NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

2007-1349

GENERAL ATOMICS DIAZYME LABORATORIES DIVISION,

Plaintiff/Counterclaim Defendant-Appellee,

and

CAROLINA LIQUID CHEMISTRIES CORPORATION,

Counterclaim/Defendant-Appellee,

v.

AXIS-SHIELD ASA,

Defendant/Counterclaimant-Appellant.

Steven E. Comer, Morrison & Foerster LLP, of San Diego, California, argued for plaintiff/counterclaim defendant-appellee and counterclaim/defendant-appellee. With him on the brief were David C. Doyle, Peng Chen, Anders T. Aannestad, and Brian M. Kramer.

Timothy P. Walker, Kirkpatrick & Lockhart, Preston Gates Ellis, LLP, of San Francisco, California, argued for defendant/counterclaimant-appellant. Of counsel on the brief was Paul C. Nyquist, Voss, Cook & Thel LLP, of Newport Beach, California.

Appealed from: United States District Court for the Northern District of California

Judge Susan Illston

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GENERAL ATOMICS DIAZYME LABORATORIES DIVISION,

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CAROLINA LIQUID CHEMISTRIES CORPORATION,

Counterclaim/Defendant-Appellee,

v.

AXIS-SHIELD ASA,

Defendant/Counterclaimant-Appellant.

Appeal from the United States District Court for the Northern District of California in Case No. 3:05-CV-04074, Judge Susan Illston.

DECIDED: May 12, 2008

Before LOURIE, GAJARSA, and DYK, Circuit Judges.

LOURIE, Circuit Judge.

Axis-Shield ASA ("Axis-Shield") appeals from the final judgment of the U.S. District Court for the Northern District of California finding noninfringement of Axis-Shield's patents by General Atomics, Diazyme Laboratories Division and Carolina Liquid Chemistries Corporation (collectively "General Atomics"). Because we conclude that the district court did not err in its claim construction and thus properly granted summary judgment of noninfringement, we affirm.

BACKGROUND

Axis-Shield is the assignee of the patents in suit, viz., U.S. Patents 5,631,127 ("the '127 patent") and 5,958,717 ("the '717 patent"). The patents relate to methods and kits for assaying homocysteine in a sample such as blood, plasma, or urine. Homocysteine is an intermediary amino acid produced in the body when methionine is metabolized to cysteine. '127 patent col.1 ll.8-14. Under normal conditions, homocysteine is quickly metabolized and its concentration is virtually negligible. Id. Elevated levels of homocysteine, however, have been associated with the presence of atherosclerosis and other cardiac and vascular diseases. Id. at col.1 ll.42-29. Thus, the detection of homocysteine levels in biological samples is of great clinical significance. Id. at col.1 ll.15-16.

Claim 1 of the '127 patent, the only independent claim of that patent, is a representative claim.[1] That claim reads as follows:

> 1. In a method for assaying homocysteine in a sample, said method comprising the steps of

[1] The '127 and '717 patents derive from the same parent application and have nearly identical specifications. For ease of reference, throughout the opinion we will cite the '127 patent when referencing the common specification.

> (i) contacting said sample with a homocysteine converting enzyme and at least one substrate for said enzyme other than homocysteine, and
>
> (ii) assessing an analyte which is a substrate for said enzyme,
>
> wherein the improvement comprises in step (i) contacting said sample with a said substrate other than homocysteine and in step (ii) without chromatographic separation assessing a non-labelled analyte selected from the group consisting of a homocysteine co-substrate and the homocysteine conversion products of the enzymic conversion of homocysteine by said enzyme.

Id. claim 1 (emphases added). Claim 1 of the '717 patent, which is also the only independent claim of that patent, contains similar claim language. That claim reads as follows:

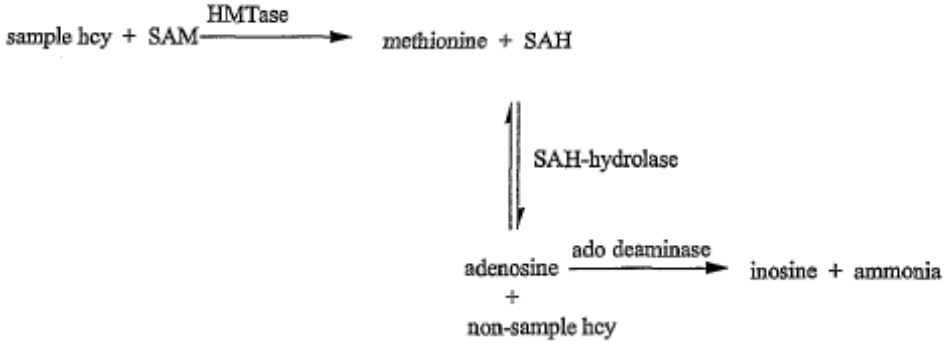
> 1. In a method for assaying homocysteine in a sample, said method comprising the steps of
>
> (i) contacting said sample with a homocysteine-converting enzyme and
>
> (ii) assessing an analyte,
>
> wherein the improvement comprises in step (ii) without chromatographic separation assessing a non-labelled analyte selected from the group consisting of the homocysteine conversion products of the enzymic conversion of homocysteine by said enzyme.

'717 patent claim 1 (emphases added). The claimed methods thus involve the steps of contacting the sample with a homocysteine converting enzyme and assessing an analyte. For the '717 patent, the analyte must be "selected from the group consisting of the homocysteine conversion products of the enzymic conversion of homocysteine by [the homocysteine converting] enzyme." The '127 patent, in contrast, requires that the analyte be selected from either the "homocysteine co-substrate" or the "homocysteine conversion products of the enzymic conversion of homocysteine by said enzyme." In addition, both patents specify that chromatographic separation, a time-consuming and

cumbersome prior art method that "requires highly specialized and sophisticated equipment," is not used to assess the analyte. '127 patent col.2 ll.6-9.

General Atomics manufactures and sells enzymatic homocysteine assays for the detection of homocysteine levels in human samples. For purposes of this appeal, the accused assay detects the level of homocysteine in a sample in the following general manner: 1) a co-substrate referred to as S-adenosyl-L-methionine ("SAM") is added to the sample; 2) an enzyme referred to as homocysteine-methionine methyl transferase ("HMTase") is then added; 3) the HMTase acts to remove a methyl group from the co-substrate SAM and attach it to the homocysteine, converting the homocysteine into methionine and SAM into S-adenosyl-L-homocysteine ("SAH"); 4) simultaneously, a second enzyme is added, SAH-hydrolase, which catalyzes a reaction that converts SAH to adenosine and non-sample homocysteine; 5) additional steps occur, involving adenosine deaminase and spectrophotometric monitoring, to determine the level of SAH produced. Gen. Atomics v. Axis-Shield, No. 05-4074, 2007 WL 1089698, at *3-4 (N.D. Cal. Apr. 11, 2007).[2] Those steps can be graphically depicted in the following manner:

[2] The parties disputed certain aspects of the process employed in the accused assay. For purposes of summary judgment, however, the court drew all reasonable inferences in favor of Axis-Shield as the nonmoving party and accepted as true Axis-Shield's characterization of the process. Id. at *3-5. The description of the accused assay above is representative of Axis-Shield's characterization.



The level of SAH present in the accused assay is proportional to the level of homocysteine in the sample. Thus, "measuring SAH allows the amount of homocysteine to be determined." Id.

Axis-Shield informed General Atomics of its belief that its enzymatic homocysteine assays infringe the '127 and '717 patents. In October 2005, General Atomics filed a declaratory judgment action against Axis-Shield seeking a declaration that its products do not infringe and that the patents in suit were invalid and unenforceable. In response, Axis-Shield counterclaimed, asserting claims of patent infringement. In addition to the patents in suit, Axis-Shield originally asserted two other patents, viz., U.S. Patents 6,063,581 ("the '581 patent") and 5,827,645 ("the '645 patent"). All four patents named Erling Sundrehagen as the inventor and Axis Biochemicals as the assignee. Early in the case, however, Axis-Shield dismissed its claims regarding the '581 and '645 patents.

On March 3, 2006, pursuant to the Northern District of California's Patent Local Rules, Axis-Shield served its preliminary infringement contentions and identified its first infringement theory. Axis-Shield asserted that the accused assay infringes the patents in suit based on the manner in which the HMTase enzyme is used in the assay. In particular, Axis-Shield asserted that in the accused assay the sample homocysteine

interacts with HMTase enzyme and SAM, which Axis-Shield characterized, respectively, as the "homocysteine converting enzyme" and the "homocysteine co-substrate." Axis-Shield further asserted that the enzymatic reaction forms two "homocysteine conversion products," viz., methionine and SAH, and that the accused assay assesses the level of SAH without chromatographic separation. Based on those characterizations, Axis-Shield contended that the accused assay met all of the limitations of the asserted claims. That infringement theory was referred to as the "HMTase infringement theory."

On April 14, 2006, General Atomics moved for summary judgment based on Axis-Shield's HMTase infringement theory. While that motion was pending, Axis-Shield moved to amend its preliminary infringement contentions. In doing so, Axis-Shield asserted an alternative infringement theory, referred to as the "SAH-hydrolase infringement theory." That theory focused on the latter stage of the assay during which the level of SAH is determined. Axis-Shield argued that the SAH-hydrolase acts as the "homocysteine converting enzyme," adenosine acts as the "homocysteine co-substrate," and SAH acts as the "homocysteine conversion product."

On July 19, 2006, the district court granted General Atomics' motion for summary judgment. The court focused on the "assessing" claim limitation required by both patents in suit. Claim 1 of the '127 patent requires "assessing a non-labelled analyte selected from the group consisting of a homocysteine co-substrate and the homocysteine conversion products of the enzymic conversion of homocysteine by said enzyme." Claim 1 of the '717 patent, in contrast, only requires "assessing a non-labelled analyte selected from the group consisting of the homocysteine conversion products of the enzymic conversion of homocysteine by said enzyme." Based on that

language, the district court determined that in order to infringe, the analyte assessed in the accused assay must be either a "homocysteine co-substrate" or a "homocysteine conversion product[] of the enzymic conversion of homocysteine by said enzyme." After construing those claim terms, the court concluded that the SAH produced in General Atomics' assay was neither a "homocysteine co-substrate" nor a "homocysteine conversion product[] of the enzymic conversion of homocysteine by said enzyme" and granted summary judgment in favor of General Atomics.

On August 7, 2006, the district court granted Axis-Shield's pending motion to amend its preliminary infringement contentions. The court issued a claim construction ruling on September 26, 2006. General Atomics then brought a second summary judgment motion based on Axis-Shield's SAH-hydrolase infringement theory. On April 11, 2007, the court granted the motion. The court noted that under Axis-Shield's new infringement theory, SAH is the analyte that is assessed. The court determined, however, that Axis-Shield failed to show that the SAH is a "homocysteine conversion product[] of the enzymic conversion of homocysteine by said enzyme." Under the new theory, the term "said enzyme" referred to SAH-hydrolase, and Axis-Shield could not show that the SAH produced in the assay was a product of the SAH-hydrolase enzymic conversion of homocysteine. As such, the court concluded that Axis-Shield failed to show that the accused assay met the "assessing a non-labelled analyte" limitation required by the asserted claims and again granted summary judgment of noninfringement in favor of General Atomics.

On May 1, 2007, the parties stipulated to the dismissal of all outstanding claims. The district court entered final judgment on May 2, 2007. Axis-Shield timely appealed the court's decision. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

We review a district court's grant of summary judgment de novo, reapplying the standard applicable at the district court. See Rodime PLC v. Seagate Tech., Inc., 174 F.3d 1294, 1301 (Fed. Cir. 1999). Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). In addition, in deciding a motion for summary judgment, "[t]he evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986).

A determination of infringement requires a two-step analysis. "First, the court determines the scope and meaning of the patent claims asserted. . . . [Second,] the properly construed claims are compared to the allegedly infringing device." Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc) (citations omitted). Step one, claim construction, is an issue of law, Markman v. Westview Instruments, Inc., 52 F.3d 967, 970-71 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996), that we review de novo, Cybor, 138 F.3d at 1456. Step two, comparison of the claim to the accused device, requires a determination that every claim limitation or its equivalent be found in the accused device. See Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 29 (1997). Those determinations are questions of fact, and on summary

judgment, the issue is whether there is no genuine issue of material fact regarding infringement. Bai v. L & L Wings, Inc., 160 F.3d 1350, 1353 (Fed. Cir. 1998).

Axis-Shield raises a myriad of arguments on appeal, not all of which need to be treated by this court in light of the conclusions we have reached. Axis-Shield primarily asserts that the district court erred in granting summary judgment under both infringement theories because the court's conclusions were premised on incorrect claim construction. With respect to the first summary judgment decision relating to its HMTase infringement theory, Axis-Shield argues that the court erred in construing "homocysteine conversion products" and thus erred in concluding that the accused assay did not meet that claim limitation. With regard to the second summary judgment decision relating to the SAH-hydrolase infringement theory, Axis-Shield argues that the court erred in determining that the accused assay did not meet the "assessing" limitation of the claims. According to Axis-Shield, the court's error was based on incorrect claim construction of several claim terms, including "homocysteine conversion products," "homocysteine converting enzyme," and "homocysteine co-substrate."

In response, General Atomics defends the district court's claim construction. Thus, according to General Atomics, summary judgment of noninfringement was proper because there were no genuine issues of material fact as to whether the accused assay infringed the asserted claims and General Atomics was entitled to judgment as a matter of law.

A. Axis-Shield's HMTase Infringement Theory

We first address the district court's grant of summary judgment that was premised on Axis-Shield's HMTase infringement theory. The crux of the district court's

decision rested on the claim term "homocysteine conversion products." In construing that term, the court concluded that "homocysteine conversion products" are "those products of the homocysteine conversion reaction that are derived from homocysteine." Gen. Atomics v. Axis-Shield, 440 F. Supp. 2d 1083, 1095 (N.D. Cal. 2006). The relevant issue on appeal with respect to that term is whether the district court correctly concluded that a homocysteine conversion product must be derived from homocysteine. We agree with General Atomics and the district court that it does.[3]

To determine the proper meaning of "homocysteine conversion products," we need do little more than to look to the language of the claims. Here, the plain language of both independent claims supports the district court's construction. The claims recite that the assessed analyte is "selected from the group consisting of the homocysteine conversion products of the enzymic conversion of homocysteine by said enzyme." '127 patent claim 1, '717 patent claim 1 (emphases added). That language indicates that the "products" are those products that result from the conversion of homocysteine. Indeed, the latter portion of the claim limitation—"of the enzymic conversion of homocysteine by said enzyme"—emphasizes this point by focusing solely on homocysteine and its conversion into another compound or compounds.

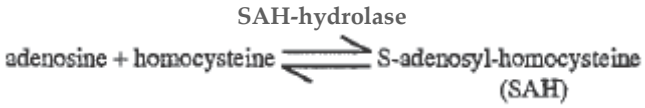
Contrary to Axis-Shield's assertion, the language of the claim does not refer to just any product resulting from the homocysteine conversion reaction. Had the claim been written as "homocysteine conversion reaction products," or "products of the

[3] Axis-Shield does not argue that, under its HMTase infringement theory, the accused assay is within the '127 patent claims because the analyte that is assessed is a homocysteine co-substrate. Therefore, our discussion with respect to Axis-Shield's HMTase infringement theory is confined to the construction of the "homocysteine conversion product" limitation.

homocysteine conversion reaction," Axis-Shield's argument might be more tenable because that might suggest that the products may be any products resulting from a homocysteine conversion reaction. Indeed, when referencing the reaction as a whole in the specification, the patentee used broader terms such as "homocysteine conversion reaction" or "reaction." See '127 patent col.2 ll.42-45 ("The homocysteine co-substrate assessed in the method of the invention is a compound which reacts with homocysteine in the enzyme catalyzed . . . homocysteine conversion reaction.") (emphasis added); id. at col.3 ll.1-4 ("[t]he preferred homocysteine converting enzyme used according to the invention is S-adenosyl-homocysteine hydrolase (SAH-hydrolase) which catalyses [sic] the homocysteine reaction") (emphasis added). However, because the plain language of the claim refers specifically to the conversion of homocysteine when defining the group of "products" from which an analyte may be selected, the claim as written indicates that "products" refers to products that result from the enzymic conversion of homocysteine, not products that otherwise result from the reaction. Such a construction gives full meaning to every word of the entire claim term. Bicon, Inc. v. Straumann Co., 441 F.3d 945, 950 (Fed. Cir. 2006) ("claims are interpreted with an eye toward giving effect to all terms in the claim"). A homocysteine conversion product of the enzymic conversion of homocysteine is a product converted from homocysteine by an enzyme. For example, methionine is a homocysteine conversion product because it is simply homocysteine in which a hydrogen atom has been replaced by a methyl group. It is a modification of homocysteine. Thus, the district court's construction, which requires the homocysteine conversion products to be derived from the homocysteine compound, is supported by the plain language of the claim.

In addition to the clear guidance provided by the claim language, we may also turn to the specification to determine whether the patentee attributed a different meaning to the term. As an initial matter, we note that aside from the Abstract, which mirrors the claim language, the term "homocysteine conversion products" does not appear in the specification. While the specification refers to other terms such as "conversion products" or "products," those references, which do not relate to "homocysteine conversion products," shed no light on the meaning of that claim term.

The district court's claim construction actually tracks the first embodiment disclosed in the specification. In describing the invention, the specification discloses the following homocysteine reaction which is catalyzed by the enzyme SAH-hydrolase:



'127 patent col.3 ll.1-9. According to the specification, SAH-hydrolase is the preferred homocysteine converting enzyme. The specification further discloses that the above reaction is reversible; that is, the reaction could run in either direction. In the forward direction, adenosine and homocysteine combine to form SAH. In the reverse reaction, SAH hydrolyzes to form adenosine and homocysteine. Id. at col.3 ll.10-20.

This embodiment reflects the forward direction of the reaction. Adenosine acts as the homocysteine co-substrate, which the patent defines as "a compound which reacts with homocysteine in the enzyme catalysed [sic], e.g., a SAH-hydrolase catalysed [sic], homocysteine conversion reaction." Id. at col.2 ll.42-45. SAH-hydrolase acts as the homocysteine converting enzyme. Both adenosine and homocysteine react in the presence of SAH-hydrolase to yield SAH—the homocysteine conversion product.

The specification teaches that "the amount of homocysteine in the sample can . . . be determined from the alteration in the adenosine concentration." Id. at col.2 ll.44-45. Because SAH is derived from the homocysteine molecule and is the homocysteine conversion product, the district court's construction of "homocysteine conversion products" reflects that embodiment.

Axis-Shield asserts that the court's claim construction is unduly narrow in light of other embodiments disclosed in the specification, including the second embodiment referred to as the inhibition embodiment. That embodiment "take[s] particular advantage of the fact that homocysteine acts as an inhibitor of SAH-hydrolase, suppressing the hydrolysis reaction which forms homocysteine and adenosine and pushing the reaction equilibrium in favour [sic] of SAH synthesis." Id. at col.3 ll.16-20. In that embodiment, the level of homocysteine is measured by contacting the test sample with SAH and SAH-hydrolase. Id. at col.3 ll.48-55. As a result of the hydrolysis reaction, SAH would break apart to form homocysteine and adenosine. Id. Because of the inhibiting effect homocysteine has on SAH-hydrolase, however, "[a]ny homocysteine present in the test sample will counteract this net reaction, and thus inhibit the formation of adenosine, the amount of which is monitored." Id. at col.3 ll.52-55. Thus, by measuring the amount of remaining adenosine, the level of homocysteine can be determined. Specifically, the amount of adenosine would be inversely proportional to the amount of sample homocysteine. Axis-Shield argues that the district court's claim construction cannot be correct because it would not cover this inhibition embodiment. In particular, Axis-Shield notes that adenosine—which is the analyte being assessed—is neither a homocysteine conversion product because it is not derived from

homocysteine, nor a homocysteine co-substrate because it does not react with homocysteine in the homocysteine conversion reaction of the assay under the court's construction.

We are not persuaded by Axis-Shield's argument. A claim need not cover all embodiments in a patent specification. PSN Ill., LLC v. Ivoclar Vivadent, Inc., No. 2007-1512, 2008 WL 1946550, at *5 (Fed. Cir. May 6, 2008). Prosecution strategies may evolve so that some embodiments are covered in a patent and others are not. Here, while it is correct that the inhibition embodiment is not covered by the asserted claims under the district court's claim construction because the analyte that is assessed (adenosine) is neither a homocysteine conversion product nor a homocysteine co-substrate, it appears from the record that that inhibition embodiment is covered by claim 17 of the '581 patent resulting from the parent application of the patents in suit, which was originally asserted against General Atomics but subsequently dismissed from this case.[4] Thus, Axis-Shield's assertion that "homocysteine conversion products" must be

[4] Claim 17 of the '581 patent reads as follows:

> An immunological method for indirectly assaying homocysteine in a sample, said method comprising the steps of:
>
> (a) contacting said sample with S-adenosyl homocysteine hydrolase enzyme and S-adenosyl homocysteine wherein said S-adenosyl homocysteine hydrolase converts said S-adenosyl-homocysteine into a non-labelled analyte wherein said non-labelled analyte is adenosine; and
>
> (b) determining the presence or amount of the non-labelled analyte without chromatographic separation by contacting said sample with an antibody which specifically binds with said non-labelled analyte and with a detectable hapten for said antibody other than said non-labelled analyte and wherein determining the presence or amount of said non-labelled analyte is effected indirectly by determining the presence or amount of said detectable hapten either bound or not bound to said antibody,

construed broadly so that the asserted claims cover the inhibition embodiment is inapt, particularly in light of the plain language of the claim, which is both clear and unambiguous, see Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp., 93 F.3d 1572, 1579 (Fed. Cir. 1996) (rejecting a proffered construction because "the plain meaning of the claim [would] not bear [such] a reading"), and the coverage of this embodiment in the parent patent. The patentee chose to use the term "homocysteine conversion products" in the asserted claims of the '127 and '717 patents, which require that the products at issue are those that result from the conversion of homocysteine. As such, we decline to depart from the plain meaning of the claim term by expanding the scope of "products" to include any product resulting from the homocysteine conversion reaction.

Accordingly, because the analyte assessed in the accused assay is SAH, which is a conversion product of SAM, not of homocysteine, we conclude that the court properly granted summary judgment of noninfringement based on Axis-Shields' HMTase infringement theory.

B. Axis-Shield's SAH-Hydrolase Infringement Theory

The district court also granted summary judgment based on Axis-Shield's SAH-hydrolase infringement theory, in which Axis-Shield appears to assert that the accused assay infringes the asserted claims because it allegedly uses a homocysteine conversion enzyme, viz., SAH-hydrolase, and assesses an analyte that is either a homocysteine co-substrate (adenosine) or a homocysteine conversion product (SAH),

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> wherein the amount of the non-labelled analyte is indirectly proportional to the amount of homocysteine in said sample.

'581 patent claim 17 (emphases added).

during the latter phase of the process. The district court rejected Axis-Shield's assertion. In a well-reasoned opinion, the court determined that the accused assay fails to meet the properly-construed claim limitations because it cannot differentiate between SAH produced from a SAH-hydrolase reaction and that from an HMTase reaction. It therefore does not meet the "assessing a non-labelled analyte" limitation.

In challenging the court's decision, Axis-Shield raises several arguments in asserting that the accused product infringes under this alternate theory. Axis-Shield relies in part on its previous argument that the court erred in construing the term "homocysteine conversion products." For the reasons stated above, that argument is rejected. Axis-Shield further argues that the court erred by improperly construing the terms "homocysteine converting enzyme" and "homocysteine co-substrate," and also erred by failing to correctly apply other constructions stipulated by the parties. Having carefully reviewed Axis-Shield's arguments, we find no error in the court's analysis and conclude that Axis-Shield fails to identify any basis for reversing the court's decision. Accordingly, we thus affirm the court's grant of summary judgment based on Axis-Shield's alternate theory.

We have considered all of the remaining arguments Axis-Shield has raised in its briefs with regard to its theories of infringement and find them unpersuasive.

CONCLUSION

For the foregoing reasons, the district court correctly construed the relevant disputed terms, properly applied the stipulated claim construction, and appropriately granted summary judgment of noninfringement in favor of General Atomics. The decision of the district court is therefore affirmed.

AFFIRMED