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**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA**

INOVA DIAGNOSTICS, INC., a
California Corporation,

Plaintiff / Counterclaim-Defendant,

vs.

EURO-DIAGNOSTICA AB, a
corporation of Sweden; AXIS-SHIELD
DIAGNOSTICS LTD, a corporation of
Scotland; STICHTING VOOR DE
TECHNISCHE WETENSCHAPPEN, an
institution of the Netherlands; EURO-
DIAGNOSTICA BV, a corporation of the
Netherlands,

Defendants / Counterclaim-Plaintiffs.

CASE NO. 08-CV-0845 H (JMA)

**CLAIM CONSTRUCTION
ORDER FOR UNITED STATES
PATENT NUMBER 7,335,724**

On August 21, 2009, the Court conducted a claim construction hearing in this matter for U.S. Patent No. 7,335,724. Morgan Chu, David Gindler, Erin McCracken, Amir Naini, and Lucy Stark appeared on behalf of the Plaintiff. Anders Aannestad, Gregory Reilly, and Steven Comer appeared on behalf of the Defendant. After due consideration of the parties' briefing, submitted evidence, and the testimony at the hearing, the Court issues the following claim construction order.

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1 **I. Claim Construction – Legal Standard**

2 The claims of a patent define the scope of the patented invention. Vitronics Corp. v.
3 Conceptronic, Inc., 90 F.3d 1576 (Fed. Cir. 1996). In construing claim terms, a court must
4 determine the meaning of any disputed words from the perspective of one of ordinary skill in
5 the pertinent art at the time of filing. Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir.
6 2005).

7 There is a heavy presumption that claim terms carry their “ordinary and customary”
8 meanings. CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002). The
9 “ordinary and customary” meaning is that which a person of ordinary skill in the art would
10 understand the term to mean at the time of invention. Phillips, 415 F.3d at 1313. The person
11 of ordinary skill in the art is “deemed to read the claim term not only in the context of the
12 particular claim . . . but in the context of the entire patent, including the specification.” Id.
13 The use of the term in both asserted and unasserted claims may shed light on the meaning of
14 a particular term. Id. at 1315. If the meaning of a term is not readily apparent, the court must
15 then look to other intrinsic evidence to define the term. See id. at 1314.

16 A court must read claims “in view of the specification, of which they are a part.”
17 Markman, 52 F.3d 967, 979 (Fed. Cir. 1995). The specification “is always highly relevant to
18 the claim construction analysis. Usually, it is dispositive; it is the single best guide to the
19 meaning of a disputed term.” Vitronics, 90 F.3d at 1582. Although the specification is useful
20 in determining the meaning of a term, a court must not import limitations from the
21 specification into the claim. Phillips, 415 F.3d at 1323.

22 A court may also consult the prosecution history, if in evidence, during claim
23 construction. The prosecution history “provides evidence of how the PTO and the inventor
24 understood the patent.” Phillips, 415 F.3d at 1317. However, the prosecution history is the
25 result of a negotiation between the inventor and the patent office and therefore “often lacks the
26 clarity of the specification and thus is less useful for claim construction purposes.” Id.

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1 Extrinsic evidence “is less reliable than the patent and its prosecution history in
2 determining how to read claims.” Phillips, 415 F.3d at 1318. Indeed, “intrinsic evidence is
3 the most significant source of the legally operative meaning of disputed claim language.”
4 Vitronics, 90 F.3d at 1583. A court may only rely on extrinsic evidence in claim construction
5 when the intrinsic evidence fails to resolve ambiguity in disputed claim terms. Id. at 1583.

6 **II. Construction of Disputed Terms**

7 The Court’s constructions are set forth in the chart below. The Court first explains the
8 reasoning behind its constructions of certain disputed terms.

9 **A. “An antigen”**

10 The parties agree that the “antigen” of claim 1 is something to which an antibody binds.
11 (Pl.’s Br. at 8; Def.’s Br. at 6.) The only dispute is whether the antigen in claim 1 should be
12 construed as a “substance to which antibodies bind” according to the Plaintiff’s construction
13 or as “a molecule to which antibodies bind” as in Defendants’ construction.

14 The “words of a claim are generally given their ordinary and customary meaning” –
15 “the meaning that the term would have to a person of ordinary skill in the art in question at the
16 time of the invention.” Phillips, 415 F.3d at 1312. In this case, Defendant has not shown that
17 the word “antigen” limits the invention to a molecule. If such a limitation exists, it stems from
18 language following the term “antigen.” See Hitzeman v. Rutter, 243 F.3d 1345, 1349 (Fed.
19 Cir. 2001) (discussing a different antigen “comprised of a cluster of protein molecules”).
20 Accordingly, because Plaintiff’s construction is an accurate definition of the term and is
21 consistent with all intrinsic evidence, the Court adopts it.

22 **B. “consisting of a cyclic peptide”**

23 Claim 1 states that the claimed antigen consists of a cyclic peptide. ‘724 Patent col.15
24 1.23. The parties dispute whether this language limits the claim to exactly one cyclic peptide.
25 The Court concludes that it does. The phrase “consisting of” is “a term of patent convention
26 meaning that the claimed invention contains only what is expressly set forth in the claim.
27 However, while ‘consisting of’ limits the claimed invention, it does not limit aspects unrelated
28 to the invention.” Norian Corp. v. Stryker Corp., 363 F.3d 1321, 1331 (Fed. Cir. 2004)

1 (“Norian I”) (citation omitted). For example, the Norian I court held that, where a patent
2 claimed a kit for preparing a calcium mineral “consisting of” several chemicals, the kit was
3 limited to the claimed chemicals and no other chemicals. Id. Because a spatula was not part
4 of the described invention, its presence in such a kit was irrelevant. Id. at 1332.

5 Plaintiff argues that, because claim 1 refers to “a cyclic peptide,” it is limited to only
6 one such peptide. In patent construction, the “question whether ‘a’ or ‘an’ is treated as singular
7 or plural depends heavily on the context of its use.” TIVO, Inc. v. Echostar Commc’ns Corp.,
8 516 F.3d 1290, 1303 (Fed. Cir. 2008). The Federal Circuit typically interprets “a” in its
9 singular sense when “used in conjunction with the closed transitional phrase ‘consisting of.’”
10 Norian Corp. v. Stryker Corp., 432 F.3d 1356, 1359 (Fed. Cir. 2005) (“Norian II”); see also
11 Abbott Labs v. Baxter Pharm. Prods., Inc., 334 F.3d 1274, 1281 (Fed. Cir. 2003) (“[A]lthough
12 ‘a’ without more generally could mean one or more in an open-ended patent claim, ‘a’ with
13 ‘consisting of’ in this case indicates only one member of a Markush group.”). In Norian II, the
14 Federal Circuit held that “the claim language ‘consisting of . . . a sodium phosphate,’ on its
15 own, suggests the use of a single sodium phosphate.” Norian II, 432 F.3d at 1359. Here, the
16 ‘724 Patent claims an antigen “consisting of a cyclic peptide.” col.15 l.23. As in the Norian
17 cases, this language suggests the use of a single cyclic peptide as the invention itself.
18 Defendant has not shown why a deviation from this convention is warranted in this case.

19 Defendant argues that the claim language and specification of the ‘724 Patent show that
20 “a peptide” refers to one or more peptides. (Def.’s Br. at 9, Def.’s Resp. Br. at 9.) As
21 Defendant points out, the specification states that “two or more peptides according to the
22 invention may be part of one oligopeptide.” ‘724 Patent col.3 l.42-44. However, the fact that
23 an oligopeptide is created from the combination of two peptides does not mean that, once
24 formed it is two peptides. Instead, the specification’s reference to “one oligopeptide” suggests
25 that it is still one peptide; the “oligo-” prefix designates the origin of the molecule, not its
26 nature. Accordingly, the specification language relied upon by Defendant does not support its
27 argument that claim 1 is not limited to one peptide.

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1 Defendant further argues that, because the peptide of claim 1 is a fragment, and the
2 fragment can be made up of multiple peptides, claim 1 is not limited to one peptide. (Def.’s
3 Br. at 9-10.) However, the Court does not agree that the fragment of claim 1 can be multiple
4 peptides.

5 The parties agree that a “cyclic peptide” is a peptide that includes one or more bonds
6 contributing to looped structures in the chain. (Doc. No. 105 at 2.) The parties dispute the
7 nature of the bonds that form these loops. Plaintiff argues that these must be covalent bonds,
8 while Defendant objects to such a limitation. (Pl.’s Br. at 14; Def.’s Br. at 10.) Declining to
9 import this limitation into the claim, the Court agrees with Defendant.

10 Plaintiff points out that the specification of the ‘724 Patent describes only cyclic
11 peptides containing covalent bonds – specifically, disulfide bridges between cysteine side
12 chains.¹ col.2 1.25-27; col.5 1.60-63. However, it is improper to confine patent claims to the
13 preferred embodiment. Phillips, 415 F.3d at 1323 (“[A]lthough the specification often
14 describes very specific embodiments of the invention, we have repeatedly warned against
15 confining the claims to those embodiments.”). Moreover, the specification of the ‘724 Patent
16 states that bond between cysteine residues is provided as an example. col. 2 1.25-27
17 (“According to a favourable embodiment the peptide is a cyclic peptide, for instance, due to
18 the presence of a cysteine residue.”) In prosecuting the ‘724 Patent, the patentee intended that
19 claim 1 encompass “a cyclic peptide, regardless of the means of its cyclization” stating that
20 “the important aspect here is that a cyclic peptide is formed, not how it is formed.” (Aannestad
21 Decl. ISO Def.’s Br. Ex. C at 31.)

22 “Even where a patent describes only a single embodiment, claims will not be read
23 restrictively unless the patentee has demonstrated a clear intention to limit the claim scope.”
24 Saunders Group, Inc. v. Comfortrac, Inc., 492 F.3d 1326, 1332 (Fed. Cir. 2007). Here, in light
25 of the open language of the specification and prosecution history, the patentee has not
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27 ¹ Covalent bonds involve the sharing of electrons between atoms, as opposed to
28 hydrogen bonds (interaction between positively charged hydrogen atoms and atoms with a
negative charge) and van der Waals interactions (caused by temporarily uneven charge
distributions).

1 demonstrated a clear intention to require covalent bonds. The Court concludes that, “after
2 reading the entire patent,” an ordinary artisan in the relevant field would construe the ordinary
3 meaning of “cyclic peptide” as a sequence of amino acids, that includes one or more bonds that
4 form one or more looped structures in the peptide. Phillips, 415 F.3d at 1321.

5 The parties also dispute whether the cyclizing bonds “form one or more looped
6 structures” or “cause the peptide to form one or more looped structures.” (Doc. No. 105 at 2.)
7 Defendant objects to Plaintiff’s use of the word “cause,” arguing that this construction
8 improperly requires that the bond initiate the looping process. (Def.’s Br. at 12-13.) However,
9 Plaintiff disclaims any temporal aspect to its construction. Accordingly, this dispute turns on
10 a distinction without a difference. The parties agree that the cyclizing bonds keep the loops
11 in place, and the Court’s construction conveys this idea.

12 **C. “a fragment”**

13 Claim 1 states that the claimed peptide is “a fragment of filaggrin.” ‘724 Patent col.15
14 1.23-24. Plaintiff argues that the term “fragment” is indefinite in the context of claims 1 and
15 8. (Pl.’s Br. at 17-18.) Plaintiff requests that the Court defer construction of this term until
16 after it has considered Plaintiff’s forthcoming motion for summary judgment on the issue of
17 indefiniteness. The Court declines to defer construction. A claim is indefinite “only if
18 reasonable efforts at claim construction prove futile.” Datamize, LLC v. Plumtree Software,
19 Inc., 417 F.3d 1342, 1347 (Fed. Cir. 2005). Here, the Court construes this term to possess its
20 “ordinary and customary meaning” – an incomplete part. Phillips, 415 F.3d at 1312. This
21 construction is consistent with the prosecution history of the ‘724 Patent. The claim that
22 became claim 1 was previously rejected by the patent examiner because it read only upon the
23 full-length filaggrin protein put into cyclic form. (Aannestad Decl. Ex. C at 43.) In response,
24 the patentee amended the claim to cover fragments, “not the cyclic form of the entire amino
25 acid sequence.” (Id. at 48, 50.) The prosecution history of a patent is relevant to construction,
26 as it “provides evidence of how the PTO and the inventor understood the patent.” Phillips, 415
27 F.3d at 1317.

1 The Court's construction does not preclude Plaintiff's indefiniteness argument.
2 Halliburton Energy Servs., Inc. v. M-I LLC, 514 F.3d 1244, 1251 (Fed. Cir. 2008) ("Even if
3 a claim term's definition can be reduced to words, the claim is still indefinite if a person of
4 ordinary skill in the art cannot translate the definition into meaningfully precise claim scope.").

5 **D. "which fragment comprises"**

6 Claim 1 states that the peptide fragment comprises an amino acid sequence derived from
7 filaggrin. '724 Patent col.15 1.25-26. "The transitional term 'comprising' . . . is inclusive or
8 open-ended and does not exclude additional, unrecited elements or method steps." MPEP §
9 2111.03. Under Federal Circuit law, "comprising" is a term of art meaning that "the named
10 elements are essential, but other elements may be added and still form a construct within the
11 scope of the claim." Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501 (Fed. Cir. 1997). It
12 is well understood to mean "including but not limited to." CIAS, Inc. v. Alliance Gaming
13 Corp., 504 F.3d 1356, 1360 (Fed. Cir. 2007).

14 Defendant's proposed construction for claim 1 states that the fragment "can include
15 amino acids and amino acid sequences in addition to the amino acid sequence of filaggrin."
16 (Doc. No. 105 at 4.) Plaintiff objects to this specific language, suggesting instead that the
17 fragment "must contain what is expressly set forth in the claim, but can include additional
18 elements." (Id.) The Court adopts Plaintiff's construction as it is based directly on the case
19 law interpreting the meaning of "comprising." The parties agree that the fragment may contain
20 elements in addition to an amino acid sequence derived from filaggrin, but the Court declines
21 to elaborate on what additional elements are permissible. As discussed below, the extent to
22 which a fragment may deviate from filaggrin and still fall within the claim is a question of fact
23 for the jury. See PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1354-55 (Fed. Cir.
24 1998) (holding that whether a substance had a composition "consisting essentially of" listed
25 ingredients was not a matter of claim construction but an infringement issue for the jury).

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1 **E. “derived from said filaggrin by replacing at least one arginine residue in the**
2 **amino acid sequence with a citrulline residue”**

3 Claim 1 states that the claimed fragment comprises an amino acid sequence derived
4 from filaggrin by replacing at least one arginine with a citrulline. ‘724 Patent col.15 l.25-28.
5 Plaintiff’s construction provides for an amino acid sequence obtained from filaggrin and
6 “changed by substituting at least one arginine residue in the filaggrin sequence with a citrulline
7 residue.” (Doc. No. 105 at 5.) Defendant’s construction states that the amino acid sequence
8 “includes an amino acid sequence of filaggrin (SEQ ID NO: 19) with changes including at
9 least one arginine residue substituted by a citrulline residue.” (Id.) Defendant’s construction
10 is more open-ended, while Plaintiff’s implies that the only permissible change is the arginine-
11 citrulline substitution. The Court agrees with Defendant on this issue.

12 The Court first notes that the use of the word “comprises” indicates that the fragment’s
13 composition is open-ended – including but not limited to an amino acid sequence derived from
14 filaggrin. CIAS, 504 F.3d at 1360. In addition to the language of the claim itself, the patent’s
15 specification is “the single best guide to the meaning of a disputed term.” Vitronics, 90 F.3d
16 at 1582. Here, the Patent’s specification confirms Defendant’s interpretation:

17 To a person skilled in the art it will be apparent that there are a number of
18 possible variations to the present invention as specified by the appended claims.
19 For instance, the peptides mentioned on the formula sheet may also be part of
20 other oligopeptides. They may be provided at one or both ends with one or more
21 amino acids while also, two or more peptides according to the invention may be
22 part of one oligopeptide. It is also possible to shorten the peptides by one or
23 more amino acids, provided this does not have a significantly adverse effect on
24 the reactivity.

25 ‘724 Patent col.3 l.37-46. Thus, the specification expressly provides for modification of the
26 amino acid sequence beyond citrullination.

27 Plaintiff argues that the claim is limited by statement that the sequence is “derived from
28 filaggrin.” Plaintiff contends that “an amino acid sequence cannot be considered to be

1 'derived' from the parent sequence if it has been changed beyond recognition to something that
2 cannot be recognized as having been originally obtained, actually or theoretically, from the
3 parent sequence." (Pl.'s Br. at 20.) Plaintiff objects to the fact that Defendant's proposed
4 construction places no limit on the extent of changes that may be made to filaggrin sequence.
5 However, Defendant's construction is consistent with the patent language itself. Neither
6 proposed construction specifies the scope of allowable changes. This is appropriate, as the
7 extent to which a fragment may deviate from filaggrin and still fall within the claim is a
8 question of fact for the jury. See PPG Indus., 156 F.3d at 1354-55 (holding that whether a
9 substance had a composition "consisting essentially of" listed ingredients was not a matter of
10 claim construction but an infringement issue for the jury).

11 **F. "specifically immunoreactive"**

12 Claim 1 states that the antigen is "specifically immunoreactive with anti-filaggrin
13 antibodies present in the serum of subject suffering from rheumatoid arthritis." '724 Patent
14 col.15 l. 29-31.) Plaintiff argues that the phrase "specifically immunoreactive" requires that
15 the antigen recognize and bind to form complexes "only with anti-filaggrin antibodies present
16 in the serum portion of the blood of individuals suffering from rheumatoid arthritis." 9Doc.
17 No. 105 at 6.) Defendant's construction is less demanding, requiring only that the antigen
18 "preferentially reacts with anti-filaggrin antibodies present in the serum portion of the blood
19 of individuals suffering from rheumatoid arthritis." (Id.) The Court agrees with Defendant.

20 A patent's specification is "always highly relevant to the claim construction analysis.
21 Usually, it is dispositive; it is the single best guide to the meaning of a disputed term."
22 Phillips, 415 F.3d at 1315 (quotation omitted). Here, the specification consistently uses the
23 term "specifically" as a matter of degree, not an absolute. For example, it states that the
24 claimed peptide is "suitable for diagnostic research with increased specificity." '724 Patent
25 col.1 l.49-50. It explains that the use of a cyclic peptide enhances "specificity." col.6 l.14-17.
26 It points out that a prior art test is "not very specific." col.1 l.65 - col.2 l.1. Finally, it states
27 that the claimed invention is suitable for "high-specificity testing." col.2 l.54-55. In the
28 context of binding specificity, the specification refers to an "organic compound comprising a

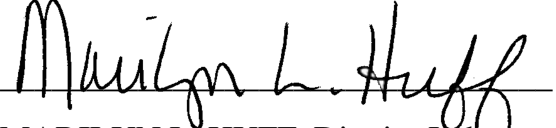
1 part that is able to compete with a peptide of the invention for binding to an antibody which
2 is specific for said peptide.” ‘724 Patent col.3 l.4-7. Even though this antibody is “specific”
3 for the peptide, the invention relates to another compound that also binds with the antibody.
4 Thus, the specification describes specificity as something that can be increased and enhanced,
5 something that varies from antigen to antigen. This treatment is inconsistent with Plaintiff’s
6 construction that specificity equals exclusivity. Under Federal Circuit law, “when a patentee
7 uses a claim term throughout the entire patent specification, in a manner consistent with only
8 a single meaning, he has defined that term by implication.” Bell Atl. Network Servs., Inc. v.
9 Covad Commc’ns Group, Inc., 262 F.3d 1258, 1271 (Fed. Cir. 2001).

10 **Conclusion**

11 The Court compliments the parties for their excellent presentations.

12 IT IS SO ORDERED.

13 DATED: August 24, 2009

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15 MARILYN L. HUFF, District Judge
16 UNITED STATES DISTRICT COURT
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CLAIM 1

(language for which the parties submitted proposed construction in **bold**)

An **antigen consisting of a cyclic peptide** which peptide is a **fragment** of the amino acid sequence of filaggrin (SEQ ID NO: 19) and which fragment **comprises** an amino acid sequence **derived from said filaggrin by replacing at least one arginine residue in the filaggrin amino acid sequence, with a citrulline residue,**

which **antigen is specifically immunoreactive with anti-filaggrin antibodies** present in the serum of subjects suffering from rheumatoid arthritis.

Claim Language	INOVA Diagnostics	Euro-Diagnostica et al.	Court's Construction
"An antigen . . . "	"substance to which antibodies bind"	"a molecule to which antibodies bind"	a substance to which an antibody binds
". . . consisting of . . . "	"consisting of" means that the claimed invention contains only what is expressly set forth in the claim and does not exclude additional components that are unrelated to the invention	"consisting of" means that the claimed invention contains only what is expressly set forth in the claim and does not exclude additional components that are unrelated to the invention	"consisting of" means that the claimed invention contains only what is expressly set forth in the claim and does not exclude additional components that are unrelated to the invention [The Court adopts the parties' stipulated construction.]
". . . a cyclic peptide . . . "	"one peptide, a sequence of amino acids, that includes one or more covalent bonds that cause the peptide to form one or more looped structures"	"a sequence of amino acids that includes one or more bonds forming one or more looped structures"	one peptide, a sequence of amino acids, that includes one or more bonds forming one or more looped structures in the peptide

Claim Language	INOVA Diagnostics	Euro-Diagnostica et al.	Court's Construction
“. . . a fragment of the amino acid sequence . . .”	the term “fragment” is indefinite in the context of the claim, and as such cannot be construed	“an incomplete part”	an incomplete part
“. . . which fragment comprises . . .”	“comprises” means that the claimed fragment must contain what is expressly set forth in the claim, but can include additional elements	“comprises” is open-ended, which means the fragment can include amino acids and amino acid sequences in addition to the amino acid sequence of filaggrin	The claimed fragment must contain what is expressly set forth in the claim, but can include additional elements.
“. . . amino acid sequence derived from said filaggrin by replacing at least one arginine residue in the filaggrin amino acid sequence with a citrulline residue . . . ”	“a sequence of amino acids that is obtained from filaggrin and changed by substituting at least one arginine residue in the filaggrin sequence with a citrulline residue”	“the amino acid sequence includes an amino acid sequence of filaggrin (SEQ ID NO: 19) with changes including at least one arginine residue substituted by a citrulline residue”	a sequence of amino acids that is obtained from filaggrin with changes including at least one arginine residue substituted by a citrulline residue
“. . . which antigen is specifically immunoreactive with anti-filaggrin antibodies present in the serum of subjects suffering from rheumatoid arthritis . . .”	“which antigen recognizes and binds to form complexes only with anti-filaggrin antibodies present in the serum portion of the blood of individuals suffering from rheumatoid arthritis”	“the antigen preferentially reacts with anti-filaggrin antibodies present in the serum portion of the blood of individuals suffering from rheumatoid arthritis”	The antigen preferentially reacts with anti-filaggrin antibodies present in the serum portion of the blood of individuals suffering from rheumatoid arthritis.

CLAIM 2

(language for which the parties submitted proposed construction in **bold**)

The **antigen of claim 1** wherein **one arginine is replaced by citrulline**.

Claim Language	INOVA Diagnostics	Euro-Diagnostica et al.	Court's Construction
"The antigen of claim 1 . . ."	This claim is dependent upon claim 1, thus incorporating all of the elements of claim 1.	This claim is dependent upon claim 1, thus incorporating all of the elements of claim 1.	This claim is dependent upon claim 1, thus incorporating all of the elements of claim 1.
". . . wherein one arginine is replaced by citrulline ."	"wherein one arginine is substituted by one citrulline in the filaggrin sequence"	"wherein one arginine is substituted by one citrulline in the filaggrin sequence"	"wherein one arginine is substituted by one citrulline in the filaggrin sequence" [The Court adopts the parties' stipulated construction.]

CLAIM 3

(language for which the parties submitted proposed construction in **bold**)

The **antigen of claim 1** wherein **two or more arginines are replaced by citrulline**.

Claim Language	INOVA Diagnostics	Euro-Diagnostica et al.	Court's Construction
"The antigen of claim 1 . . ."	This claim is dependent upon claim 1, thus incorporating all of the elements of claim 1.	This claim is dependent upon claim 1, thus incorporating all of the elements of claim 1.	This claim is dependent upon claim 1, thus incorporating all of the elements of claim 1.
". . . wherein two or more arginines are replaced by citrulline ."	"wherein two or more arginines are substituted by two or more citrullines in the filaggrin sequence"	"wherein two or more arginines are substituted by two or more citrullines in the filaggrin sequence"	"wherein two or more arginines are substituted by two or more citrullines in the filaggrin sequence" [The Court adopts the parties' stipulated construction.]

CLAIM 4

(language for which the parties submitted proposed construction in **bold**)

The **antigen of claim 1** which **contains at least two cysteines**.

Claim Language	INOVA Diagnostics	Euro-Diagnostica et al.	Court's Construction
"The antigen of claim 1 . . ."	This claim is dependent upon claim 1, thus incorporating all of the elements of claim 1.	This claim is dependent upon claim 1, thus incorporating all of the elements of claim 1.	This claim is dependent upon claim 1, thus incorporating all of the elements of claim 1.
". . . which contains at least two cysteines ."	"the antigen has two or more cysteine amino acids"	"the antigen has two or more cysteine amino acids"	"the antigen has two or more cysteine amino acids" [The Court adopts the parties' stipulated construction.]

CLAIM 8

(language for which the parties submitted proposed construction in **bold**)

A method to detect rheumatoid arthritis by detecting an autoimmune antibody in the serum of a subject, said method **comprising**:

contacting the antigen of claim 1 with said serums, and detecting the presence or absence of a complex between the antigen and an antibody;

wherein the presence of said complex detects rheumatoid arthritis.

Claim Language	INOVA Diagnostics	Euro-Diagnostica et al.	Court's Construction
"... said method comprising ..."	the accused method must contain every element of the claimed method, but can also include additional, unclaimed elements	the accused method must contain every element of the claimed method, but can also include additional, unclaimed elements	the accused method must contain every element of the claimed method, but can also include additional, unclaimed elements [The Court adopts the parties' stipulated construction.]
"... contacting ..."	"touching"	"touching"	"touching" [The Court adopts the parties' stipulated construction.]
"... the antigen of claim 1 ..."	This claim incorporates all of the elements of claim 1.	This claim incorporates all of the elements of claim 1.	This claim incorporates all of the elements of claim 1.

Claim Language	INOVA Diagnostics	Euro-Diagnostica et al.	Court's Construction
". . . said serums . . ."	"the serum of a subject"	"the serum of a subject"	<p>"the serum of a subject"</p> <p>[The Court adopts the parties' stipulated construction.]</p>

CLAIM 9

(language for which the parties submitted proposed construction in **bold**)

The **method of claim 8** wherein **the detecting** comprises use of an **antihuman antibody**.

Claim Language	INOVA Diagnostics	Euro-Diagnostica et al.	Court's Construction
"The method of claim 8 . . ."	This claim is dependent upon claim 8, thus incorporating all of the elements claimed in claim 8.	This claim is dependent upon claim 8, thus incorporating all of the elements claimed in claim 8.	This claim is dependent upon claim 8, thus incorporating all of the elements claimed in claim 8.
". . . the detecting . . ."	the "detecting" step of claim 8	the "detecting" step of claim 8	the "detecting" step of claim 8 [The Court adopts the parties' stipulated construction.]
". . . comprises . . ."	In order to infringe, the accused method must contain every element of the "detecting" claim limitation, but can also include additional unclaimed elements.	In order to infringe, the accused method must contain every element of the "detecting" claim limitation, but can also include additional unclaimed elements.	In order to infringe, the accused method must contain every element of the "detecting" claim limitation, but can also include additional unclaimed elements. [The Court adopts the parties' stipulated construction.]
". . . use of an antihuman antibody. "	"use of an antibody that binds to human antibodies"	"use of an antibody that binds to human antibodies"	"use of an antibody that binds to human antibodies" [The Court adopts the parties' stipulated construction.]

CLAIM 10

(language for which the parties submitted proposed construction in **bold**)

The **method of claim 8** wherein **the detecting** comprises use of an enzyme-linked immunosorbent assay (ELISA).

Claim Language	INOVA Diagnostics	Euro-Diagnostica et al.	Court's Construction
"The method of claim 8 . . ."	This claim is dependent upon claim 8, thus incorporating all of the elements claimed in claim 8.	This claim is dependent upon claim 8, thus incorporating all of the elements claimed in claim 8.	This claim is dependent upon claim 8, thus incorporating all of the elements claimed in claim 8.
". . . the detecting . . ."	the "detecting" step of claim 8	the "detecting" step of claim 8	the "detecting" step of claim 8 [The Court adopts the parties' stipulated construction.]
". . . comprises . . ."	In order to infringe, the accused method must contain every element of the "detecting" claim limitation, but can also include additional unclaimed elements.	In order to infringe, the accused method must contain every element of the "detecting" claim limitation, but can also include additional unclaimed elements.	In order to infringe, the accused method must contain every element of the "detecting" claim limitation, but can also include additional unclaimed elements. [The Court adopts the parties' stipulated construction.]
". . . use of an enzyme-linked immunosorbent assay (ELISA) ."	"use of a test that uses an enzyme, a protein that catalyzes a biochemical reaction, and an antibody or antigen linked thereto"	"use of a test that uses an enzyme, a protein that catalyzes a biochemical reaction, and an antibody or antigen linked thereto"	"use of a test that uses an enzyme, a protein that catalyzes a biochemical reaction, and an antibody or antigen linked thereto" [The Court adopts the parties' stipulated construction.]

CLAIM 11

(language for which the parties submitted proposed construction in **bold**)

The **method of claim 8** wherein **the antigen contains at least two cysteines**.

Claim Language	INOVA Diagnostics	Euro-Diagnostica et al.	Court's Construction
"The method of claim 8 . . ."	This claim is dependent upon claim 8, thus incorporating all of the elements claimed in claim 8.	This claim is dependent upon claim 8, thus incorporating all of the elements claimed in claim 8.	This claim is dependent upon claim 8, thus incorporating all of the elements claimed in claim 8.
". . . wherein the antigen contains at least two cysteines ."	"the antigen has two or more cysteine amino acids"	"the antigen has two or more cysteine amino acids"	"the antigen has two or more cysteine amino acids" [The Court adopts the parties' stipulated construction.]