

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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PCT

NOTIFICATION OF TRANSMITTAL OF
INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Rule 71.1)

Date of mailing
(day/month/year)

04 OCT 2016

Applicant's or agent's file reference

CHE-015 PCT

IMPORTANT NOTIFICATION

International application No.

PCT/US15/17480

International filing date (day/month/year)

25 February 2015 (25.02.2015)

Priority date (day/month/year)

02 April 2014 (02.04.2014)

Applicant

CHEMBIO DIAGNOSTIC SYSTEMS, INC

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the *PCT Applicant's Guide*.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed invention is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

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Form PCT/IPEA/416 (January 2004)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference CHE-015 PCT	FOR FURTHER ACTION		See Form PCT/IPEA/416																								
International application No. PCT/US15/17480	International filing date (<i>day/month/year</i>) 25 February 2015 (25.02.2015)	Priority date (<i>day/month/year</i>) 02 April 2014 (02.04.2014)																									
International Patent Classification (IPC) or national classification and IPC IPC: C12M 1/34(2006.01),G01N 33/52,G01N 33/543,C40B 60/12,G01N 21/75,G01N 33/538 CPC: C12M 1/34,C40B 60/12,G01N 21/75,G01N 33/538,G01N 33/52,G01N 33/543,G01N 33/54353																											
Applicant CHEMBIO DIAGNOSTIC SYSTEMS, INC																											
1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of <u>11</u> sheets, including this cover sheet. 3. This report is also accompanied by ANNEXES, comprising: a. ☐ (<i>sent to the applicant and to the International Bureau</i>) a total of <u>0</u> sheets, as follows: ☐ sheets of the description, claims and/or drawings which have been amended and/or sheets containing rectifications authorized by this Authority, unless those sheets were superseded or cancelled, and any accompanying letters (see Rules 46.5, 66.8, 70.16, 91.2, and Section 607 of the Administrative Instructions). ☐ sheets containing rectifications, where the decision was made by this Authority not to take them into account because they were not authorized by or notified to this Authority at the time when this Authority began to draw up this report, and any accompanying letters (Rules 66.4bis, 70.2(e), 70.16 and 91.2). ☐ superseded sheets and any accompanying letters, where this Authority either considers that the superseding sheets contain an amendment that goes beyond the disclosure in the international application as filed, or the superseding sheets were not accompanied by a letter indicating the basis for the amendments in the application as filed, as indicated in item 4 of Box No.I and the Supplemental Box (see Rule 70.16(b)). b. ☐ (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) _____ containing a sequence listing, in the form of an Annex C/ST.25 text file, as indicated in the Supplemental Box Relating to Sequence Listing (see paragraph 3ter of Annex C of the Administrative Instructions).																											
4. This report contains indications relating to the following items: <table style="width: 100%; border: none;"> <tr> <td style="width: 10%; text-align: center;">☒</td> <td style="width: 30%;">Box No. I</td> <td style="width: 60%;">Basis of the report</td> </tr> <tr> <td style="text-align: center;">☐</td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;">☒</td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;">☒</td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td style="text-align: center;">☒</td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;">☒</td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;">☐</td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;">☒</td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>				☒	Box No. I	Basis of the report	☐	Box No. II	Priority	☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	☒	Box No. IV	Lack of unity of invention	☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement	☒	Box No. VI	Certain documents cited	☐	Box No. VII	Certain defects in the international application	☒	Box No. VIII	Certain observations on the international application
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Date of submission of the demand 17 March 2016 (17.03.2016)		Date of completion of this report 21 September 2016 (21.09.2016)																									
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-8300		Authorized officer Melanie Y. Brown Telephone No. (571) 272-2933																									

Form PCT/IPEA/409 (cover sheet) (January 2015)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US15/17480

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into English which is the language of a translation furnished for the purposes of:
- ☐ international search (Rules 12.3(a) and 23.1(b)).
- ☐ publication of the international application (Rule 12.4(a)).
- ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a) and (b)).

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- ☒ the international application as originally filed/furnished
- ☒ the description:
pages 1-22 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____
- ☒ the claims:
Nos. 23-30 as originally filed/furnished
Nos.* NONE as amended (together with any statement) under Article 19
Nos.* NONE received by this Authority on _____
- ☒ the drawings:
pages 1/5-5/5 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____
- ☐ a sequence listing - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since either they are considered to go beyond the disclosure as filed, or they were not accompanied by a letter indicating the basis for the amendments in the application as filed, as indicated in the Supplemental Box (Rules 70.2(c) and (c-bis)):

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____

5. ☐ This report has been established:

- ☐ taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rules 66.1(d-bis) and 70.2(e)).
- ☐ without taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rules 66.4bis) and 70.2(e)).

6. ☒ With regard to top-up searches (Rules 66.1ter and 70.2(f)):

- ☒ A top-up search was carried out by this Authority on 21 September 2016 (21.09.2016)
- ☐ Additional relevant documents have been discovered during the top-up search.
- ☐ No top-up search was carried out by this Authority because it would serve no useful purpose.

7. ☐ Supplementary international search report(s) from Authority(ies) _____ has/have been received and taken into account in establishing this report (Rule 45bis.8(b) and (c)).

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US15/17480

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
☒ claims Nos. 5-9,11-15,19,20 and 25-33

because:

- ☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require an international preliminary examination (*specify*):

- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 5-9,11-15,19,20,25-33 and 37 are so unclear that no meaningful opinion could be formed (*specify*):

the claims have improper multiple dependency under PCT Rule 6.4(a).

- ☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

- ☐ no international search report has been established for said claims Nos. _____

- ☐ a meaningful opinion could not be formed without the sequence listing: the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing in the form of an Annex C/ST.25 text file, and such listing was not available to the International Preliminary Examining Authority in the form and manner acceptable to it: or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.

- ☐ furnish a sequence listing on paper or in the form of an image file complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in the form and manner acceptable to it: or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.

- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b) and 13*ter*.2.

- ☐ See Supplemental Box for further details

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US15/17480

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation to restrict or pay additional fees the applicant has, within the applicable time limit:
 - ☐ restricted the claims.
 - ☒ paid additional fees.
 - ☐ paid additional fees under protest, and, where applicable, the protest fee.
 - ☐ paid additional fees under protest but the applicable protest fee was not paid.
 - ☐ neither restricted the claims nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:
 - ☐ complied with.
 - ☒ not complied with for the following reasons:

Please See Continuation Sheet

4. Consequently, this report has been established in respect of the following parts of the international application:
 - ☒ all parts.
 - ☐ the parts relating to claims Nos. _____

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US15/17480**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)

Claims 34-36, 40, 43 YESClaims 1-4, 10, 16-18, 21-24, 38, 39, 41-42 NO

Inventive Step (IS)

Claims 34-36 YESClaims 1-4, 10, 16-18, 21-24, 38, 39, 41-43 NO

Industrial Applicability (IA)

Claims 1-4, 10, 16-18, 21-24, 34-36, 38, 39, 40-43 YESClaims NONE NO

2. Citations and Explanations (Rule 70.7)

Claims 34-36 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest first molecules and second conjugates in a second migration path.

----- NEW CITATIONS -----

Claims 41 and 42 lack novelty under PCT Article 33(2) as being anticipated by Song et al. (US 2008/0145949).

Song et al. teach a method for testing a sample for a first ligand comprising:
Providing a lateral flow test device (20, Fig. 1) having a sorbent strip (23, Fig. 1), a marker conjugate (22, Fig. 1) and a test site having an immobilized first ligand binding mechanism for the first ligand (31, Fig. 1); and depleting from the sample second ligand that is different from but related to the first ligand before the second ligand reaches the test site (35, Fig. 1, quenching zone removes interfering ligands from the test sample, the second ligand is related to the first ligand in that the ligands are within the same sample, par. 53).

With respect to claim 42, Song et al. teach depleting comprising bringing the second ligand into contact with a depletion conjugate adapted to bind to the second ligand (par. 53).

Claim 43 lacks an inventive step under PCT Article 33(3) as being obvious over Song et al.

Regarding Claim 43, Song et al. teach the particles of said second conjugate comprise latex particles (par. 34) but does not specifically disclose white. To a person of ordinary skill in the art, it would have been obvious through routine experimentation to providing a colorless interferent removal molecule (par. 14).

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US15/17480

Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

Application No
Patent No.
US 2008/0145949

Publication Date
(day/month/year)
19 June 2008 (19.06.2008)

Filing Date
(day/month/year)
15 December 2006 (15.12.2006)

Priority date (valid claim)
(day/month/year)
15 December 2006 (15.12.2006)

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure

Date of non-written disclosure
(day/month/year)

Date of written disclosure
referring to non-written disclosure
(day/month/year)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US15/17480

Box No. VIII **Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 14 and 15 are objected to under PCT Article 6 as lacking clarity because claim 14 and 15 are indefinite for the following reason(s): Claim 15 depends from itself which is improper dependency.

The recitations of "said first flu antibody" and "said second flu antibody" in claims 14 and 15 lack antecedent basis in the claims.

Claim 34 recites two features "e)" which is vague and indefinite because it is unclear whether both features are required.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

IV. 3. This Authority considers that the requirement of unity of invention is accordance with Rules 13.1, 13.2 and 13.3 is not complied with for the following reasons:

REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), an international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an international application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

WHEN CLAIMS ARE DIRECTED TO MULTIPLE PROCESSES, PRODUCTS, AND/OR APPARATUSES

Products, processes of manufacture, processes of use, and apparatuses are different categories of invention. When an application includes claims to more than one product, process, or apparatus, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the "main invention" in the claims. In the case of non-compliance with unity of invention and where no additional fees are timely paid, the international search and/or international preliminary examination, as appropriate, will be based on the main invention in the claims. See PCT Article 17(3)(a), 37 CFR 1.475(d), 37 CFR 1.476(c) and 37 CFR 1.488(b)(3).

As provided in 37 CFR 1.475(b), an international application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Supplemental Box

Group I, claim(s) 1-4, 10, 34-36 and 38-40, drawn to a test device.

Group II, claim(s) 16-18, 21-24 and 41-43, drawn to a method for testing.

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I and II lack unity of invention because even though the inventions of these groups require the technical feature of a test device as recited in claim 1, this technical feature is not a special technical feature as it does not make a contribution over the prior art in view of Esfandiari (US 2006/0134803). Esfandiari teaches a test device for determining the presence of a first ligand in a liquid sample (par. 30), comprising: a) a first sorbent strip having a first location for receiving a solution and defining a first migration path (Fig. 1, 9, par. 61, 62 and 65, buffer solution received at strip 31, migrating along the path of strip, conjugates 39A and 39B); c) a second sorbent strip distinct from the first sorbent strip and having a second location for receiving the liquid sample and defining a second migration path (Fig. 9, par. 67, sample added to second sorbent material 32'', migrating sample along strip to conjugate 39'', and to test area 63'', and test line, 50); d) depletion molecules located on or in the second migration path wherein the depletion molecules include an immobilized ligand binding element adapted to bind to second ligands that are different from but related to the first ligand (Fig. 9, par. 66, 67, conjugate 39'', p24 antibody-biotin conjugate binding to antigen or to streptavidin), and e) a test site located on or in the first sorbent strip (Fig. 9, par. 67, test area 63'' and test line, 50), the test site having an immobilized first ligand binding mechanism for the first ligand (par. 66) and the first and second sorbent strips touching each other at the test site location (par. 92), wherein the second location is removed from the test site such that the sample applied to the second location requires time to migrate to the test site and does not immediately wet the test site (Fig. 9, par. 67, migrate from sorbent material 32'' to test area 63'' and test line 50).

Claims 1-4, 10, 16-18, 21-24, 38 and 39 lack novelty under PCT Article 33(2) as being anticipated by 2014/0045172 (Esfandiari).

With respect to claim 1, Esfandiari teaches a test device for determining the presence of a first ligand in a liquid sample (par. 30), comprising: a) a first sorbent strip having a first location for receiving a solution and defining a first migration path (Fig. 1, 9, par. 61, 62 and 65, buffer solution received at strip 31, migrating along the path of strip, conjugates 39A and 39B); c) a second sorbent strip distinct from the first sorbent strip and having a second location for receiving the liquid sample and defining a second migration path (Fig. 9, par. 67, sample added to second sorbent material 32'', migrating sample along strip to conjugate 39'', and to test area 63'', and test line, 50); d) depletion molecules located on or in the second migration path wherein the depletion molecules include an immobilized ligand binding element adapted to bind to second ligands that are different from but related to the first ligand (Fig. 9, par. 66, 67, conjugate 39'', p24 antibody-biotin conjugate binding to antigen or to streptavidin), and e) a test site located on or in the first sorbent strip (Fig. 9, par. 67, test area 63'' and test line, 50), the test site having an immobilized first ligand binding mechanism for the first ligand (par. 66) and the first and second sorbent strips touching each other at the test site location (par. 92), wherein the second location is removed from the test site such that the sample applied to the second location requires time to migrate to the test site and does not immediately wet the test site (Fig. 9, par. 67, migrate from sorbent material 32'' to test area 63'' and test line 50).

Applicant's arguments against the reference of Esfandiari have been entered and considered.

Applicant argues that Esfandiari teaches a p24 monoclonal antibody-biotin conjugate 39'' that binds to a p24 antigen (first ligand) and mobilizes toward a test site and the marker conjugate 39 on the first sorbent strip also binds to the first ligand, p24 antigen. Thus Esfandiari teaches a marker conjugate that binds to the same antigen as conjugate 39'' and not to second ligands that are different from but related to the first ligand.

Applicant's argument has been considered but do not overcome the rejection of record because Esfandiari is not interpreted in the way described by applicant. The first ligand to which the marker binds is p24 antigen. The depletion molecules are biotin immobilized to a p24 antibody. Therefore the ligand binding element is biotin and streptavidin is the second ligand, which is different from but related to the first ligand by immobilization. Upon application of a sample to the second location, the biotin becomes bound to the immobilized streptavidin in the test site which provides an immobilized first ligand (p24 antigen) to which the marker conjugate binds. This is the same manner in which the first ligand is provided to the test site in the instant disclosure.

Supplemental Box

With respect to claim 2, Esfandiari teaches the test device further comprising a housing defining a first opening adjacent the first location, a second opening adjacent the second location and a window adjacent the test site through which the test site is viewable (Fig. 1; par. 49, 52, first and second holes, 24 and 26, and window 28).

With respect to claim 3, Esfandiari teaches the ligand binding mechanism of the test site being an antibody for the first ligand and the marker conjugate comprising an antigen or antibody for the first ligand and a marker coupled to the antibody (par. 50).

With respect to claim 4, Esfandiari teaches the marker being a colored marker viewable in the visible spectrum (par. 65).

With respect to claim 10, Esfandiari teaches at least one of the first sorbent strip and the second sorbent strip including a control site, and either the window sized to permit viewing of the control site or a second window provided in the housing to permit viewing of the control site (Fig. 1; par. 49, window 28, control line, 50).

With respect to claim 16, Esfandiari teaches a method comprising: providing the test device of claim 1 (see claim 1 description above); applying the sample to the second location (par. 52); after applying the sample, applying a solution to the first location to cause the marker conjugate to migrate along the first migration path (par. 52, 54 and 60); and inspecting the test site to determine an indication of the presence or lack thereof of the first ligand in the sample (par. 91, 92).

With respect to claim 17, Esfandiari teaches depletion molecules comprising a conjugate of an antigen for the second ligand (par. 67 and 81) and particles that are not readily seen by the human eye against a background of the test site (par. 86 and 89).

With respect to claim 18, Esfandiari teaches a test device having a housing defining a first opening adjacent the first location, a second opening adjacent the second location and a window adjacent the test site through which the test site is viewable (Fig. 1; par. 49, window, 28 and control line 50), applying the sample comprising depositing the sample through the second opening to the second location (par. 52), the applying the solution comprises depositing the solution through the first opening to the first location (par. 52, 54 and 60) and inspecting comprises inspecting through the window (par. 91 and 92).

With respect to claim 21, Esfandiari teaches a method for testing a sample comprising: Combining the sample with depletion molecules to obtain a mixture, said depletion molecules comprising molecules chosen to bind to analyze having a second ligand different from but related to said first ligand, thereby generating bound second ligand and a remainder (Fig. 8; para [0052], [0065], biotin-anti-p24 antibody conjugate, for binding to p24 antigen, which may be applied in mixture in the second strip, wherein sample migrates to test lines, 50A, 50B, and 50C.); b) applying at least the remainder to an immunoassay device (Fig. 1; para [0052], conjugate continues to migrate to control line, 60.); and c) inspecting the immunoassay device to determine the presence of the first ligand (para [0091], [0092]).

Applicant's arguments regarding claim 21 have been considered, but are not persuasive because the depletion molecule taught by Esfandiari is the biotin conjugated to the anti-p24 antibody, which is combined with the sample prior to contact with the immunoassay, the second ligand is the biotin molecule while the first ligand is the p24 antigen.

Regarding Claim 22, Esfandiari further discloses a method according to claim 21, wherein: said depletion molecules comprise a conjugate of said second ligand with a larger particle (para [0064], [0089], conjugates with and without particles).

Regarding Claim 23, Esfandiari further discloses a method according to claim 22, wherein: said larger particle is one of a latex particle and a colloid (para [0089]).

Regarding Claim 24, Esfandiari further discloses a method according to either of claims 22 or 23, wherein: said larger particle is a colored latex (para [0064], [0089], conjugates with and without colored particles.).

Regarding Claim 38, Esfandiari discloses a lateral flow test device for determining the presence of a first ligand in a liquid sample, comprising: a) a sorbent strip having a first location for receiving a solution and defining a migration path (Figs. 1, 8; para [0061], [0062], [0065], buffer solution received at strip, 31, migrating along path of strip.); b) a marker conjugate adapted to move along said migration path and bind to said first ligand (Figs. 1, 8; para [0061], [0062], [0065], conjugates, 39A and 39B.); c) depletion molecules located on or in said migration path wherein said depletion molecules include an immobilized ligand-binding element adapted to bind to second ligands that are different from but related to said first ligand (Fig. 8; para [0052], [0065], latex conjugates, 39A and 39B, for binding to antibodies or antigens present in the sample.); and

d) a test site located on or in said sorbent strip, said test site having an immobilized first ligand binding mechanism for said first ligand (Fig. 8; para [0052], [0065], migrate from sorbent material, 32, to test area, 63, and test lines, 50A, 50B, and 50C.).

Regarding Claim 39, Esfandiari further discloses a lateral flow test device according to claim 38, wherein: said depletion molecules comprise a conjugate including an antigen or antibody for the second ligand (para [0067], [0081]) and particles that are not readily seen by the human eye against a background of said test site (para [0086], [0089]).

Supplemental Box

Claim 40 lacks an inventive step under PCT Article 33(3) as being obvious over Esfandiari

Regarding Claim 40, Esfandiari further discloses a lateral flow test device according to either of claims 38 or 39 or 35, wherein: said particles of said second conjugate comprise colored latex particles (para [0089]); but does not specifically disclose white. To a person of ordinary skill in the art, it would have been obvious through routine experimentation to vary the color of the latex particle in order to optimize indication of the presence or lack of a ligand in the sample (para [0091]).

Applicant's arguments regarding the reference of O'Farrell are persuasive and the rejection has been withdrawn.

Claims 1-4, 10, 16-18, 21-24, 34-36 and 38-43 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

----- NEW CITATIONS -----

Claims 41 and 42 lack novelty under PCT Article 33(2) as being anticipated by Song et al. (US 2008/0145949).

Song et al. teach a method for testing a sample for a first ligand comprising:
Providing a lateral flow test device (20, Fig. 1) having a sorbent strip (23, Fig. 1), a marker conjugate (22, Fig. 1) and a test site having an immobilized first ligand binding mechanism for the first ligand (31, Fig. 1); and depleting from the sample second ligand that is different from but related to the first ligand before the second ligand reaches the test site (35, Fig. 1, quenching zone removes interfering ligands from the test sample, the second ligand is related to the first ligand in that the ligands are within the same sample, par. 53).

With respect to claim 42, Song et al. teach depleting comprising bringing the second ligand into contact with a depletion conjugate adapted to bind to the second ligand (par. 53).

Claim 43 lacks an inventive step under PCT Article 33(3) as being obvious over Song et al.

Regarding Claim 43, Song et al. teach the particles of said second conjugate comprise latex particles (par. 34) but does not specifically disclose white. To a person of ordinary skill in the art, it would have been obvious through routine experimentation to providing a colorless interferent removal molecule (par. 14).