>
> (f) means for visually displaying results of said measurement.

J.A. 220–21. As Pharma Tech's expert acknowledged, this originally presented claim was "broad enough to essentially cover any test strip with two working electrodes." J.A. 698.

In a first office action, the examiner rejected the inventors' pending claims in view of U.S. Patent No. 5,385,846 (Kuhn), U.S. Patent No. 5,288,636 (Pollmann), and U.S. Patent No. 5,108,564 (Szuminsky). The inventors' October 1997 response to the examiner's office action amended application claim 4 (which later issued as '069 patent claim 1). Among other things, the claim was amended to require: (1) obtaining at least two Cottrell current readings; (2) converting the plurality of Cottrell current readings to analyte concentration measurements; and (3) linearly comparing the plurality of analyte concentration measurements:

> e) means for measuring a first Cottrell current reading though said sample at a first predetermined time after said electrical potential is applied and for obtaining at least one additional Cottrell current reading through said sample, said at least one additional Cottrell current reading occurring at a second predetermined time following said first predetermined time,
>
> f) means for converting said first Cottrell current reading into a first analyte concentration measurement, and for converting said at least one additional Cottrell current reading into an additional analyte concentration measurement, and for

> linearly comparing said first analyte concentration measurement to said additional analyte concentration measurement[.]

J.A. 303 (underlined text added by amendment).

In the remarks accompanying the October 1997 amendment, the inventors emphasized the new claim language and distinguished the asserted prior art based thereon. For example, the inventors argued, "Kuhn is not applicable to claims 4 or 66 as now amended, in that obtaining a plurality of readings by taking repeated measurements is not the same as the multiple readings now claimed, *wherein those readings are converted to analyte concentration* and then linearly compared to one another." J.A. 307 (emphasis added). The inventors distinguished Pollmann and Szuminsky on the same basis, asserting: "Pollmann likewise does not suggest the present claimed means for *comparing the concentration* derived from the first measurement and at least one additional concentration derived from an additional measurement to verify the result." J.A. 307–08 (emphasis added); *see also* J.A. 308 ("Claims 66–69 all include the additional multiple measurement limitation, wherein the multiple measurements are used to verify the result by *comparing concentrations* determined at different times during the measurement."[1] (emphasis added)).

In a second office action, the examiner rejected the pending claims as anticipated by U.S. Patent No. 5,508,171

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[1] The October 1997 amendment amended application claim 66 to depend from application claim 4. Claims 67–69, which issued as independent claims 4–6 of the '069 patent, were amended to recite limitations requiring obtaining a plurality of current readings and comparing analyte concentrations derived from said current readings. J.A. 304–06.

(Walling) and as obvious over Walling in view of Szuminsky or U.S. Patent No. 5,243,516 (White). J.A. 359–61. The examiner explained that Walling discloses "means for applying an electrical potential between the electrodes and means for measuring a resulting diffusion limiting current at multiple times." J.A. 360 (citing Walling col. 3 l. 29, col. 8 l. 55–col. 12 l. 55). Noting that Szuminsky and White each disclose a microprocessor to take measurements in a sensor similar to that of Walling, the examiner concluded that "[i]t would have been obvious for Walling to adopt a microprocessor in view of Sz[u]minsky or White." J.A. 361. The examiner further concluded that the applicants' "linearly comparing" limitation did not change the obviousness analysis, because "any microprocessor is capable of carrying out that function." J.A. 361.

In response, the inventors again highlighted the "converting" and "comparing" claim language added by the October 1997 amendment. For example, the inventors emphasized that "Walling et al and Szuminsky et al do not even disclose taking multiple analyte concentration measurements and comparing such to confirm proper operation of a measuring system." J.A. 378. Similarly, to distinguish White, the inventors argued that "[i]n contrast to the teachings in White, the present invention compares analyte concentration readings at different times." J.A. 378.

The examiner again rejected the claims as obvious over Walling in view of White in a third office action. Following an examiner interview, the inventors filed another response in which they repeatedly distinguished the prior art based on the "converting" and "comparing" limitations. The inventors asserted:

> the present invention is directed to a system which takes two different Cottrell current readings, converts them to two different analyte concentration measurements, and then compares the two analyte concentration measurements to each other to

> confirm that they are within a prescribed percentage of each other. That operation in the present invention is neither taught nor suggested by Walling et al or White ('516), or any combination thereof.

J.A. 397–98. The inventors then distinguished Walling on the basis that "Walling et al does not convert two different Cottrell current readings to first and second analyte concentration measurements, and then compare the first and second analyte concentration measurements to each other, as in the present invention." J.A. 398. Rather, they asserted, Walling "utilize[s] the multiple [current] measurements together to determine a proper analyte concentration." J.A. 398. Turning to White, the inventors asserted that "White ('516) discloses an operation in which Cottrell current measurements at two different times are taken and a ratio of the measured Cottrell currents [is] evaluated." J.A. 398. The inventors explained that the claimed "converting" limitation and the claimed "comparing" limitation each provided a basis to distinguish "the present invention" over White:

> First, in the present invention the two different Cottrell current readings are converted into first and second analyte concentration measurements. Further, in the present invention the first and second analyte concentration measurements based on the first and second Cottrell current readings are compared to each other to confirm that they are within a prescribed percentage of each other.

J.A. 398. Continuing, the inventors emphasized that because neither Walling nor White "disclose[s] or suggest[s] comparing first and second analyte concentration measurements based on first and second Cottrell current readings to each other," the combination of White and Walling cannot render the claims obvious. J.A. 399.

In response, the examiner issued a notice of allowability, and the '069 patent issued. The '411 patent, which is a continuation of the '069 patent, issued subsequently.

IV

After Pharma Tech filed a complaint for infringement of the '069 and '411 patents, LifeScan moved to dismiss Pharma Tech's complaint based on failure to state a claim upon which relief could be granted for both literal and equivalent infringement. The district court denied LifeScan's motion, allowed Pharma Tech to amend its complaint, granted expedited discovery limited to infringement of the "converting" and "comparing" limitations, and permitted LifeScan to file an early motion for summary judgment. For its doctrine of equivalents infringement claims, Pharma Tech's amended complaint identified the relevant equivalent as "the functionality of a system that (a) measures current at two different times, (b) compares the current[s] to ensure they are within a prescribed percentage and (c) converts the current readings into a glucose concentration." J.A. 1047–48.

After Pharma Tech dismissed its literal infringement allegations, LifeScan filed a motion for summary judgment of no infringement under the doctrine of equivalents. LifeScan asserted that argument-based and amendment-based prosecution history estoppel barred Pharma Tech's doctrine of equivalents infringement theory. Specifically, LifeScan asserted that when the inventors amended their claims to require conversion of Cottrell current readings to analyte concentration measurements and subsequent comparison of those analyte concentration measurements, they surrendered any claim scope covering systems and methods that do not compare analyte concentration measurements. In addition, LifeScan maintained that the inventors' arguments distinguishing the prior art constituted clear and unambiguous disclaimers of meters that do not perform the claimed conversion and comparison steps.

Pharma Tech opposed summary judgment, asserting that its October 1997 amendment of the claims to include the "conversion" and "comparison" steps was tangential to the real purpose of the amendment, which was to require a linear comparison of multiple measurements.

The district court held that amendment-based prosecution history estoppel barred Pharma Tech's claims of infringement under the doctrine of equivalents. The court reasoned that LifeScan's accused system falls within the claim scope surrendered by the inventors during prosecution of the '069 patent. In so ruling, the district court concluded that the tangentiality exception did not apply because the inventors' remarks during prosecution indicated that "comparison of analyte concentration measurements was, at a minimum, a significant aspect of the [October 1997] amendment." *Pharma Tech Sols. Inc. v. LifeScan Inc.*, 348 F. Supp. 3d 1076, 1084 (D. Nev. 2018). The district court further held that argument-based estoppel likewise barred Pharma Tech's claims, noting that the inventors "consistently relied on the comparison of two *analyte concentration measurements* as a distinguishing feature of [their] claims." *Id.* Accordingly, the district court granted LifeScan's motion for summary judgment.

Pharma Tech appeals. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

I

We apply the standard of review of the regional circuit in reviewing a grant of summary judgment. *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1334 (Fed. Cir. 2016). The Ninth Circuit reviews a district court's grant of summary judgment de novo. *Forester v. Chertoff*, 500 F.3d 920, 923 (9th Cir. 2007). "Viewing the evidence in the light most favorable to the non-moving party, we must decide whether any genuine issues of material fact exist and whether the

district court correctly applied relevant substantive law." *Id.* "Whether prosecution history estoppel applies, and thus whether the doctrine of equivalents is available for a particular claim limitation, is a question of law reviewed de novo." *Spectrum Pharm., Inc. v. Sandoz Inc.*, 802 F.3d 1326, 1337 (Fed. Cir. 2015).

II

"Prosecution history estoppel applies as part of an infringement analysis to prevent a patentee from using the doctrine of equivalents to recapture subject matter surrendered from the literal scope of a claim during prosecution." *Trading Techs. Int'l, Inc. v. Open E Cry, LLC*, 728 F.3d 1309, 1322 (Fed. Cir. 2013). Prosecution history estoppel can occur in two ways: "either (1) by making a narrowing amendment to the claim ('amendment-based estoppel') or (2) by surrendering claim scope through argument to the patent examiner ('argument-based estoppel')." *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1363 (Fed. Cir. 2006).

With respect to amendment-based prosecution history estoppel, the Supreme Court has recognized that a "patentee's decision to narrow his claims through amendment may be presumed to be a general disclaimer of the territory between the original claim and the amended claim." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 740 (2002). The presumption may be overcome if the patentee can show the applicability of one of several exceptions identified by the Supreme Court: (1) the equivalent was "unforeseeable at the time of the application"; (2) "the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question"; or (3) "there may be some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question." *Id.* at 740–41.

Pharma Tech does not dispute that the October 1997 amendment was narrowing, and relies on one of these exceptions on appeal: that the rationale of its amendment bore no more than a tangential relation to the equivalent in question. "The tangential relation inquiry 'focuses on the patentee's objectively apparent reason for the narrowing amendment,' which 'should be discernible from the prosecution history record.'" *Integrated Tech. Corp. v. Rudolph Techs., Inc.*, 734 F.3d 1352, 1358 (Fed. Cir. 2013) (quoting *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1369 (Fed. Cir. 2003)).

Turning to argument-based prosecution history estoppel, "the prosecution history must evince a clear and unmistakable surrender of subject matter." *Conoco*, 460 F.3d at 1364 (quoting *Deering Precision Instruments, L.L.C. v. Vector Distribution Sys., Inc.*, 347 F.3d 1314, 1326 (Fed. Cir. 2003)). We have explained that "[c]lear assertions made during prosecution in support of patentability, whether or not actually required to secure allowance of the claim, may also create an estoppel . . . because [t]he relevant inquiry is whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter." *PODS, Inc. v. Porta Stor, Inc.*, 484 F.3d 1359, 1368 (Fed. Cir. 2007) (alterations in original) (citations omitted).

III

We hold that amendment-based and argument-based prosecution history estoppel bar Pharma Tech's infringement claims under the doctrine of equivalents. Pharma Tech's asserted equivalent is within the territory that the inventors surrendered during prosecution of the '069 patent. Moreover, the inventors' arguments accompanying and following the October 1997 amendment clearly and unmistakably surrendered systems that do not convert Cottrell current readings to analyte concentration measurements and compare those analyte concentration

measurements. The inventors' clear statements not only establish argument-based estoppel, but also negate Pharma Tech's reliance on the tangential relation exception.

A

Prior to the inventors' October 1997 amendment, application claim 4 was broad enough to cover any bioelectrical blood glucose monitoring system. The October 1997 amendment narrowed the claims to systems that convert a plurality of current readings to analyte concentration measurements and compare said analyte concentration measurements. The applicants thus presumptively surrendered any bioelectrical blood glucose monitoring systems that do not convert a plurality of current readings into analyte concentration measurements and compare the resulting analyte concentration measurements. Pharma Tech's asserted equivalent—"the functionality of a system that (a) measures current at two different times, (b) compares the current[s] to ensure they are within a prescribed percentage and (c) converts the current readings into a glucose concentration"—falls squarely within the territory between the original claim and the amended claim. J.A. 1047–48.

Resolution of the amendment-based prosecution history estoppel issue turns on whether the inventors' objectively apparent rationale underlying the narrowing amendment bore no more than a tangential relation to the accused LifeScan systems. *See Integrated Tech.*, 734 F.3d at 1358. Resolution of the argument-based estoppel issue turns on whether the prosecution history evinces a clear and unmistakable surrender of systems that do not convert and compare analyte concentration measurements. *See Conoco*, 460 F.3d at 1364. Here, the inventors clearly and unambiguously distinguished their invention over the prior art based on the converting and comparing limitations added by the October 1997 amendment. We thus

agree with the district court that the inventors' remarks accompanying the October 1997 amendment make clear that the amendment was made to achieve patentability—and for reasons more than tangentially related to the equivalent at issue. The objectively apparent reason for the October 1997 amendment was to distinguish the invention over prior art systems that measured and displayed a diffusion limiting current reading.

The inventors consistently asserted that the October 1997 amendment overcame the prior art cited by the examiner because the prior art did not compare analyte concentration measurements derived (i.e., converted) from diffusion limiting current readings. *See, e.g.*, J.A. 307 ("Kuhn is not applicable to claims 4 or 66 as now amended, in that obtaining a plurality of readings by taking repeated measurements is not the same as the multiple readings now claimed, wherein those *readings are converted to analyte concentration and then linearly compared* to one another." (emphasis added)); J.A. 307–08 ("Pollmann likewise does not suggest the present claimed means for comparing the concentration derived from the first measurement and at least one additional concentration derived from an additional measurement to verify the result."); J.A. 308 ("Claims 66–69 all include the additional multiple measurement[s] . . . [that] are used to verify the result by *comparing concentrations* determined at different times during the measurement. There is no teaching or suggestion in Pollmann or Szuminsky to verify the measurement in the way claimed in claim[s] 66–69." (emphasis added)).

The inventors' arguments to the PTO throughout the remainder of the prosecution history confirm our conclusion. The inventors repeatedly and unequivocally described "the present invention" as "a system which takes two different Cottrell current readings, converts them to two different analyte concentration measurements, and then compares the two analyte concentration measurements." J.A. 397–98. And they continually argued that

these features distinguished their invention over the prior art. For example, with respect to White, the inventors argued: "In contrast to the teachings in White, *the present invention compares analyte concentration readings* at different times." J.A. 378 (italics added). Distinguishing Walling, the inventors similarly asserted, "Walling et al does not *convert* two different Cottrell current readings to first and second analyte concentration measurements, and *then compare* the first and second analyte concentration measurements to each other, *as in the present invention*." J.A. 398 (italics added). These same inventor statements establish a clear and unmistakable surrender of subject matter. The inventors' remarks clearly and unambiguously indicate their view that the sequence of performing "converting" and "comparing" limitations was a distinguishing feature of "the present invention." *See* J.A. 398 ("White ('516) differs from the present invention in the following respects. First, *in the present invention* the two different Cottrell *current readings are converted* into first and second analyte concentration measurements. Further, *in the present invention* the first and second *analyte concentration measurements . . . are compared* to each other." (italics added)). Based on the inventors' clear statements, a competitor reviewing the prosecution history of the '069 patent would reasonably believe that the inventors had surrendered systems that do not convert diffusion limiting current readings to analyte concentration measurements and then compare the resulting analyte concentration measurements. Accordingly, we also affirm the district court's determination that argument-based prosecution history estoppel precludes Pharma Tech from asserting infringement under the doctrine of equivalents.

Citing *Pioneer Magnetics, Inc. v. Micro Linear Corp.*, 330 F.3d 1352, 1356 (Fed. Cir. 2003), Pharma Tech argues that the "converting" and "comparing" claim limitations were already disclosed in the prior art and, as such, these limitations must have been added for reasons not related

to patentability. Appellant's Br. 52. But *Pioneer Magnetics* does not support this argument. In *Pioneer Magnetics,* we held that the patentee's narrowing amendment was "related to patentability" and "clearly not tangential" to the asserted equivalent where the prior art contained the equivalent. 330 F.3d at 1357. That the October 1997 amendment may have ceded more claim scope than necessary to overcome prior art does not mean that the tangential relation exception applies here. Indeed, we have held that "[t]he fact that the inventors may have thought after the fact that they could have relied on other distinctions in order to defend their claims is irrelevant" to discerning the objective reason for their amendment. *Int'l Rectifier Corp. v. IXYS Corp.*, 515 F.3d 1353, 1359 (Fed. Cir. 2008) (quoting *Schwarz Pharma, Inc. v. Paddock Labs., Inc.*, 504 F.3d 1371, 1377 (Fed. Cir. 2007)); *see also Eli Lilly & Co. v. Hospira, Inc.*, 933 F.3d 1320, 1332 (Fed. Cir. 2019) ("Amendments are not construed to cede only that which is necessary to overcome the prior art." (citing *Schwarz*, 504 F.3d at 1377)). Accordingly, we reject Pharma Tech's argument based on *Pioneer Magnetics*.

B

Finally, Pharma Tech analogizes the facts here to those in cases where we held that amendment-based prosecution history estoppel did not apply. For example, Pharma Tech argues that *Insituform Technologies, Inc. v. CAT Contracting, Inc.*, 385 F.3d 1360 (Fed. Cir. 2004), controls the result here. We disagree. In *Insituform*, the remarks accompanying the patentee's amendment did not emphasize or rely on the added claim language to distinguish the prior art in a manner relevant to the asserted equivalent. *Id.* at 1370. This court held that Insituform's amendment narrowing the claim to a one-cup vacuum process located near a resin source was merely tangentially related to an equivalent multiple-cup vacuum process because the rationale underlying the amendment "was to avoid the need to use a large compressor when the vacuum is created a significant

distance from the resin source." *Id.* (quoting *Insituform Techs., Inc. v. Cat Contracting, Inc.*, 161 F.3d 688, 692 (Fed. Cir. 1998)). *Insituform* noted "no indication in the prosecution history of any relationship between the narrowing amendment and a multiple cup process." *Id.*

Here, by contrast, the applicants' October 1997 amendment sought to avoid prior art systems that measured and displayed diffusion limiting current. To distinguish their claims from Kuhn, Pollmann, and Szuminsky, which measured and displayed diffusion limiting current, the inventors amended their claims to require obtaining a plurality of current readings, converting the current readings to analyte concentration measurements, and comparing the analyte concentration measurements to detect errors. The inventors' remarks accompanying the October 1997 amendment distinguished the prior art based on the newly added sequential "converting" and "comparing" limitations. It is undisputed that—like the prior art—LifeScan's meter does not convert diffusion limiting current readings to analyte concentration measurements and then compare analyte concentration measurements to one another to detect errors.

Recent cases from this court addressing amendment-based prosecution history estoppel and the tangential relation exception are similarly distinguishable. In *Eli Lilly*, for example, the patentee's amendment narrowed the claims in relevant part from requiring "an antifolate" to requiring "permetrexed disodium." 933 F.3d at 1325–26. The equivalent at issue in *Eli Lilly* was permetrexed ditromethamine, a permetrexed salt functionally identical to permetrexed disodium. *Id.* at 1327, 1336. We held that the patentee's amendment was merely tangentially related to the equivalent at issue, because the prosecution history "indicate[d] that the reason for the amendment was not to cede other, functionally identical, permetrexed salts." *Id.* at 1331. Rather, "[t]he reason for Lilly's amendment . . . was to narrow original claim 2 to avoid Arsenyan, which

only discloses treatments using methotrexate, a different antifolate." *Id.* Functionally equivalent permetrexed salts were merely tangential to avoiding prior art disclosing an antifolate other than permetrexed. Here, the comparison of analyte concentration measurements was integral to the inventors' October 1997 amendment. The prosecution history indicates that throughout prosecution, the inventors viewed the "converting" and "comparing" limitations as necessary to overcome the prior art. *See, e.g.*, J.A. 307, 377–78, 398–99. Accordingly, *Eli Lilly* is distinguishable.

Likewise, in *Ajinomoto,* this court held that the rationale underlying the patentee's amendment narrowing the scope of the claimed DNA sequences to avoid the YfiK prior art protein was unrelated to the asserted equivalent—selecting from the codon-randomized sequences that correspond to the YddG protein. *Ajinomoto Co. v. Int'l Trade Comm'n*, 932 F.3d 1342, 1355 (Fed. Cir. 2019). Here, by contrast, the rationale for the October 1997 amendment—avoiding prior art that does not convert a plurality of current readings or compare a plurality of analyte concentration measurements—directly relates to the accused equivalent, a system which also does not convert a plurality of current readings or compare a plurality of analyte concentration measurements.

CONCLUSION

We have considered Pharma Tech's remaining arguments, but do not find them persuasive. The district court did not err in determining that prosecution history estoppel bars Pharma Tech from succeeding on its infringement claims under the doctrine of equivalents. Accordingly, we affirm the district court's order granting LifeScan's motion for summary judgment.

AFFIRMED