**Day Two Problems**

Patent Fundamentals Bootcamp 2021: *An Introduction to Patent Drafting, Prosecution, and Litigation*

June 3, 2021

**DAY 2- AMENDMENT DRAFTING PROBLEM**

You have filed the application and figures as attached. You have received the Office Action (also attached) with a primary reference, the Easy Chair Reference.

Now, you must

1. Respond to the Office Action amending OR traversing where appropriate.

2. Prepare your Amendment in compliance with the Revised Amendment Practice attached.

NOTE: The Client has mentioned to you that obtaining a patent quickly is more of a priority than the scope of the patent. The Client feels that a continuation may be filed to obtain broader protection later if necessary. Please keep this in mind when considering how to respond to the Office Action.

**REVISED AMENDMENT PRACTICE: 37 CFR 1.121 CHANGED COMPLIANCE IS MANDATORY** - **Effective Date: July 30, 2003**

All amendments filed on or after the effective date noted above must comply with revised 37 CFR 1.121. See Final Rule: **Changes To Implement Electronic Maintenance of Official Patent Application Records** (68 *Fed. Reg.*

38611 (June 30, 2003), posted on the Office's website at: <http://www.uspto.gov/web/patents/ifw/>

with related information. The amendment practice set forth in revised 37 CFR 1.121, and described below, replaces the voluntary revised amendment format available to applicants since February 2003. **NOTE: STRICT COMPLIANCE WITH THE REVISED 37 CFR 1.121 IS REQUIRED AS OF THE EFFECTIVE DATE (July**

**30, 2003).** The Office will notify applicants of amendments that are not accepted because they do not comply with revised 37 CFR 1.121 via a Notice of Non-Compliant Amendment. See MPEP 714.03 (Rev. 1, Feb. 2003). The non­ compliant section(s) will have to be corrected and the entire corrected section(s) resubmitted within a set period.

***Bold underlined italic font has been used below to highlight the major differences between the revised 3***7 ***CFR 1.121 and the voluntary revised amendment format that applicants could use since February, 2003.***

Note: The amendment practice for **reissues** and **reexamination proceedings,** except for drawings, has not changed.

**REVISED AMENDMENT PRACTICE**

1. **Begin each section of an amendment document on a separate sheet:**

Each section of an amendment document *(e.g.,* Specification Amendments, Claim Amendments, Drawing Amendments, and Remarks) must begin on a separate sheet. Starting each separate section on a new page will facilitate the process of separately indexing and scanning each section of an amendment document for placement in an image file wrapper.

1. **Two versions of amended part(s) no longer required:**

37 **CFR 1.121 has been revised to no longer require two versions (a clean version and a marked up version) of each replacement paragraph or section, or amended claim. Note, however, the requirements for a clean version and a marked up version for substitute specifications under 37 CFR 1.125 have been retained.**

1. **Amendments to the claims:**

Each amendment document that includes a change to an existing claim, cancellation of a claim or submission of a new claim, **must include a complete listing** of all claims in the application. After each claim number **in** the listing, the status must be indicated in a parenthetical expression, and **the text of each pending claim** (with markings to show current changes) must be presented. The claims in the listing will replace all prior claims in the application.

* 1. The current status of all of the claims in the application, including any previously canceled, not entered or withdrawn claims, must be given in a parenthetical expression following the claim number using only one of the following seven status identifiers: (original), (currently amended), (canceled), (withdrawn), (new), ***(previously presented) and (not entered).*** The text of all pending claims, ***including withdrawn claims,*** must be submitted each time any claim is amended. Canceled ***and not entered*** claims must be indicated by only the claim number and status, without presenting the text of the claims.
  2. The text of all claims being currently amended must be presented in the claim listing with markings to indicate the changes that have been made relative to the immediate prior version. The changes in any amended claim must be shown by underlining (for added matter) or strikethrough (for deleted matter) with 2 exceptions: (1) for ***deletion of five characters or fewer, double brackets may be used (e.g., [[eroor]]); and (2) if strikethrough cannot be easily perceived (e.g., deletion of the number "4" or certain punctuation marks),***

***double brackets must be used (e.g., [[4]]). As an alternative to using double brackets, however, extra***

***portions of text may be included before and alter text being deleted, all in strikethrough, followed by including and underlining the extra text with the desired change*** *(e.g., ~~number 4 as~~ number 14 as).* An accompanying clean version is not required and should not be presented. Only claims of the status "currently amended," and "withdrawn" that are being amended, may include markings.

* 1. The text of pending claims not being currently amended, ***including withdrawn claims,*** must be presented in the claim listing in clean version, *i.e.,* without any markings. Any claim text presented in clean version will constitute an assertion that it has not been changed relative to the immediate prior version except to omit markings that may have been present in the immediate prior version of the claims.

**Rev. 3 (07/24/03) Flyer for mailing with all Office actions by all TCs**

* 1. A claim being canceled must be listed in the claim listing with the status identifier "canceled"; the text of the claim must not be presented. Providing an instruction to cancel is optional.
  2. Any claims added by amendment must be presented in the claim listing with the status identifier "(new)”; the text of the claim must not be underlined.
  3. All of the claims in the claim listing must be presented in ascending numerical order. Consecutive canceled, or not entered, claims may be aggregated into one statement (*e.g.*, Claims 1 - 5 (canceled)).

**Example of listing of claims (use of the word "claim" before the claim number is optional):**

Claims 1-5 (canceled)

Claim 6 (previously presented): A bucket with a handle. Claim 7 (withdrawn): A handle comprising an elongated wire.

Claim 8 (withdrawn): The handle of claim 7 further comprising a plastic grip. Claim 9 (currently amended): A bucket with a ~~green~~ blue handle.

Claim 10 (original): The bucket of claim 9 wherein the handle is made of wood. Claim 11 (canceled)

Claim 12 (not entered)

Claim 13 (new): A bucket with plastic sides and bottom.

1. **Amendments to the specification:**

Amendments to the specification, including the abstract, must be made by presenting a replacement paragraph or section or abstract marked up to show changes made relative to the immediate prior version. An accompanying clean version is not required and should not be presented. Newly added paragraphs or sections, including a new abstract (instead of a replacement abstract), must not be underlined. A replacement or new abstract must be submitted on a separate sheet, 37 CFR 1.72. If a substitute specification is being submitted to incorporate extensive amendments, both a clean version (which will be entered) and a marked up version must be submitted as per 37 CFR 1.125.

The changes in any replacement paragraph or section, or substitute specification must be shown by underlining (for added matter) or strikethrough (for deleted matter) with 2 exceptions: (1) for ***deletion of five characters or fewer, double brackets may be used (e.g., [[eroor]]); and (2) if strikethrough cannot be easily perceived (e.g., deletion of***

***the number "4" or certain punctuation marks), double brackets must be used (e.g., [[4]]). As an alternative to***

***using double brackets, however, extra portions of text may be included before and after text being deleted, all in strikethrough, followed by including and underlining the extra text with the desired change*** *(e.g., ~~number 4 as~~ number 14 as)*

1. **Amendments to drawing figures:**

Drawing changes must be made by presenting replacement figures which incorporate the desired changes and which comply with 37 CFR 1.84. An explanation of the changes made must be presented either in the drawing amendments, or remarks, section of the amendment, ***and may be accompanied by a marked-up copy of one or more of the figures being amended. with annotations.*** Any replacement drawing sheet must ***be identified in the top margin as "Replacement Sheet"*** and include all of the figures appearing on the immediate prior version of the sheet, even though only one figure may be amended. ***Any marked-up (annotated) copy showing changes must be labeled "Annotated Marked-up Drawings" and accompany the replacement sheet in the amendment (e.g., as an appendix).*** The figure or figure number of the amended drawing(s) must **not** be labeled as "amended." If the changes to the drawing figure(s) are not accepted by the examiner, applicant will be notified of any required corrective action in the next Office action. No further drawing submission will be required, unless applicant is notified.

Questions regarding the submission of amendments pursuant to the revised practice set forth in this flyer should be directed to: Elizabeth Dougherty or Gena Jones, Legal Advisors, or Joe Narcavage, Senior Special Projects Examiner, Office of Patent Legal Administration, by e-mail to [patentpractice@uspto.gov](mailto:patentpractice@uspto.gov) or by phone at (703) 305-1616.

**Rev. 3 (07/24/03) Flyer for mailing with all Office actions by all TCs**

UNITED STATES PATENT APPLICATION FOR

PORTABLE APPARATUS FOR SITTING

Inventors:

John Q. Public Jane B. Doe

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**PORTABLE APPARATUS FOR SITTING**

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to an apparatus for supporting a human in a sitting position, and more particularly to an apparatus that is portable and stable.

1. Background of Related Art

As known in the prior art, a person walking around their environment and from place to place can become tired and want to rest. One way to rest is to lie on the ground. However, in many areas the ground is dirty and people usually want to rest without becoming dirty. In some areas, rocks, logs and stumps are abundant and people have found that placing their buttock on these rocks, logs and stumps allows them to rest without lying on the ground and becoming dirty. People using this resting technique often say that they "sit” on the rocks, logs or stumps, or are "sitting," and the position when their buttock is on the rock, log or stump is known as a sitting position. In some areas there are very few rocks, logs and stumps and so humans find it difficult to sit. This can be a particular problem in areas with homes, where the rocks, logs and stumps are used to construct the home, and are no longer available for sitting.

Even in areas where rocks, logs and stumps are plentiful, they may not be concentrated in the locations where people want to sit, such as when they gather together as a group around a fire and tell stories.

What is needed is an apparatus that people can use for sitting in all areas, such as areas with few rocks, logs and stumps. What is also needed is an apparatus that is portable so people can easily carry or move the apparatus from place to place, allowing them to sit with others in groups.

SUMMARY OF THE INVENTION

In one embodiment the invention provides an apparatus that includes a substantially planar surface or seat with a first and a second surface, and at least three elongate members or legs. The members or legs each have a first end and a second end. The first ends are connected to the first surface of the planar surface and are oriented with respect to the planar surface such that the legs are substantially perpendicular to the planar surface and are substantially parallel to each other. The length of the legs is approximately equal to the distance between the knee and the ankle of an adult leg. The planar surface is approximately equal in areas to the area of the back surface of an adult buttock,

In one embodiment, the apparatus includes three elongate members or legs.

In one embodiment, the apparatus includes four elongate members or legs.

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In one embodiment , the apparatus includes a support member or back that is attached to the second surface of the planar surface or seat.

DESCRIPTION OF THE DRAWINGS

The foregoing features and other aspects of the invention are explained in the following description taken in conjunction with the accompanying figures wherein:

FIG. 1 illustrates one embodiment of the invention with three elongate members, or legs attached to a planar surface or seat;

FIG. 2 illustrates one embodiment of the invention with four elongate members, or legs attached to a planar surface or seat; and

FIG. 3 illustrates one embodiment of the invention with a support member or back attached to a planar surface or seat.

It is understood that the drawings are for illustration only and are not limiting.

DETAILED DESCRIPTION OF THE DRAWINGS

Referring first to FIG. 1, one embodiment of apparatus 100 of the invention includes a planar surface or "seat: 102. Planar surface or seat 102 is preferably formed of wood, and in some embodiments planar surface or seat 102 is round, rectangular or square.

Elongate members or "legs" 104 of apparatus 100 have two ends, with one end connected to planar surface 102. In the embodiment that is illustrated in FIG. 1, apparatus 100 has three elongate members 104. In the embodiment that is illustrated in FIG. 2, apparatus 100 has four elongate members 104.

Although not illustrated in the figures, in one embodiment, elongate members 104 are first formed as separate pieces and then they are joined to planar surface 102. In another embodiment, elongate members 104 and planar surface 102 are all formed together. In one embodiment, when elongate members 104 and planar surface 102 are formed as separate pieces and then joined, the connection between elongate members 104 and planar surface 102 is generally rigid and semi-permanent, such as with glue. In another embodiment elongate members l04 are generally rigid and easily connected and removed from planar surface 102, such as by threading.

The physical relationship between elongate members 104 and planar surface 102 is such that elongate members 104 are generally parallel to each other and also perpendicular to planar surface 102. This configuration is illustrated in FIGs. 1 and 2. It is possible that elongate members 104 are not generally parallel to each other. However, when elongate members are strongly divergent (i.e., form a wide angle) the configuration has less strength and may result in breakage of elongate members 104.

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As is illustrated in FIGs. I and, apparatus 100 includes at least three elongate members.

When fewer than three elongate members were tried, it was found stable and resting was therefore difficult. With three elongate members, as illustrated in FIGs., apparatus 100 is very stable and it has been found that as long as the length of the elongate members is generally the same, slight differences in length do not matter. With four elongate members, as is illustrated in FIG. 2, apparatus 100 is even more stable, although it has been found that a substantially uniform length of elongate members 104 is important. Therefore, there are relative advantages and disadvantages for each of the three "leg" and four "leg" embodiments is illustrated in FIGs. 1 and 2 respectively.

Referring now to FIG. 3, another embodiment of apparatus 100 includes a support member 106. In this embodiment, support member 106 is connected to the side of planar surface 102 that is opposite the side of planar surface 102 where elongate members 104 are connected. It has been found that by configuring support member 106 so that it extends in a generally opposite direction from the elongate members, a person can place or lean their back against the support member while resting. This has been shown to significantly enhance the resting and sitting experience. For this reason, support member 106 is also termed a "back".

For ease of description herein, the embodiment with only legs (FIGs. 1 and 2) is called a stool, and the embodiment with legs and a back (FIG. 3) is called a chair.

In normal sitting use, apparatus 100 is oriented as illustrated in FIGs. 1 and 2, with the elongate members below planar surface 102. In this configuration, the ends of elongate members I04 that are furthest from planar surface 102 contact the ground. This elevates planar surface 102 above the ground, and also positions planar surface 102 in a generally horizontal or parallel orientation to the ground.

In order for apparatus 100 to be most effective when used for sitting, there are certain preferred sizes or dimensions for planar surface 102 and elongate members 104. In one embodiment, the area of planar surface or seat 102 is generally about the same area as the area of an adult buttock. In one embodiment, the length of elongate members 104 is generally about the same distance from the knee to the ankle of the leg of an adult. This is one of the reasons for using the term "leg" to apply to elongate members 104. Of course, if apparatus 100 is constructed for use by children, the length of leg 104 may be somewhat shorter. The same considerations apply for the area of planar surface 102.

Although illustrative embodiments have been described herein in detail, it should be noted and will be appreciated by those skilled in the art that numerous variations may be made within the scope of this invention without departing from the principle of this invention and without sacrificing its chief advantages.

Unless otherwise specifically stated, the terms and expressions have been used herein as terms of description and not terms of limitations. There is no intention to use the terms or expressions to exclude any equivalents of features shown and described or portions thereof and this invention should be defined in accordance with the claims that follow.

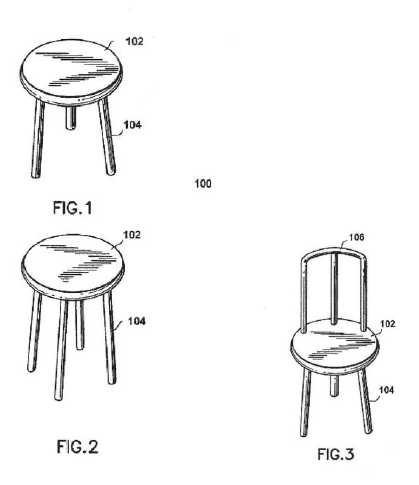
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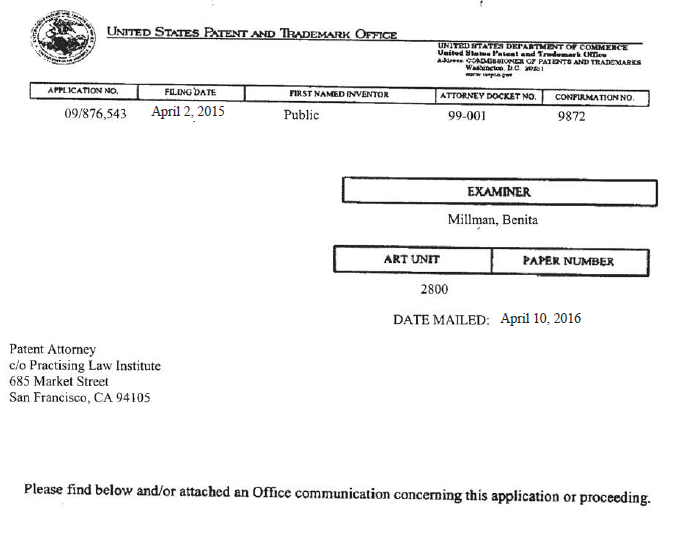
We claim:

1. An apparatus comprising: a substantially planar surface with a first and a second surface; and at least three elongate members, the members each having a first end and a second end, the first ends connected to the first surface of the planar surface and oriented with respect to the planar surface such that the elongate members are substantially perpendicular to the planar surface and the elongate members are substantially parallel to each other.
2. An apparatus according to claim 1, further comprising a support member connected to the second surface of the planar surface and oriented in a direction generally parallel to the elongate members.
3. An apparatus according to claim 1, further comprising exactly three elongate members.
4. An apparatus according to claim 1, further comprising exactly four elongate members.
5. An apparatus according to claim 1, wherein the planar surface and elongate members are wood.
6. An apparatus according to claim 1, wherein the length of each of the elongate members is approximately equal to the distance between the knee and the ankle of an adult human leg.
7. An apparatus according to claim 1, wherein the area of the planar surface is approximately equal to the area of the back surface of an adult human buttock.

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Text

Description automatically generated

##### DETAILED ACTION

***Claim Rejections* - *35 USC § 112***

The following is a quotation of 35 U.S.C. 112(b):

(B) CONCLUSION.---The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre -AIA ), second paragraph:

The specification shall conclude with one or more claim particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

* 1. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
  2. In Claim 1, the term "first ends" lacks antecedent basis.
  3. In Claim 1, the term "oriented with respect to" is unclear and indefinite.
  4. In Claim 6, the terms "the distance" and "the knee" and "the ankle" lack antecedent basis.

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***Claim Rejections – 35 USC§ 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country. more than one year prior to the date of application for patent in the United States.

Claim 1, 2, 4-7 are rejected under 35 USC 102(b) as anticipated by the Easy Chair Reference attached.

WRT Claim 1

* 1. To the extent definite, Claim 1 is anticipated by the Easy Living Chair shown in the printed publication attached to this Office Action ("Easy Chair Reference"). Claim 1 is anticipated by the Easy Chair Reference as a printed publication, as a public use bar and as being on sale more than 1 year before the priority date of May 28, 1998.
  2. The Easy Chair Reference discloses:

a substantially planar surface with a first and a second surface (Seat); and at least three elongate members (Legs),

the members each having a first end and a second end (Legs),

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the first ends connected to the first surface of the planar surface and oriented with respect to the planar surface such that the elongate members are substantially perpendicular to the planar surface (legs are perpendicular to seat); and

the elongate members are substantially parallel to each other (legs parallel to each other).

WRT Claim2

* 1. To the extent definite, claim 2 is anticipated by the Easy Chair Reference.

The Easy Chair Reference discloses:

a support member connected to the second surface of the planar surface and oriented in a direction generally parallel to the elongate members (Seat has a back).

WRT Claim 4

* 1. To the extent definite, claim 4 is anticipated by the Easy Chair Reference.

The Easy Chair Reference discloses:

exactly four elongate members (chair has four legs).

WRT Claim 5

* 1. To the extent definite, claim 5 is anticipated by the Easy Chair Reference.

The Easy Chair Reference discloses:

the surface and elongate members are wood (chair legs appear to be made of wood).

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WRT Claim 6

* 1. To the extent definite, claim 6 is anticipated by the Easy Chair Reference.

The Easy Chair Reference discloses:

the length of each of the elongate members is approximately equal to the distance between the knee and the ankle of an adult human leg (the chair looks to have the distance from the seat to the floor of the distance from a knee to an ankle).

WRT Claim 7

* 1. To the extent definite, claim 7 is anticipated by the Easy Chair Reference.

The Easy Chair Reference discloses:

the area of the planar surface is approximately equal to the area of the back surface of an adult human buttock (seat is size of human buttock).

***Claim Rejections* - *35 USC* § *103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

* 1. Claim 3 is rejected under 35 USC 103(a) as obvious in view of the Easy Chair Reference.
  2. The Easy Chair Reference discloses a chair with 4 legs. Claim 3 calls for a chair with:

exactly three elongate members.

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* 1. It would have been obvious for one skilled in the art at the time of this invention to remove a leg from the four legs of the Easy Chair Reference to come up with the three legs of the present invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benita Millman whose telephone number is 703-555- 1212. The examiner can normally be reached on Monday-Friday from 8:30AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, John Supervisor, can be reached on 703-555 -1213. The fax phone numbers for the organization where this application or proceeding is assigned are 703-555-1214

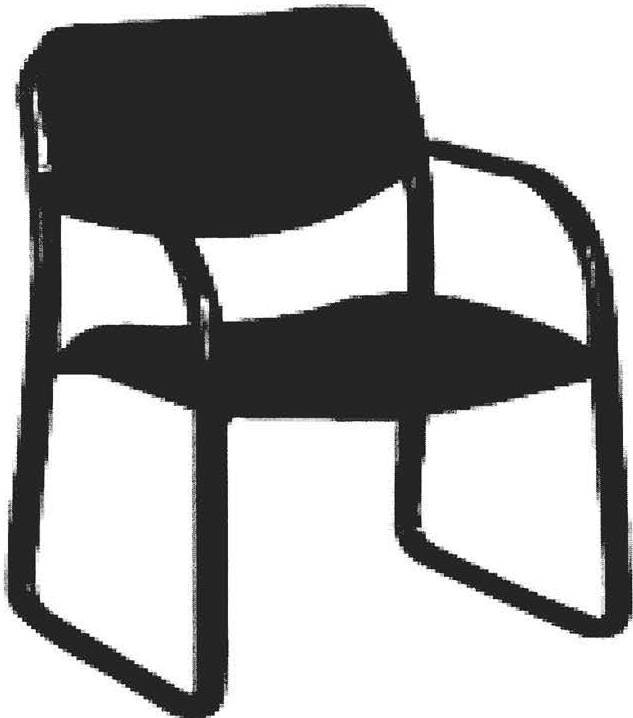
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-555- 1216.

Benita Millman Patent Examiner GAU 2800

April 10, 2016

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**EASY LIVING CHAIRS**



The EASYLIVING™ chair for your comfort. Best seller since 1995!

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| **SCIENCE** |

This Biotechnology Supplemental Problem is based on a theoretical Lyme disease vaccine based on an outer-membrane protein from the causative agent, *Borrelia burgdorferi*, which is transmitted by an infected tick bite. Symptoms can include arthritis, cardiac and neurological problems if left untreated. No FDA approved vaccine is currently available.

|  |  |
| --- | --- |
| Valneva banks $130M as Pfizer buys into Lyme disease vaccine program |  2020-04-30 | BioWorld |  |
| A  Shows a tick biting skin, delivering a load of *B. burgdorferi,* the causative agent of Lyme disease | B  Depicts the outer multilayer membrane of *B. burgdorferi*, including lipoproteins (e.g., OspA and OspA), which are important virulence factors that help the bacteria attach to and colonize host cells. |

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| **DIRECTIONS** |

Review (a) the specification (relevant portions); (b) the pending claims; and (c) the prior art, RefA, RefB, and RefC. Next, review and address by amendment and/or argument the following rejections: (I) indefiniteness; (II) patent eligibility; (III) written description and enablement; (IV) novelty based on RefA; and (V) non-obviousness over RefA in view of RefB and RefC.

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| **SPECIFICATION** |

***Title: IMPROVED VACCINE FOR LYME DISEASE***

***Background of the Invention***

Lyme disease has become an insidious epidemic in the United States. Caused by bacteria (*Borrelia burgdorferi*) transmitted by an infected tick bite, symptoms can include arthritis, cardiac and neurological problems if left untreated. It is the most common tick-borne illness in the United States, and the Centers for Disease Control and Prevention estimates that around 300,000 people likely contract the disease each year.

When a susceptible person is bitten by an infected tick, *B. burgdorferi* organisms enter the skin. The bacteria can then enter the circulatory system of the host and are spread to various organs, including the brain and joints. The spreading of the pathogen produces a variety of clinical syndromes, including myocarditis and chronic arthritis. In many patients, the infection of some tissues, particularly the brain and joints, persists for years and can be severely disabling. These forms of chronic Lyme disease are a consequence of the host's inability to rid itself of the infectious agent and perhaps the development of an autoimmune reaction.

In 1998, the FDA approved a new recombinant Lyme vaccine, LYMErix™, which reduced new infections in vaccinated adults by nearly 80%. Just 3 years later, the manufacturer voluntarily withdrew its product from the market amidst media coverage, reports of vaccine adverse effects, and declining sales due to the media’s reporting of ‘vaccine victims.’ Efforts continue today to create an improved human vaccine that avoids adverse effects while remaining sufficiently effective.

There remains today no approved vaccine to prevent Lyme disease. Although effective post-infection therapies for Lyme disease exist (e.g., antibiotics), prevention of infection remains the best approach as it eliminates the risk of infection-related long-term persistent effects of Lyme disease. Preventive measures include the following strategies: exposure reduction, post-tick bite prophylaxis, and vaccination.

A vaccine works by introducing (using a variety of means, e.g., vaccination with a dead or replication-deficient virus or bacteria or with a recombinant vaccine form that only express certain immunogenic parts of the pathogenic agent) proteins from the disease-causing agent into the body to trigger the body’s immune response, which includes making antibodies against bacterial proteins. Thus, vaccines stimulate an immune response to prevent future infections with the same microbe.

Successful development of a vaccine will require exquisite understanding the Lyme bacteria and its interaction with the human host.

*B. burgdorferi* spirochaetes are helically shaped, motile cells with an outer cell membrane that surrounds a protoplasmic cylinder complex, consisting of the cytoplasm, the cell wall, the inner cell membrane and the flagella which are located not at the cell surface but in the periplasmic space between the outer cell membrane and the protoplasmic cylinder. The outer cell membrane and the flagella are assumed to play an important role in the host-parasite interactions during the disease and has been subjected to several investigations, including the identification of major surface-exposed proteins as key immunogens.

It has been shown that the earliest antibodies formed against antigens of the *B. burgdorferi* are directed against a genus-specific flagellar polypeptide, termed flagellin. As the disease progresses, antibodies also form against other immunogens, especially against two abundant proteins known as OspA (31 kd) and OspB (34 kd), which are located on the surface of the Lyme bacteria, embedded in its outer cell membrane. The OspA protein varies significantly (e.g., in size) among different strains of the Lyme bacteria, but OspB is relatively conserved among strains. These surface proteins allow the bacteria to interact with the host and are thought to be a key driving force in the binding and colonization of host cells.

The failed Lyme vaccine mentioned above, LYMErix™, comprised OspA as its key active immunogen.

It would be desirable to provide individuals such as humans and animals with a broad protection against Lyme disease by means of immunization.

***Summary***

The present invention meets the abovementioned need in the art by providing a modified OspA-based vaccine for the immunization against Lyme disease that is based on the surprising finding that an amino acid region of OspA (amino acid residues 11-30 of SEQ ID NO: 1) results in unwanted hyper-immunogenic side-effects reported previously for LYMErix™, which was based on wildtype OspA. The inventors demonstrate for the first time that by removing residues 11-30 from wildtype OspA, the unwanted hyper-immunogenic side-effects reported for wildtype OspA were eliminated. In addition, the inventors demonstrated for the first time that the 11-30 amino acid epitope of OspA on its own was sufficiently immunogenic and could be used alone to generate a protective immune response against reinfection from *B. burgdorferi.* Lastly, the inventors also demonstrated that OspB could be modified by fusing it to the 11-30 amino acid epitope of OspA to create a chimeric OspB/OspA fusion protein that produced a stronger immune response than OspB alone.

The following amino acid sequences are part of the disclosure:

1. Wildtype OspA protein (274 AA):

**MKKYLLGIGL** **ILALIACKQN VSSLDEKNSV** **SVDLPGGMTV** LVSKEKDKDG

KYSLDATVDK LELKGTSDKN NGSGTLEGEK TDKSKVKLTI ADDLSQTKFE

IFKEDGKTLV SKKVTLKDKS STEEKFNEKG ETSEKTIVRA NGTRLEYTDI

KSDGSGKAKE VLKDFTLEGT LAADGKTTLK VTEGTVVLSK NILKSGEITV

ALDDSDTTQA TKKTGNWDSK SSTLTISVNS QKTKNLVFTK EDTITVQKYD

SAGTNLEGKA VEITTLKELK AALK (SEQ ID NO: 1)

1. Modified OspA protein: “OspA11-30” (which removes the red-bolded region above, corresponding to amino acid residues 11-30 of SEQ ID NO: 1. This deletion results in a modified OspA protein referred to herein as OspA11-30):

**MKKYLLGIGL SVDLPGGMTV** LVSKEKDKDG KYSLDATVDK LELKGTSDKN NGSGTLEGEK TDKSKVKLTI ADDLSQTKFE IFKEDGKTLV SKKVTLKDKS STEEKFNEKG ETSEKTIVRA NGTRLEYTDI KSDGSGKAKE VLKDFTLEGT LAADGKTTLK VTEGTVVLSK NILKSGEITV ALDDSDTTQA TKKTGNWDSK SSTLTISVNS QKTKNLVFTK EDTITVQKYD SAGTNLEGKA VEITTLKELK

AALK (SEQ ID NO: 2).

1. The linear OspA epitope

**ILALIACKQN VSSLDEKNSV** (SEQ ID NO: 3).

1. OspB/OspA11-30 chimeric protein:

MRLLIGFALA LALIGCAQKG AESIGSQKEN DLNLEDSSKK SHQNAKQDLP

AVTEDSVSLF NGNKIFVSKE KNSSGKYDLR ATIDQVELKG TSDKNNGSGT

LEGSKPDKSK VKLTVSADLN TVTLEAFDAS NQKISSKVTK KQGSITEETL

KANKLDSKKL TRSNGTTLEY SQITDADNAT KAVETLKNSI KLEGSLVGGK

TTVEIKEGTV TLKREIEKDG KVKVFLNDTA GSNKKTGKWE DSTSTLTISA

DSKKTKDLVF LTDGTITVQQ YNTAGTSLEG SASEIKNLSE LKNALK**SGGS**

**GGSGGSGGIL ALIACKQNVS SLDEKNSV** (SEQ ID NO: 4)

Key: blue font – OspB; orange font – linker; red font – OspA11-30

1. OspB:OspA:OspB (1:2 ratio chimeric protein):

MRLLIGFALA LALIGCAQKG AESIGSQKEN DLNLEDSSKK SHQNAKQDLP

AVTEDSVSLF NGNKIFVSKE KNSSGKYDLR ATIDQVELKG TSDKNNGSGT

LEGSKPDKSK VKLTVSADLN TVTLEAFDAS NQKISSKVTK KQGSITEETL

KANKLDSKKL TRSNGTTLEY SQITDADNAT KAVETLKNSI KLEGSLVGGK

TTVEIKEGTV TLKREIEKDG KVKVFLNDTA GSNKKTGKWE DSTSTLTISA

DSKKTKDLVF LTDGTITVQQ YNTAGTSLEG SASEIKNLSE LKNALK**SGGS**

**GGSGGSGGIL** MKKYLLGIGL **ILALIACKQN VSSLDEKNSV** SVDLPGGMTV

LVSKEKDKDG KYSLDATVDK LELKGTSDKN NGSGTLEGEK TDKSKVKLTI

ADDLSQTKFE IFKEDGKTLV SKKVTLKDKS STEEKFNEKG ETSEKTIVRA

NGTRLEYTDI KSDGSGKAKE VLKDFTLEGT LAADGKTTLK VTEGTVVLSK

NILKSGEITV ALDDSDTTQA TKKTGNWDSK SSTLTISVNS QKTKNLVFTK

EDTITVQKYD SAGTNLEGKA VEITTLKELK AALK**SSGGSG GSGGSGGILG**

MRLLIGFALA LALIGCAQKG AESIGSQKEN DLNLEDSSKK SHQNAKQDLP

AVTEDSVSLF NGNKIFVSKE KNSSGKYDLR ATIDQVELKG TSDKNNGSGT

LEGSKPDKSK VKLTVSADLN TVTLEAFDAS NQKISSKVTK KQGSITEETL

KANKLDSKKL TRSNGTTLEY SQITDADNAT KAVETLKNSI KLEGSLVGGK

TTVEIKEGTV TLKREIEKDG KVKVFLNDTA GSNKKTGKWE DSTSTLTISA

DSKKTKDLVF LTDGTITVQQ YNTAGTSLEG SASEIKNLSE LKNALK (SEQ ID NO: 5)

Key: blue font – OspB; orange font – linker; black font – wildtype OspA (with red font showing the OspA11-30 linear epitope)

Accordingly, the present invention relates to at least three new vaccines: (1) a modified OspA protein that is deleted in the linear epitope of amino acids 11-30 of the wildtype sequence, (2) the linear OspA epitope itself; and (3) a chimeric protein comprising a fusion of OspB and the linear OspA epitope. The inventors also developed the OspB:OspA:OspB chimeric fusion protein, shown in Example 1. The present disclosure includes experimental data showing that each new composition is immunogenic when injected into animal models, and some result in the production of antibodies that bind to and neutralize *B. burgdorferi* activity *in vitro*, and some produce a lasting immunity in animal models (e.g., dog) for Lyme disease.

***Detailed Description***

In a first aspect, the present invention relates to an immunogenic composition comprising an immunologically effective amount of a modified OspA polypeptide of SEQ ID NO: 2, which comprises a deletion in the linear epitope of amino acids 11-30 relative to the wildtype OspA protein of SEQ ID NO: 1.

In a second aspect, the present invention relates to an immunogenic composition comprising an immunologically effective amount of an OspA polypeptide immunogenic fragment of SEQ ID NO: 3, which comprises the linear epitope of amino acids 11-30 relative to the wildtype OspA protein of SEQ ID NO: 1.

In a third aspect, the present invention relates to an immunogenic composition comprising an immunologically effective amount of a chimeric polypeptide of SEQ ID NO: 4, which comprises an OspB polypeptide fused to the above-described immunogenic fragment of OspA, which comprises the linear epitope of amino acids 11-30 relative to the wildtype OspA protein of SEQ ID NO: 1.

In a fourth aspect, the present invention relates to an immunogenic composition comprising an immunologically effective amount of a chimeric polypeptide of SEQ ID NO: 5, which comprises an OspB fused to the N-terminus of OspA, which is then fused at its C-terminus to another subunit of OspB.

In a fifth aspect, the present invention relates to an immunogenic composition comprising a mixture of OspA proteins from different strains of *B. burgdorferi*. The level of immunogenicity of the combined mixture of OspA proteins is synergistically increased relative to the level of immunogenicity of either protein alone. The sequences are not identical.

The present disclosure also describes the following aspects in detail (not shown here):

1. Methods for making and purifying the three classes of recombinant immunogenic proteins of SEQ ID NO: 2, 3, 4, and 5;
2. Methods for generating antibodies against each of the three recombinant immunogenic proteins in mouse models;
3. Methods for evaluating the generated antibodies from the mouse models as to their ability to neutralize the activity of *B. burgdorferi* activity *in vitro*; and
4. Methods for testing whether the three classes of recombinant immunogenic proteins of SEQ ID NO: 2, 3, 4, and 5 are capable of producing a lasting immunity in animal models for Lyme disease;
5. Compositions and methods for making and using effective amounts of the immunogenic proteins described herein in vaccine compositions for use in immunizing against Lyme disease in humans;
6. Methods for vaccinating humans against Lyme disease;
7. Data showing that by combining naturally occurring OspA proteins from different strains of *B. burgdorferi*, one can synergistically increase the immunogenicity of either OspA administered alone.

***Examples***

**Example 1. OspA is naturally complexed with OspB in the outer membrane of *B. burgdorferi*; construction of OspB:OspA:OspB fusion (SEQ ID NO: 5)**

The inventors conducted one or more experiments that demonstrated for the first time that the outer membrane proteins, OspA and OspB, form a dual-protein complex in *B. burgdorferi*. They do not exist separate from one another in nature, at least not in a stable form.

The inventors further constructed a chimeric fusion protein between OspA and OspB in a 1:2 ratio, i.e., wherein said fusion protein comprises an OspA protein with an OspB polypeptide fusion to the N-terminus of OspA and a second OspB polypeptide fused to C-terminus of OspA (OspB:OspA:OspB). See SEQ ID NO: 5, above. The chimeric protein was shown to produce neutralizing antibodies against the Lyme disease agent. This result was surprising since an OspA:OspB fusion protein (1:1 ratio) did not produce neutralizing antibodies.

**Example 2. Deletion of residues 11-30 from OspA reduces the adverse effects of wildtype OspA**

The inventors conducted an experiment that demonstrated for the first time that by removing residues 11-30 from wildtype OspA, the unwanted hyper-immunogenic side-effects reported for wildtype OspA were eliminated in an animal model of Lyme disease.

The inventors also examined whether an overlapping series of amino acid regions 31-40, 45-60, 55-72, 68-80, 75-100, 140-165, 152-180, and 220-242 would similarly reduce the hyper-immunogenic side-effects associated with wildtype OspA. None of these other regions had the desired effect.

**Example 3. Administering the linear OspA epitope induces immunogenic response in animal models**

The inventors conducted an experiment that demonstrated for the first time that residues 11-30 from wildtype OspA (i.e., the linear OspA epitope), when administered to a mouse model, produced an immune response specific for the OspA11-30 fragment. No measurable unwanted hyper-immunogenic side-effects were observed.

**Example 4. Isolated linear OspA epitope elicits *B. burgdorferi* neutralizing antibodies**

The inventors isolated antibodies against the OspA11-30 fragment from the blood of the animals from Example 3 and tested their ability to neutralize the ability of the linear OspA epitopeto produce an immune response in animals. The inventors showed that mice administered two doses of neutralizing antibody prior to exposure to linear OspA epitopedid not produce a detectable immune response against the fragments.

**Example 5. Chimeric protein comprising wildtype OspB fused at its C-terminus to the** l**inear OspA epitope produced an immunogenic response, including the formation of *B. burgdorferi* neutralizing antibodies**

The inventors conducted an experiment that compared the immunogenicity in mice of the wildtype OspB protein with that of the modified OspB fused at its C-terminus to the linear OspA epitope**.** The chimeric fusion protein (SEQ ID NO: 4) produced an immune response in the test mice that was on average 80% higher than the immune response of OspB alone, suggesting that the linear OspA epitopewas capable of enhancing the immunogenicity of OspB. In addition, the inventors isolated antibodies from the blood of the mice that were capable of neutralizing the immunogenicity of the either the OspB wildtype protein or the chimeric protein. No measurable unwanted hyper-immunogenic side-effects were observed.

**Example 6. Immunogenic composition comprising OspA11-30 produces a protective immune response *in vivo* against reinfection by *B. burgdorferi* in dogs without unwanted hyper-immunogenic side-effects**

The inventors prepared immunogenic compositions comprising OspA11-30 by combining an effective amount of the variant OspA protein with one or more standard pharmaceutical vaccine formulations. The inventors also prepared control immunogenic compositions comprising a wildtype OspA and another containing wildtype OspB. The compositions were tested in dogs to determine whether they were protective against infection by the Lyme agent. The experiments showed that the variant OspA11-30 composition produced a protective effect when the animals were reinfected with the Lyme agent up through the period of testing of 6 months. No measurable unwanted hyper-immunogenic side-effects were observed.

The inventors plan to conduct the same experiments with the OspA linear epitope and the chimeric OspB-OspA protein to determine whether these proteins are capable of establishing a protective effect *in vivo* in dogs. Given that both protein variants were shown to produce neutralizing antibodies in mice, and that the OspA11-30 variant produced a protective effect in dogs, the inventors predict that both the OspA linear epitope and the chimeric OspB-OspA protein will provide a protective effect in dogs.

The results from Examples 2-6 are summarized, as follows:

|  |  |  |
| --- | --- | --- |
| **Immunogenic composition** | **Results** | **Interpretation** |
| **Control – OspA**  **SEQ ID NO: 1** | Immune response + neutralizing antibodies + hyperimmune response in mice | Like LYMErix™, this composition was immunogenic and produced neutralizing antibodies, but resulted in a hyperimmune response. Poor vaccine candidate |
| **Control – OspB**  **SEQ ID NO: 6** | Low immune response; no neutralizing antibodies | Poor vaccine candidate |
| **OspA11-30 variant**  **SEQ ID NO: 2** | Strong immune response; production of neutralizing antibodies; no hyperimmune response in mice; protects against infection by Lyme agent in dogs *in vivo*. No measurable unwanted hyper-immunogenic side-effects were observed. | Good vaccine candidate |
| **11-30 OspA fragment**  **SEQ ID NO: 3** | Strong immune response; production of neutralizing antibodies. Protective effect to be tested and confirmed in dogs. | Potentially good vaccine candidate but further testing needed to show protection effect *in vivo* |
| **chimeric OspB: OspA11-30**  **SEQ ID NO: 4** | Strong immune response; production of neutralizing antibodies. Protective effect to be tested and confirmed in dogs. | Potentially good vaccine candidate but further testing needed to show protection effect *in vivo* |
| **chimeric OspB:OspA:OspB**  **SEQ ID NO: 5** | Strong immune response; production of neutralizing antibodies. Protective effect to be tested and confirmed in dogs. | Potentially good vaccine candidate but further testing needed to show protection effect *in vivo* |

**Example 7. Immunogenic composition comprising a 1:2 ratio of OspA proteins from *B. burgdorferi* strain Groton and strain New London results in improved immunogenicity with minimal levels of unwanted immunological side-effects. (i.e., a mixture of two different OspA proteins)**

The inventors showed that by isolating and combining OspA proteins from different strains of *B. burgdorferi*, the level of immunogenicity of the combined mixture of OspA proteins is synergistically increased relative to the level of immunogenicity of either protein alone. The sequences are not identical. The resulting composition produced neutralizing antibodies in mice and a stronger protective effect against infection by the Lyme agent *in vivo* in dogs which was at least 45% greater than administering either protein alone. In addition, the combination of wildtype OspA proteins from different strains reduced the level of unwanted hyperimmune response side-effects in mice and dogs. These results were not expected and could not be predicted.

These results are summarized, as follows:

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| --- | --- | --- |
| **Immunogenic composition** | **Results** | **Interpretation** |
| **Control – OspA – strain 1** | Immune response + neutralizing antibodies + hyperimmune response in mice | Like LYMErix™, this composition was immunogenic and produced neutralizing antibodies, but resulted in a hyperimmune response. Poor vaccine candidate |
| **Control – OspA – strain 2** | Immune response + neutralizing antibodies + hyperimmune response in mice | Like LYMErix™, this composition was immunogenic and produced neutralizing antibodies, but resulted in a hyperimmune response. Poor vaccine candidate |
| **OspA (strain 1) : OspA (strain 2) in a 1:2 ratio** | Strong immune response; production of neutralizing antibodies; no hyperimmune response in mice or dogs; protects against infection by Lyme agent in dogs *in vivo* at a level that was at least 45% greater than either OspA protein alone | Good vaccine candidate |

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| **EXAMINED CLAIMS** |

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| Original Claims | Rejected under |
| 1. A vaccine comprising:  a minimal concentration of an outer membrane protein from *B. burgdorferi*; and  an immunologically acceptable carrier or vehicle. | § 112-I  § 112-WD  § 112-E  § 102 |
| 2. The vaccine of claim 1, wherein the outer membrane protein is OspA or immunogenic variant or fragment thereof. | § 112-E  § 102 |
| 3. The vaccine of claim 2, wherein the OspA comprises SEQ ID NO: 1. | § 102 |
| 4. The vaccine of claim 2, wherein the immunogenic variant comprises a deletion corresponding to amino acids 11-30 of SEQ ID NO: 1. | § 103 |
| 5. The vaccine of claim 2, wherein the immunogenic variant of OspA comprises a fusion between OspA and OspB. | § 112-E  § 112-WD  § 103 |
| 6. The vaccine of claim 2, wherein the immunogenic fragment of OspA comprises SEQ ID NO: 3. | § 103 |
| 7. The vaccine of claim 1, wherein the outer membrane protein is OspA. | § 112-WD  § 112-E  § 102 |
| 8. A vaccine composition comprising substantially isolated OspA or variant or fragment thereof. | § 101  § 102 |
| 9. A vaccine composition comprising substantially pure OspA from two or more strains of *Borrelia burgdorferi* and an immunologically acceptable carrier or vehicle. | § 101 |
| 10. A method of inducing a protective immunological response against *Borrelia burgdorferi* in an animal or human susceptible to Lyme disease comprising administering the vaccine of any one of claims 1-7 to the animal or human in an amount effective to induce the protective immunological response. | § 112-E  § 102 |
| 11. A method for producing a vaccine containing a substantially pure OspA protein comprising recovering the OspA protein from a host organism transformed with a vector containing DNA encoding the OspA protein, and admixing the OspA protein with an immunologically acceptable carrier or vehicle. | § 102 |

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| **PRIOR ART** |

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| RefA | Scientific journal article that teaches that the failed 1998 OspA FDA vaccine, LYMErix™, was due to the presence of a linear epitope corresponding to residues 211-240 of the wildtype OspA protein. This particular epitope was shown to be associated with an autoimmune response because of its similarity to a native human protein having the same sequence as the OspA epitope.  RefA does not teach that region 11-30 of OspA could similarly reduce the unwanted immunogenic/autoimmunogenic effects of OspA.  RefA does not teach that region 11-30 could alone be used as an immunogenic composition.  RefA does not teach that region 11-30 could be used in combination with OspB as a chimeric protein to increase the immunogenic effect of OspB alone. |
| RefB | Teaches in general that the use of recombinant chimeric outer membrane proteins from bacteria can be a suitable strategy to develop anti-bacterial vaccines because the chimeric nature can produce an enhanced immunogenicity relative to either protein alone.  Also teaches that short amino acid regions in outer membrane proteins can be associated with hyper-immunogenic responses and removal of such regions can result in the reduction of unwanted hyper-immunogenic side-reaction of vaccines comprising said modified outer membrane proteins.  RefB does not specifically teach *Borrelia* or Lyme disease vaccine development.  RefB does not specifically teach OspB, or a chimeric version of OspB. Does not teach the OspB and OspA can be prepared as a chimeric protein or that the immunogenicity of OspB can be improved by fusing it to OspA or a region thereof. |
| RefC | Teaches that a human protein, LFA-2, comprises a domain having a sequence that is 90% similar to region 11-30 of OspA and that said domain is linked with an autoimmune condition associated with LFA-2 in certain individuals. |

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| **REJECTION (1): INDEFINITENESS** |

**Claim 1**

Claim 1 has been rejected under 35 U.S.C. 112(b) as the term “minimal concentration” is indefinite. The term “minimal” is a relative term.

Claim 1 has been rejected under 35 U.S.C. 112(b) as the term “non-reactive” is indefinite. The meaning of the term “non-reactive” is unclear. Is the non-reactivity relative to *in vitro* conditions or *in vivo* conditions? What is considered to be non-reactive? Non-reactive is not generally a term recognized in the context of the claimed technology.

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| **REJECTION (2): PATENT ELIGIBILITY** |

**Claim 8**

Claim 8 is rejected under 35 U.S.C. § 101 as being directed to a naturally occurring product. Under the *Alice/Mayo* test, claim 8 recites a naturally occurring substance, i.e., “OspA.” The claim does not recite any additional feature that suggests that the OspA recited in the claim is substantially different than OspA occurring in nature. The fact that the claim specifies the OspA is “isolated” does not overcome the rejected since even isolated OspA would be the same as OspA occurring in nature. Since 35 U.S.C. § 101 precludes an Applicant from claiming a naturally occurring product, claim 8 stands rejected.

**Claim 9**

Claim 9 is rejected under 35 U.S.C. § 101 as being directed to a naturally occurring product. Under the *Alice/Mayo* test, claim 9 recites a naturally occurring substance, i.e., OspA from two strains of *Borrelia burgdorferi.* The claim does not recite any additional feature that suggests that the OspA recited in the claim is substantially different than OspA occurring in nature. The fact that the claim specifies the OspA is “substantially pure” does not overcome the rejected since even substantially pure OspA would be the same as OspA occurring in nature. Since 35 U.S.C. § 101 precludes an Applicant from claiming a naturally occurring product, claim 9 stands rejected.

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| **REJECTION (3): WRITTEN DESCRIPTION/ENABLEMENT** |

**Claim 1 (written description)**

Claim 1 is rejected as lacking written description for the term “outer membrane protein” for being overly broad and lacking appropriate support over the entire scope of the term. The specification only teaches OspA and OspB, and variants and fragments thereof.

**Claims 1-9 (enablement)**

Claims 1-9 are rejected as lacking enablement since the specification fails to teach a vaccine over the full scope of the claim. Only OspA comprises SEQ ID NO: 1 was shown to produce a protective effect in dogs. All disclosed variants were shown, however, to produce an immune response. The Examiner suggests the term “immunogenic composition” be used in place of “vaccine.”

**Claim 10 (enablement)**

Claim 10 is rejected as lacking enablement since the specification fails to teach a composition that induces a protective immunological response over the full scope of the claim. Only OspA comprising SEQ ID NO: 2 was shown to produce a protective effect in dogs. All disclosed variants were shown, however, to produce an immune response.

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| **REJECTION (4): NOVELTY BASED ON REF-A** |

**Claims 1, 2, 3, 7, 8, 10, and 11**

Claims 1, 2, 3, 7, 8, 10, and 11 are rejected under 35 U.S.C. 102 as lacking novelty in view of RefA. RefA discloses OspA is produced by the Lyme disease spirochetes, *B. burgdorferi*. RefA also reports that vaccination with substantially pure OspA elicits antibody (Ab) that can target spirochetes in the tick midgut during feeding and inhibit transmission to mammals. RefA further reports that OspA was the primary component of the human LYMErix vaccine available from 1998-2002, which was pulled from the market out of concern of adverse effects. The authors postulate that a segment of OspA shares a region of similarity to human LFA-1 protein and may trigger putative autoimmune events. The authors report that a linear epitope corresponding to amino acid residues 221-240 of wildtype OspA lacks the OspA region suggested to elicit autoimmunity. The authors further report that this fragment or peptide was immunogenic in mice and displayed antibody-mediated bactericidal activity. The RefA discloses OspA has the amino acid sequence of SEQ ID NO: 1.

Accordingly, RefA teaches a vaccine comprising a minimal concentration of an outer membrane protein from *B. burgdorferi*; and an immunologically acceptable carrier or vehicle (claim 1), that the outer membrane protein can be OspA or a variant or fragment of OspA (claim 2), that the OspA is the same as the wildtype sequence SEQ ID NO: 1 (claim 3), that the outer membrane protein is specifically OspA (claim 7), a vaccine composition with “substantially pure” OspA (claim 8), a method of vaccinating or inducing a protective response in an animal with a vaccine of claims 1-7 (claim 10), and the method of making a vaccine of claim 11.

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| **REJECTION (5): OBVIOUSNESS BASED ON REF-A IN VIEW OF REF-B** |

**Claims 4 and 6**

Claims 4 and 6 are rejection under 35 U.S.C. 103 as being obvious over RefA in combination with RefB in further view of RefC. RefA teaches a vaccine comprising an outer membrane protein which is OspA or an immunogenic variant or fragment thereof because it teaches the OspA-based LYMErix vaccine and/or a vaccine using the OspA linear epitope of amino acid residues 221-240 of OspA. However, RefA fails to teach the specific subject matter of claim 4 (and which is reflected in the sequence of claim 6), namely an OspA variant having a deletion corresponding to amino acids 11-30 of SEQ ID NO: 1 (wildtype OspA). RefB makes up for this deficiency because it teaches that short amino acid regions in outer membrane proteins can be associated with hyper-immunogenic responses and removal of such regions can result in the reduction of unwanted hyper-immunogenic side-reaction of vaccines comprising said modified outer membrane proteins. RefB would have motivated a person having ordinary skill in the art to modify OspA by removing amino acid regions 11-30 of SEQ ID NO: 1, particularly in further view of RefC which teaches that a similar peptide region of the human protein, LFA-2, is linked with an autoimmune condition associated with LFA-2 in certain individuals. The person of ordinary skill in the art would have had a reasonable expectation of success that the modified OspA protein with the deletion of amino acids 11-30 would have produced a viable vaccine with reduced hyper-immunogenicity because removal of a similar region from a human protein (LFA-2) resulted in reduced occurrence of the autoimmune condition associated with wildtype human LFA-2 in certain individuals. According, claim 4 and 6 are not patentable because they would have been obvious.

**Claim 5**

Claim 5 is rejected under 35 U.S.C. 103 as being obvious over RefA in combination with RefB. RefA teaches a vaccine comprising an outer membrane protein which is OspA or an immunogenic variant or fragment thereof because it teaches the OspA-based LYMErix vaccine and/or a vaccine using the OspA linear epitope of amino acid residues 221-240 of OspA. However, RefA fails to teach an immunogenic variant of OspA comprising a fusion between OspA and OspB. RefB teaches in general that the use of recombinant chimeric outer membrane proteins from bacteria can be a suitable strategy to develop anti-bacterial vaccines because the chimeric nature can produce an enhanced immunogenicity relative to either protein alone. It would have been obvious based on the general teachings and motivations of RefB to modify the OspA protein from RefA with OspB, which was also known in the art at the time of the invention. RefB provides motivation because it suggests that chimeric proteins can have enhanced immunogenicity. The skilled person would have also had a reasonable expectation of success based on the teachings of RefB.

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PLI Software (Computer Science) Supplemental Problem

SUBJECT MATTER ELIGIBIILITY

Your client has a patent application covering an invention directed to a new way to identify and analyze behavioral data of livestock animals, such as dairy cattle. Broadly, the invention regards identifying animals with aberrant behavior. In specific embodiments, animals that are identified with aberrant behavior are separated from the herd by a gating system or treated with a modified diet intended to address disease of which the aberrant behavior is a symptom.

You have received an Office Action from the Patent Office that rejects the claims for defining subject matter that is not eligible for patent protection on the grounds of being abstract. You have reported the Office Action to your client and received the following instructions.

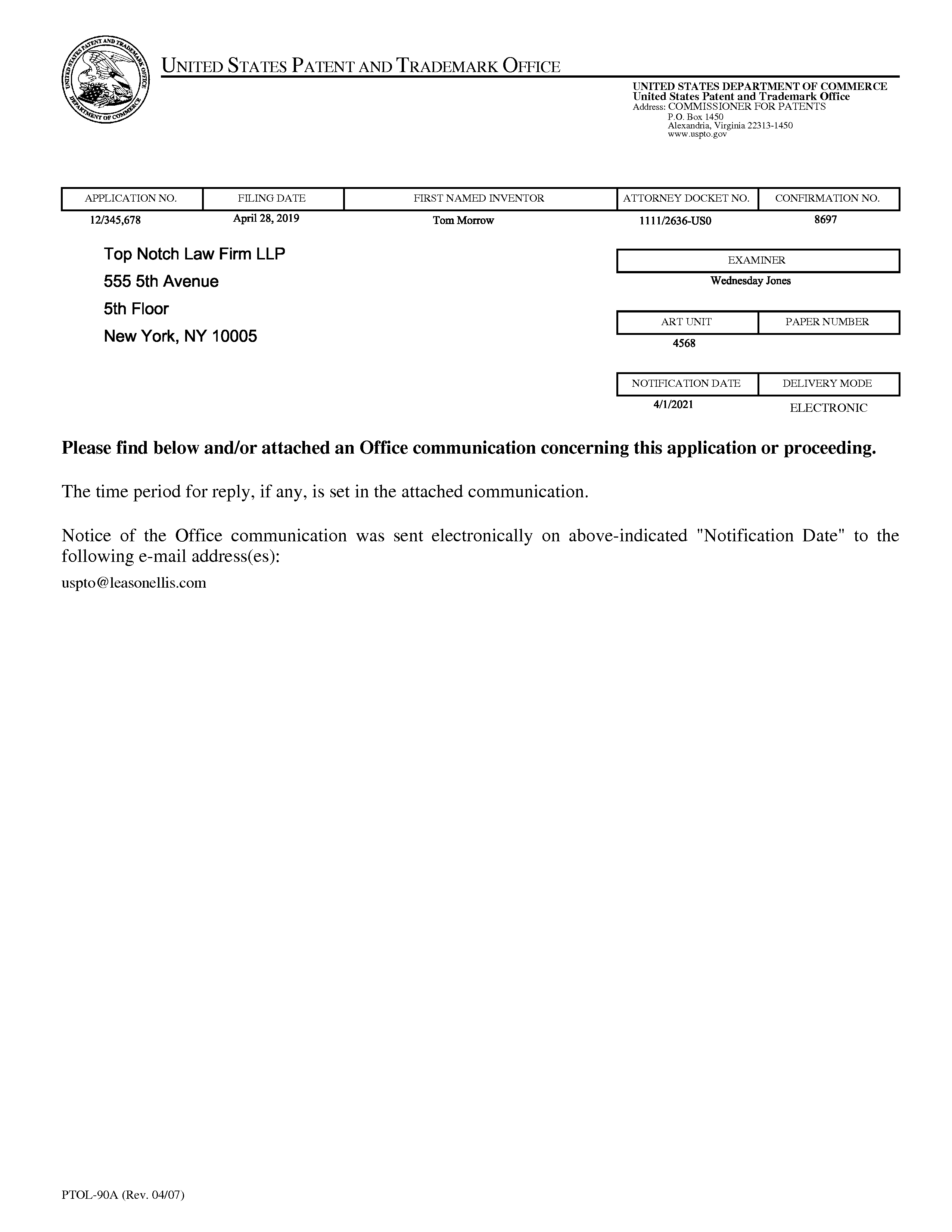
“We disagree with the Examiner that the invention is abstract, however, this is an important invention and we would like the application allowed.

In our view, at least the additional features of dispensing feed that includes supplement goes far beyond an abstract idea. Please prepare a draft amendment and response that covers this for our review.

In addition, we would like you to pursue broader scope, since we view the inclusion of dispensing feed as very narrow. To that end, please also include in the draft amendment at least one claim that includes the blockchain technology that our invention uses. As you are aware, our herd database is implemented on a blockchain, which we believe also extends beyond abstract subject matter.

Thank you.”

Prepare the draft amendment and response to the Office Action using the Office Action Response Template.



PTOL-90A (Rev. 04/07)

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***Claim Rejections - 35USC§101***

11. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or

composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

**Claims 1-8** are rejected under 35 U.S.C. 101 because the claimed invention is directed to a judicial exception (i.e., a law of nature, a natural phenomenon, or an abstract idea) without significantly more.

Under the USPTO October Update, a claim recites a judicial exception when such an exception is explicitly set forth or implicitly described in the claim. Two steps, Step 1 and Step 2, are applied in the analysis to determine when a claim recites a judicial exception.

Based on this interpretation, the USPTO finds that combination of limitations in the claims are an observation and an evaluation, respectively. Thus, they are acts that can be practically performed in the human mind, and fall within the mental processes category of abstract ideas. Further, the recitation of a processor in this claim does not negate the mental nature of these limitations because the claim here merely uses the processor as a tool to perform the otherwise mental processes.

Applying step 2A(i), the USPTO finds that the claims recite the abstract idea of performing an evaluation. This evaluation of “whether the particular animal is exhibiting an aberrant behavioral pattern, wherein the analysis is performed by comparing the accessed animal data representing past behavior of the particular animal with the obtained animal-specific data” could practically be performed in the human mind by observing the animal.

Moving on to step 2A(ii), the USPTO identifies the additional elements as the memory, the display, the processor, the livestock interface, and limitation (c). The first three of these elements are rapidly dismissed as being non-substantive for purposes of the § 101 analysis, because they represent no more than mere instructions to apply the judicial exception on a computer and nothing more than an attempt to generally link the use of the judicial exception to the technological environment of a computer.

Additionally, the USPTO finds that the livestock interface is just insignificant extra-solution activity because it is used for data gathering and is recited at a high level of generality. The remaining limitations only perform the necessary software tasks so that the result of the abstract mental process is displayed. Thus, the additional elements, when considered in isolation, do not integrate the abstract idea into a practical application.

The step 2A(ii) analysis also requires considering the additional elements in combination with one another and the rest of the claim. The claim as a whole does no more than automate the mental processes that the farmer used to perform (e.g., the mental inspection and evaluation of the livestock animals' behavior), using the computer components as a tool. Notably, while this type of automation improves the daily life of farmers (by minimizing or eliminating the need for mentally evaluating the behavior of livestock animals), there is no change to the computers and other technology that are recited in the claim as automating the abstract ideas, and thus this claim cannot improve computer functionality or other technology. Therefore, the claim fails to integrate the abstract idea.

Step 2B proceeds similarly as that of step 2A(ii). The memory, display, and processor are at best the equivalent of merely adding the words “apply it” to the judicial exception. The livestock interface and limitation (c) are still extra-solution activity. Accordingly, even when considered in combination, these additional elements represent mere instructions to apply an exception and insignificant extra-solution activity, which cannot provide an inventive concept.

As a consequence, independent claims 1 and 7 are ineligible for patent protection under 35 U.S.C. 101.

Since claims 2, 3, 4, 5, 6, and 8 incorporate all elements of claim 1 or claim 7 and two of those incorporated elements have already been found to recite an abstract idea, claim 2, 3, 4, 5, 6, and 8 also recite an abstract idea.

When viewed as a whole, the claims do not include additional limitations that are sufficient to amount to significantly more than the judicial exception because the claims recite processes that are routine and well-understood in the art, which is not enough to qualify as "significantly more" as described herein. Specifically, the claims do not include additional limitations that are sufficient to amount to significantly more than the judicial exception because the additional limitations merely represent insignificant, conventional extra-solution activities well-understood in the industry. These merely encompasses the abstract ideas similar to court identified abstract ideas in Alice, Bilski or Perkin-Elmer and Electric Power Group, and do not, when either view alone or in an ordered combination, add anything significantly more than the abstract idea(s).

Thus, taken alone, the additional elements do not amount to significantly more than the above- identified judicial exception (the abstract idea). Looking at the limitations as an ordered combination adds nothing that is not already present when looking at the elements taken individually. There is no indication that the combination of the elements improves the functioning of a computer or improves any other technology. Their collective functions merely provide conventional computer implementation.

Therefore, claims 1-8 are therefore not drawn to eligible subject matter as they are directed to an abstract idea without significantly more.

***Conclusion***

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **Wednesday Jones**, whose telephone number is 987.654.3210. The Examiner can normally be reached on Monday-Friday, 9:30am-5:00pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Chester Day, can be reached at 986.321.5896.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866.217.9197 (tollfree).

**/WEDNESDAY JONES/**

Primary Examiner, Art Unit 4568

31 March 2021

**Livestock Management SYSTEM AND METHOD**

**Field**

1. The present disclosure relates, generally, to data management and, more particularly, to processing data associated with behavior of livestock animals in response to environment and

physiological conditions.

**Background**

1. Monitoring the behavior of livestock animals such as dairy cattle in response to environment and physiological conditions can provide vital clues as to their general health. Traditionally, farmers have monitored livestock animal behavior by physically and visually inspecting the animals during regular intervals. These traditional practices, however, are labor intensive and require the farmer to remain in close physical proximity to the herd. Further, by the time that an animal’s behavior is immediately identifiable as aberrant by such physical or visual inspection, the animal is often in significant distress and it may be difficult or impossible to quickly return the animal to optimal health.
2. For instance, grass tetany is a serious and sometimes fatal nutritional deficiency associated with low magnesium levels and/or poor magnesium absorption. Grass tetany often manifests in late winter and early spring, particularly in pasturage that contains high levels of potassium. Early signs of grass tetany may be non-specific, e.g., the affected cow may leave the herd, stop eating, or be more restless or excitable than normal. As the disorder progresses, the symptoms become more noticeable and specific to grass tetany, e.g., a combination of muscle twitching, convulsions, frequent urination, lying down and standing up repeatedly, and/or excessive chewing. When detected early, a cow affected with grass tetany often recovers when provided with a therapeutically effective amount of supplemental salt and minerals, or in some cases, more invasive treatment such as intravenous magnesium solutions. Unfortunately, grass tetany often is not detected until an advanced stage, for example, because early signs of the deficiency are non-specific, and farmers cannot visually inspect and evaluate the behavior of each animal in the herd on a continual basis.
3. It is with respect to these and other considerations that the disclosure made herein is presented.

**Brief Summary**

1. In one or more implementations, a system and method provide for monitoring health and activity in animals. A computing device includes a processor, a memory, and a display, and the processor is configured by executing instructions stored on the memory. In particular, the processor is configured to obtain, via a livestock interface, animal-specific data that include information representing an identification of a particular animal in a herd. The processor is further configured to obtain information representing at least one of the particular animal’s i) body position, ii) body temperature, iii) feeding behavior, and iv) a movement pattern. Moreover, the processor is configured to access, from a herd database, animal data that include information representing identities and past behaviors of animals in the herd. The processor is configured to compare the obtained animal-specific data with the accessed animal data to determine the particular animal’s identity. In addition, the processor is configured to perform an analysis to determine whether the particular animal is exhibiting an aberrant behavioral pattern. The analysis is performed by comparing the accessed animal data representing past behavior of the particular animal with the obtained animal-specific data. Thereafter, the processor is configured to display, on the display, information representing a result of the analysis.
2. In one or more implementations, the system and method include a feed dispenser that includes a feed and supplement supply. The feed dispenser is further operable to dispense individualized amounts of feed and optional supplements. The processor is further configured by executing the instructions to automatically send a control signal to the feed dispenser to dispense a therapeutically effective amount of supplemental salt and minerals mixed with feed, when the result of the analysis indicates that the animal is exhibiting an aberrant behavioral pattern indicative of grass tetany.
3. Other features of the present disclosure are shown and described herein.

**Brief Description Of The Drawings**

1. Aspects of the present disclosure will be more readily appreciated upon review of the detailed description of its various embodiments, described below, when taken in conjunction with the accompanying drawings, of which:
2. Fig. 1 is a flowchart identifying steps associated with an implementation of the present disclosure; and
3. Fig. 2 is a flowchart identifying steps associated with an additional implementation of the present disclosure.

**Detailed Description of the Embodiments**

1. By way of summary and introduction, the present disclosure includes a plurality of technological features, vis-à-vis user computing devices that are specially configured with hardware and software modules. The devices are configured for automatically detecting and tracking the behavior of livestock animals, for example, dairy cattle, and for enabling early detection of disease, infection, nutritional deficiencies, parturition, stress, and other conditions of interest.
2. In one or more implementations, a system and method are provided that include at least one computing device, a sensor for each animal in a herd, and at least one reader device for obtaining information from the animals’ sensors. The computing device can be configured with conventional components including a memory and a processor coupled to the memory, as well as a display, keyboard, network communicator, touch screen, or the like. The processor is configured by executing programmed instructions that provide a livestock interface for obtaining animal-specific information, and a monitoring component for comparing, analyzing, and displaying the obtained information. The sensors may take the form of an ear tag, leg band, collar, or other form suitable to permit animal monitoring while not interfering with the animal’s daily activities, and incorporate one or more conventional sensors such as accelerometers, global positioning satellite (GPS) sensors, temperature sensors, and the like, along with a communication component such as a radio frequency identification (RFID) tag or “smart label”. The smart label can contain various types of animal-specific information, including animal identification data, body position data, body temperature data, feeding behavior data(e.g., the animal chewed for only 30 minutes in the last three hours, and consumed only two pounds of grass), and movement pattern data (e.g., in the last eight hours, the animal spent two hours lying down and six hours walking around the pasture). The reader may be, e.g., a radio frequency reader for collecting the animal-specific information from an animal sensor having a radio frequency transponder when the animal sensor is within proximity to the radio frequency reader, and may be mounted in a variety of locations, for instance inside a milking or feeding barn, in a feeding stall, in a pasture, on a fence or gate, and the like. As the information is collected, it is stored in a herd database so that the farmer has a record of each animal’s past and present behavior. The herd database may also contain information about a plurality of possible behavioral patterns that are either normal or indicative of disease, infection, nutritional deficiencies, parturition, stress, and other conditions of interest, and may further contain data indicative of a cow or heifer’s age, pregnancy status, vaccination history, and the like. The system may also include control mechanisms that are coupled to the readers and the central computers, e.g., to automatically control a gate or a feeding device.
3. Applicant’s system and method enables a farmer to automatically monitor health and activity in dairy livestock animals, by collecting animal-specific information from a particular animal, comparing and analyzing the collected information with respect to the herd database in order to identify whether the animal is exhibiting an aberrant behavioral pattern as compared to past behavior of the animal, and then outputting the results of the analysis on a display to enable the farmer to effectively monitor the herd remotely, e.g., by checking the display at night from the farm office or the farm house. For instance, when the herd is on their way into the milking barn at night, animal-specific information from each animal’s sensor is read by the readers and processed by the livestock interface and the monitoring component to evaluate each animal’s behavioral patterns as compared to its past behavioral patterns (and if desired, a set of possible behavioral patterns that are known to occur in a given animal species).
4. The system may also send signals to control other farm equipment automatically, based on behavioral triggers. For instance, if the analysis results indicate that a particular animal is exhibiting an aberrant behavioral pattern indicative of excess stress, then the system can send a control signal to a sorting gate that is automatically operable to swing in response to a signal from the system so that the stressed animal is separated from the rest of the herd, e.g., into a holding pen, where the farmer or veterinarian can then examine the stressed animal, and treat it if needed. These sorting gates are known, and may have any suitable form, for example a frame and gates that are constructed out of metal tubing and equipped with mechanical, hydraulic, or pneumatic switches that are electronically controlled. Similarly, a reader mounted in a feeding stall can collect information from the animal that enters that particular stall, so that the animal can be identified and its behavioral patterns analyzed. If the analysis results indicate that this particular animal is exhibiting an aberrant behavioral pattern indicative of a particular disease or nutritional deficiency, or even that this particular animal requires more or less food than other animals in the herd, then the system can send a control signal to a feed dispenser to dispense an individualized amount of feed and optional supplements. For instance, if the animal is exhibiting an aberrant behavioral pattern indicative of grass tetany, the control signal may signal the feed dispenser to dispense a therapeutically effective amount of supplemental salt and minerals mixed with feed.
5. Fig. 1 is a flowchart illustrating steps 100 that are associated with an example implementation of the present disclosure. At step 102, a livestock interface is provided by a computing device including a processor, a memory, and a display. Thereafter, the livestock interface obtains animal-specific data (step 104). For example, the data include information representing an identification of a particular animal in a herd and information representing at least one of the particular animal’s i) body position, ii) body temperature, iii) feeding behavior, and iv) a movement pattern. The computing device connects to a herd database (step 106), and accesses animal data from the herd database that include information representing identities and past behaviors of animals in the herd (step 108). The computing device compares the obtained animal-specific data with the accessed animal data, such as to determine the particular animal’s identity (step 110). Thereafter, the computing device performs an analysis to determine whether the particular animal is exhibiting an aberrant behavioral pattern (step 112). For example, the analysis is performed by comparing the accessed animal data representing past behavior of the particular animal with the obtained animal-specific data. Information representing a result of the analysis is displayed on the display of the computing device (114).
6. Fig. 2 is a flowchart illustrating steps 200 that are associated with an example implementation of the present disclosure. The steps set forth in Fig. 2 are preceded by steps 100 (Fig. 1). At step 202, the results of the analysis from step 110 indicate that the animal is exhibiting aberrant behavior. More particularly, the aberrant behavior indicates grass tetany (step 204). Thereafter, a control signal is transmitted to a feed dispenser (step 206). The feed dispenser, for example, includes a feed and supplement supply, and the feed dispenser is operable to dispense individualized amounts of feed and optional supplements. At step 208, the feed dispenser receives the control signal. Thereafter, the feed dispenser dispenses therapeutically effective amounts of salt and minerals (step S210).
7. Although many of the examples shown and described herein regard distribution of coordinated presentations to a plurality of users, the invention is not so limited. Although illustrated embodiments of the present invention have been shown and described, it should be understood that various changes, substitutions, and alterations can be made by one of ordinary skill in the art without departing from the scope of the present invention.

What is Claimed is:

1. A system for monitoring health and activity in animals, the system comprising:

a computing device including a processor, a memory, and a display, wherein the processor is configured by executing instructions stored on the memory to:

obtain, via a livestock interface, animal-specific data that include information representing an identification of a particular animal in a herd and information representing at least one of the particular animal’s i) body position, ii) body temperature, iii) feeding behavior, and iv) a movement pattern;

access, from a herd database, animal data that include information representing identities and past behaviors of animals in the herd;

compare the obtained animal-specific data with the accessed animal data to determine the particular animal’s identity;

perform an analysis to determine whether the particular animal is exhibiting an aberrant behavioral pattern, wherein the analysis is performed by comparing the accessed animal data representing past behavior of the particular animal with the obtained animal-specific data, and

display, on the display, information representing a result of the analysis.

2. The system of claim 1, further comprising:

a feed dispenser comprising a feed and supplement supply, the feed dispenser operable to dispense individualized amounts of feed and optional supplements,

wherein the processor is further configured by executing the instructions to:

automatically send a control signal to the feed dispenser to dispense a therapeutically effective amount of supplemental salt and minerals mixed with feed when the result of the analysis indicates that the animal is exhibiting an aberrant behavioral pattern indicative of grass tetany.

3. The system of claim 1, further comprising:

a plurality of animal sensors, each of the plurality of animal sensors having a radio frequency transponder and each of the plurality of animal sensors coupled to a respective animal; and

a herd monitor including:

(i) a radio frequency reader configured to receive information from the plurality of animal sensors when any of the plurality of animal sensors is within a proximity to the radio frequency reader, and

(ii) a transmitter configured to transmit information received from the plurality of animal sensors to the livestock interface,

wherein the animal-specific data include at least some of the information received from the plurality of animal sensors.

4. The system of claim 1, further comprising:

a sorting gate configured with an automatic latching mechanism,

wherein the result of the analysis includes a conclusion that the particular animal is exhibiting an aberrant behavioral pattern, and

wherein, in response to the results of the analysis, the processor is further configured by executing the instructions to:

automatically send a control signal to the automatic latching mechanism to open the sorting gate and permit the particular animal to freely pass through the sorting gate.

5. The system of claim 1, further comprising:

a herd monitor including:

(i) a radio frequency reader for collecting information from a plurality of animal sensors coupled to the animals in the herd when the animal sensors are within a proximity to the radio frequency reader, each animal sensor having a radio frequency transponder, and

(ii) a transmitter for transmitting the collected animal-specific data to the livestock interface.

6. The system of claim 1, wherein the herd database includes records stored on a blockchain.

7. A method for monitoring health and activity in animals, the method comprising:

obtaining, via a livestock interface provided by a computing device including a processor, a memory, and a display, animal-specific data that include information representing an identification of a particular animal in a herd and information representing at least one of the particular animal’s i) body position, ii) body temperature, iii) feeding behavior, and iv) a movement pattern;

accessing, by the computing device, from a herd database, animal data that include information representing identities and past behaviors of animals in the herd;

comparing, by the computing device, the obtained animal-specific data with the accessed animal data to determine the particular animal’s identity;

performing, by the computing device, an analysis to determine whether the particular animal is exhibiting an aberrant behavioral pattern, wherein the analysis is performed by comparing the accessed animal data representing past behavior of the particular animal with the obtained animal-specific data, and

displaying, on the display, information representing a result of the analysis.

8. The method of claim 7, further comprising:

automatically sending, by the computing device, a control signal to a feed dispenser to dispense a therapeutically effective amount of supplemental salt and minerals mixed with feed when the result of the analysis indicates that the animal is exhibiting an aberrant behavioral pattern indicative of grass tetany,

wherein the feed dispenser comprises a feed and supplement supply, and the feed dispenser is operable to dispense individualized amounts of feed and optional supplements.

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ABSTRACT

A system and method provide for monitoring health and activity in animals is disclosed. A processor is configured to obtain, via a livestock interface, animal-specific data that include information representing an identification of a particular animal in a herd. Further, information representing at least one of the particular animal’s i) body position, ii) body temperature, iii) feeding behavior, and iv) a movement pattern is obtained. Moreover, the processor accesses, from a herd database, animal data that include information representing identities and past behaviors of animals in the herd. The obtained animal-specific data are compared with the accessed animal data to determine the particular animal’s identity. In addition, the processor is configured to perform an analysis to determine whether the particular animal is exhibiting an aberrant behavioral pattern, by comparing the accessed animal data representing past behavior of the particular animal with the obtained animal-specific data.

Diagram, table

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Table

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| In re Application of: |  |
| Tom Morrow |  |
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| Application No.: 12/345,678 | Confirmation No. 8697 |
|  |  |
| Filed: April 28, 2019 | Art Unit: 4568 |
|  |  |
| For: LIVESTOCK MANAGEMENT SYSTEM AND METHOD | Examiner: Wednesday Jones |

**RESPONSE TO NON-FINAL OFFICE ACTION**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

**INTRODUCTORY COMMENTS**

In response to the Non-Final Office Action dated April 1, 2021, please enter the following amendments.

**Amendments to the Claim** begin on page 2; and

**Remarks** begin on page 5.

**Amendments to the Claims**

**In the claims:**

Upon entry of this Amendment, the listing of claims is as follows:

1. (Original) A system for monitoring health and activity in animals, the system comprising:

a computing device including a processor, a memory, and a display, wherein the processor is configured by executing instructions stored on the memory to:

obtain, via a livestock interface, animal-specific data that include information representing an identification of a particular animal in a herd and information representing at least one of the particular animal’s i) body position, ii) body temperature, iii) feeding behavior, and iv) a movement pattern;

access, from a herd database, animal data that include information representing identities and past behaviors of animals in the herd;

compare the obtained animal-specific data with the accessed animal data to determine the particular animal’s identity;

perform an analysis to determine whether the particular animal is exhibiting an aberrant behavioral pattern, wherein the analysis is performed by comparing the accessed animal data representing past behavior of the particular animal with the obtained animal-specific data, and

display, on the display, information representing a result of the analysis.

2. (Original) The system of claim 1, further comprising:

a feed dispenser comprising a feed and supplement supply, the feed dispenser operable to dispense individualized amounts of feed and optional supplements,

wherein the processor is further configured by executing the instructions to:

automatically send a control signal to the feed dispenser to dispense a therapeutically effective amount of supplemental salt and minerals mixed with feed when the result of the analysis indicates that the animal is exhibiting an aberrant behavioral pattern indicative of grass tetany.

3. (Original) The system of claim 1, further comprising:

a plurality of animal sensors, each of the plurality of animal sensors having a radio frequency transponder and each of the plurality of animal sensors coupled to a respective animal; and

a herd monitor including:

(i) a radio frequency reader configured to receive information from the plurality of animal sensors when any of the plurality of animal sensors is within a proximity to the radio frequency reader, and

(ii) a transmitter configured to transmit information received from the plurality of animal sensors to the livestock interface,

wherein the animal-specific data include at least some of the information received from the plurality of animal sensors.

4. (Original) The system of claim 1, further comprising:

a sorting gate configured with an automatic latching mechanism,

wherein the result of the analysis includes a conclusion that the particular animal is exhibiting an aberrant behavioral pattern, and

wherein, in response to the results of the analysis, the processor is further configured by executing the instructions to:

automatically send a control signal to the automatic latching mechanism to open the sorting gate and permit the particular animal to freely pass through the sorting gate.

5. (Original) The system of claim 1, further comprising:

a herd monitor including:

(i) a radio frequency reader for collecting information from a plurality of animal sensors coupled to the animals in the herd when the animal sensors are within a proximity to the radio frequency reader, each animal sensor having a radio frequency transponder, and

(ii) a transmitter for transmitting the collected animal-specific data to the livestock interface.

6. (Original) The system of claim 1, wherein the herd database includes records stored on a blockchain.

7. (Original) A method for monitoring health and activity in animals, the method comprising:

obtaining, via a livestock interface provided by a computing device including a processor, a memory, and a display, animal-specific data that include information representing an identification of a particular animal in a herd and information representing at least one of the particular animal’s i) body position, ii) body temperature, iii) feeding behavior, and iv) a movement pattern;

accessing, by the computing device, from a herd database, animal data that include information representing identities and past behaviors of animals in the herd;

comparing, by the computing device, the obtained animal-specific data with the accessed animal data to determine the particular animal’s identity;

performing, by the computing device, an analysis to determine whether the particular animal is exhibiting an aberrant behavioral pattern, wherein the analysis is performed by comparing the accessed animal data representing past behavior of the particular animal with the obtained animal-specific data, and

displaying, on the display, information representing a result of the analysis.

8. (Original) The method of claim 7, further comprising:

automatically sending, by the computing device, a control signal to a feed dispenser to dispense a therapeutically effective amount of supplemental salt and minerals mixed with feed when the result of the analysis indicates that the animal is exhibiting an aberrant behavioral pattern indicative of grass tetany,

wherein the feed dispenser comprises a feed and supplement supply, and the feed dispenser is operable to dispense individualized amounts of feed and optional supplements.

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**remarks**

This is in response to the Non-Final Office Action mailed on April 1, 2021 concerning the above-identified application.

***Claim Rejections***

35 U.S.C. §101

Claims 1-8 stand rejected under 35 U.S.C. §101 on the grounds of allegedly being directed to non-statutory subject matter. Applicant respectfully traverses.

***ADD REMARKS HERE***

**CONCLUSION**

Applicant respectfully submits that all of the issues raised by the Examiner have been addressed and overcome by the present amendment.

In view of the foregoing, it is believed that the pending claims are in condition for allowance and it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining which the Examiner believes could be resolved through a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Dated: Respectfully submitted,

*Attorneys for Applicant* DRAFT