Day Two Answers

Patent Fundamentals Bootcamp 2021:

An Introduction to Patent Drafting, Prosecution, and Litigation

June 3, 2021

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Public, John Q. et al.		
Title:	PORTABLE APPARATUS FOR SITTING		
Serial No.:	09/876,543	Filing Date:	April 2, 2015
Examiner:	Millman, Benita	Group Art Unit:	2800
Docket No.:	03179524	Customer No.	50000

San Francisco, California
July 10, 2016

CERTIFICATE OF ELECTRONIC (EFS-WEB) TRANSMISSION
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Dated: _____ By: _____
Patent At Torney, Reg. No. 45,678

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO OFFICE ACTION UNDER 37 C.F.R. § 1.111

Dear Sir:

This Response is submitted in reply to the Office Action dated April 10, 2016 ("Office Action").

Amendments to the Claims are reflected in the listing of claims which begins on page __.

Remarks begin on page ____.

Amendments

In the Claims

1. (currently amended) An apparatus comprising:

a substantially planar surface with a first and a second surface; and

at least three elongate members, the at least three elongate members each having a first end and a second end, the first end[[s]] of each of the at least three elongate members connected to the first surface of the planar surface and oriented in a direction with respect to the planar surface such that each of the at least three elongate members are substantially perpendicular to the planar surface and each of the at least three elongate members are substantially parallel to each other, wherein the second end of each of the at least three elongate members are detached from one another.

2. (original) 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. (original) An apparatus according to claim 1, further comprising exactly three elongate members.

4. (original) An apparatus according to claim 1, further comprising exactly four elongate members.

5. (original) An apparatus according to claim 1, wherein the planar surface and elongate members are wood.

6. (currently amended) An apparatus according to claim 1, wherein the length of each of the elongate members is approximately equal to [[the]] a distance between a [[the]] knee and [[the]] an ankle of an adult human leg.

7. (currently amended) An apparatus according to claim 1, wherein the area of the planar surface is approximately equal to [[the]] an area of [[the]] a back surface of an adult human buttock.

Remarks

OVERALL POINTS:

-MAKE SURE PROPER AMENDMENT FORMAT IS FOLLOWED

-MAKE SURE REMARKS DO NOT CREATE TOO MUCH ESTOPPEL—THE LESS, THE BETTER

-NO RIGHT ANSWER—THE STUDENTS CAN TRAVERSE OR AMEND, ALTHOUGH YOU MAY WANT TO POINT OUT THAT THE CLIENT SPECIFICALLY ASKED THE STUDENT TO GET THE PATENT FAST, WHICH MAY ENCOURAGE AMENDMENT OVER TRAVERSAL.

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.

CLAIM 1 AMENDED, RATHER THAN TRAVERSED. COULD TRAVERSE, BUT CLIENT WANTS A FAST PATENT.

3. In Claim 1, the term "oriented with respect to" is unclear and indefinite.

AMENDED RATHER THAN TRAVERSED.

4. In Claim 6, the terms "the distance" and "the knee" and "the ankle" lack antecedent basis.

AMENDED RATHER THAN TRAVERSED.

5. 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.

ASSUME REFERENCE IS PRIOR ART.

6. 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),

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).

A NUMBER OF POSSIBLE ANSWERS:

1. CAN TRAVERSE THAT THE LEGS ARE NOT "SUBSTANTIALLY PERPENDICULAR" AT THE FLOOR SINCE THEY ARE PARALLEL AT THAT POINT.

2. CAN TRAVERSE THAT THERE ARE NOT 3 LEGS, BUT RATHER 2 LEGS

3. CAN AMEND AS I HAVE AMENDED—AGAIN, CLIENT WANTS FAST PATENT

WRT Claim 2

7. 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).

-RELY ON AMENDMENTS TO CLAIM 1 TO REMOVE 102 REJECTION

WRT Claim 4

8. 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).

-RELY ON AMENDMENTS TO CLAIM 1 TO REMOVE 102 REJECTION

WRT Claim 5

9. 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).

-RELY ON AMENDMENTS TO CLAIM 1 TO REMOVE 102 REJECTION

WRT Claim 6

10. 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).

-RELY ON AMENDMENTS TO CLAIM 1 TO REMOVE 102 REJECTION

-ALSO AMENDED TO REMOVE 112 REJECTIONS

WRT Claim 7

11. 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).

-RELY ON AMENDMENTS TO CLAIM 1 TO REMOVE 102 REJECTION

-ALSO, AMENDED TO REMOVE 112 REJECTIONS

12. Claim 3 is rejected under 35 USC 103(a) as obvious in view of the Easy Chair Reference.

13. The Easy Chair Reference discloses a chair with 4 legs. Claim 3 calls for a chair with:

exactly three elongate members.

-RELY ON AMENDMENTS TO CLAIM 1 TO REMOVE 103 REJECTION

III. Conclusion

For the foregoing reasons, the Applicant respectfully asserts that all claims are patentable over the cited prior art and respectfully requests that these claims be allowed.

No fee is believed due with this Response. Should additional fees be due, the Commissioner is authorized to charge any additional fees which may be required or credit any overpayment of fees, to Deposit Account No. 13-0019. A duplicate copy of this Authorization is enclosed.

Respectfully submitted,

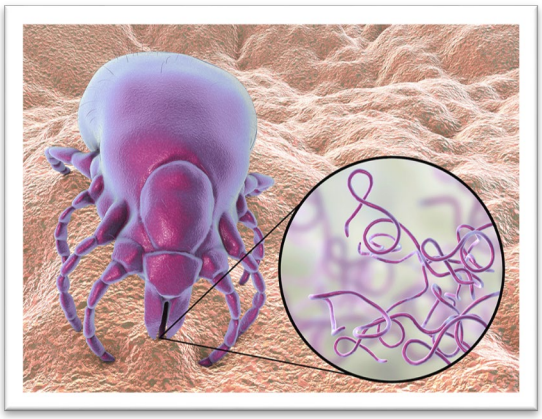
July 10, 2016

_____

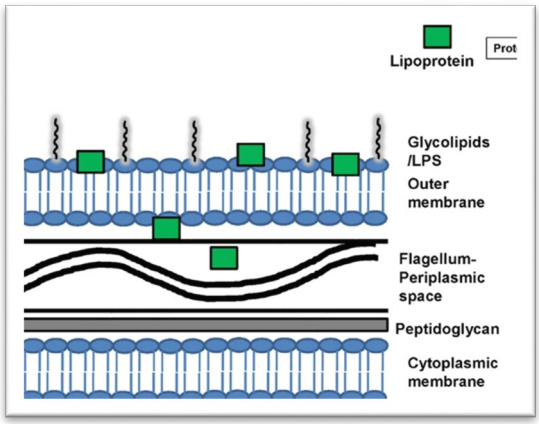
Patent Attorney
Attorney for Applicant
Reg. No.

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.



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.

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.

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)

(2) Modified OspA protein: "$OspA_{11-30}$" (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 $OspA_{11-30}$):

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).

(3) The linear OspA epitope

ILALIACKQN VSSLDEKNSV (SEQ ID NO: 3).

(4) OspB/$OspA_{11-30}$ 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 – $OspA_{11-30}$

(5) 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 $OspA_{11-30}$ 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):

(a) Methods for making and purifying the three classes of recombinant immunogenic proteins of SEQ ID NO: 2, 3, 4, and 5;
(b) Methods for generating antibodies against each of the three recombinant immunogenic proteins in mouse models;
(c) 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
(d) 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;
(e) 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;
(f) Methods for vaccinating humans against Lyme disease;
(g) 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 $OspA_{11-30}$ 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 $OspA_{11-30}$ fragment from the blood of the animals from Example 3 and tested their ability to neutralize the ability of the linear OspA epitope to produce an immune response in animals. The inventors showed that mice administered two doses of neutralizing antibody prior to exposure to linear OspA epitope did not produce a detectable immune response against the fragments.

Example 5. Chimeric protein comprising wildtype OspB fused at its C-terminus to the linear 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 epitope was 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 $OspA_{11-30}$ 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 $OspA_{11-30}$ 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 $OspA_{11-30}$ 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 $OspA_{11-30}$ 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
$OspA_{11-30}$ 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: $OspA_{11-30}$ 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:

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

EXAMINED CLAIMS

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

PROPOSED AMENDED CLAIMS (PROVIDE IN SOLUTION VERSION ONLY)

Proposed Amended Claims	Rejected under
1. A ~~vaccine~~ immunogenic composition comprising: an effective amount ~~minimal concentration~~ of an outer membrane protein from *B. burgdorferi*; and an ~~non-reactive~~ immunologically acceptable carrier or vehicle, wherein the outer membrane protein is an OspA immunogenic variant or fragment *comprising a deletion	§ 112-I § 112-WD § 112-E § 102

in an N-terminal region that reduces the hyper-immunogenicity associated with wildtype OspA.*	
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~~ immunogenic composition of claim [[2]] 1, wherein the OspA immunogenic variant or fragment comprises a immunogenic variant or fragment of SEQ ID NO: 1.	§ 102
4. The ~~vaccine~~ immunogenic composition of claim [[2]] 3, wherein the immunogenic variant comprises a deletion in OspA corresponding to amino acids 11-30 of SEQ ID NO: 1.	§ 103
5. The ~~vaccine~~ immunogenic composition of claim [[2]] 3, wherein the immunogenic variant of OspA comprises a fusion between OspA and OspB in a 1:2 ratio.	§ 112-E § 112-WD § 103
6. The ~~vaccine~~ immunogenic composition of claim [[2]] 3, 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~~ immunogenic composition comprising ~~substantially isolated~~ an OspA ~~or~~ variant or fragment thereof, wherein the OspA variant is $OspA_{11-30}$ of SEQ ID NO: 2.	§ 101 § 102
9. A ~~vaccine~~ immunogenic 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~~ immunological composition of ~~any one of~~ claim 4 ~~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~~ immunological composition containing a substantially pure OspA protein variant or fragment thereof comprising recovering the OspA protein variant or fragment thereof from a host organism transformed with a vector containing DNA encoding said ~~the~~ OspA protein variant or fragment thereof, and admixing the OspA protein variant or fragment thereof with an immunologically acceptable carrier or vehicle.	§ 102

PRIOR ART

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.

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.

Answers (provide in the Solution Version only)

Changed “minimal” to the generally art-accepted term, “effective amount.” One of ordinary skill in the art would understand the scope and meaning of an effective amount and the means by which to determine which actual amounts meet the limitation.

Changed "non-reactive" to the generally art-accepted term, "immunologically acceptable." One of ordinary skill in the art would understand the scope and meaning of an immunologically acceptable carrier or vehicle and the means by which to determine which actual materials would fall in the claim scope.

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.

Answers (provide in the Solution Version only)

Argument only
During prosecution, we showed that when one tries to isolate OspA (outer surface protein A) from *B. burgdorferi*, it co-isolates with OspB (outer surface protein B), such that "substantially pure OspA" is not something found in nature or something that can be isolated from nature; rather, one really did need to divine the sequence coding for it and express it in a recombinant system.

Amendment + Argument
Claim 8 has been amended to recite a specific OspA variant or fragment thereof, wherein the OspA variant is defined as the $OspA_{11\text{-}30}$ of SEQ ID NO: 2. The data demonstrates that this particular variant produced a strong immune response in mice, produced neutralizing antibodies and showed no hyperimmune response in mice. In addition, the $OspA_{11\text{-}30}$ fragment of SEQ ID NO: 2 protected against infection by Lyme agent *in vivo* in a dog model. The claimed OspA variant does not occur in nature since it is recombinant.

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.

Answers (provide in the Solution Version only)

Claim 9 recites an immunogenic composition comprising substantially pure OspA from two or more strains of *Borrelia burgdorferi*. As demonstrated in Example 7, the inventors discovered unexpectedly that purified OspA proteins from two different *B. burgdorferi* strains (e.g., New London and Groton strains) can produce a more effective vaccine with a protective effect that is 45% higher than either protein alone. Since the composition requires OspA proteins from two different strains, which sets forth a condition not possible in nature, claim 9 is not ineligible under 101.

In addition, as discovered in Example 1, 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. Thus, the recited "substantially pure" OspA from either strain does not exist in nature and is thus, "markedly different" from the form of OspA occurring in nature (which exists as a complex comprising both OspA and OspB). For these reasons, claim 9 does not recite ineligible subject matter.

Amendment + Argument
Claim 9 *could* be amended to include that at least one of the OspA proteins is a variant with the 11-30 amino acid deletion. Since $OspA_{11\text{-}30}$ does not occur in nature, claim 9, if limited in this way, would not be ineligible because it is not directed to a naturally occurring substance.

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.

Answers (provide in the Solution Version only)

Claim 1 has been amended to define the "outer membrane protein" as "OspA immunogenic variant or fragment." The specification only teaches a number of OspA variants, including SEQ ID NOs 2 and 4, and an OspA fragment in SEQ ID NO: 3, and provide data to demonstrate all of them are immunogenic.

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."

Answers (provide in the Solution Version only)

The claims were amended to change the terms "vaccine" to "immunogenic composition," thereby overcoming the rejection.

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.

Answers (provide in the Solution Version only)

Claim 10 was amended to match the data which showed that at least SEQ ID NO: 2 produced a protective effect in dogs. See Example 6.

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.

Answers (provide in the Solution Version only)

Amendment + Argument
Claim 1 has been amended to recite that the outer membrane protein is an "OspA immunogenic variant of fragment." Applicants argues that RefA does not teach such a protein. Applicant points out that since claims 2, 3, 7, 8, 10, and 11 all ultimately depend from claim 1, and include all of the limitations of claim 1, they also do not lack novelty.

Likely, this amendment is not sufficient to overcome novelty because RefA's linear OspA epitope of amino acids 221-240 of the wildtype OspA protein would satisfy this amended limitation. Thus, the rejection under Section 102 based on RefA would likely not be overcome.

Applicant would likely need to further limit claim 1 to one of the novel sequences disclosed in the application, such as SEQ ID NO: 2, SEQ ID NO: 3, or the chimeric protein of SEQ ID NO: 4.

Alternatively, OspA could be further amended to try to generically claim that the OspA in the claim scope has a deletion in the N-terminal region that reduces the hyper-immunogenicity associated with the wildtype OspA. However, such a broad and non-specific limitation would likely raise enablement and/or written description issues because of the lack of disclosure and/or teachings of regions other than amino acids 11-30 of OspA. In addition, Example 2 reports that the overlapping series of amino acid regions 31-40, 45-60, 55-72, 68-80, 75-100, 140-165, 152-180, and 220-242 did not similarly reduce the hyper-immunogenic side-effects associated with wildtype OspA. Thus, the non-specific limitation calling for an N-terminal region being deleted is not supported by disclosure, and in fact, includes regions that did not work.

Best approach would be to limit claim 1 to the OspA variants of SEQ ID NO: 2, SEQ ID NO: 3, or the chimeric protein of SEQ ID NO: 4.

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.

Answers (provide in the Solution Version only)

Argument only
The subject matter of claims 4 and 6 would not have been obvious over RefA in view of RefB and in further view of RefC. The Examiner tries to establish this rejection based on a *prima facie* case of obviousness based on the rational underlying MPEP 2143(G).

To reject a claim based on this rationale, the Examiner must articulate at least the following:

(1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings;
(2) a finding that there was reasonable expectation of success.

Here, the Examiner fails to establish both prongs.

First, the Examiner admits that RefA fails to teach an OspA variant having a deletion corresponding to amino acids 11-30 of SEQ ID NO: 1 (wildtype OspA), and fails to teach the OspA variant of SEQ ID NO: 3. The Examiner turns to RefB to repair this deficiency. However, RefB is merely a general teaching 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. This does not constitute a specific teaching of OspA, or the specific region identified by the inventors of amino acids 11-30. The Examiner further turns to RefC for the teaching of a similar (but not identical) linear epitope from an entirely different and human protein, LFA-2, (which has no relationship to OspA, a bacterial protein), and specifically for the teaching that in the context of LFA-2, that peptide region could be removed to limit an autoimmune disorder associated with LFA-2. RefC does not teach that removal of this peptide region from any protein, let alone a similar but not identical peptide from a bacterial protein, would limit an autoimmune response. Also, RefC does not specifically address vaccines, and issues relating to hyper-immunogenic responses of vaccines. Thus, not only does RefB fail to specifically teach or even identify amino acids 11-30 of OspA, one of ordinary skill in the art would not have been particularly motivated to specifically delete amino acids 11-30 of OspA even based on knowing the contents of RefC because that reference relates to an entirely different and human protein. In addition, the inventor's own data show that the peptide region of 11-30 was the only peptide region tested from among several which actually reduced the hyper-immunogenic response. There was no way to predict that this 11-30 region would have been particularly effective in removing the hyper-immunogenic response when many other peptide regions did not. The effect was entirely unpredictable. Accordingly, the subject matter of claim 4 and 6 was not obvious based on RefA, RefB, and RefC.

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.

Argument only
The subject matter of claim 5 would not have been obvious over RefA in view of RefB. The Examiner tries to establish this rejection based on a *prima facie* case of obviousness based on the rational underlying MPEP 2143(G).

To reject a claim based on this rationale, the Examiner must articulate at least the following:

(1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings;
(2) a finding that there was reasonable expectation of success.

Here, the Examiner fails to establish both prongs.

Neither reference specifically teaches the claimed OspA-OspB fusion protein or that such a specific fusion protein would have been able to produce a immune response. As reported in Example 1, the inventors 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. 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. Applicant has amended claim 5 to reflect this finding, which was surprising since the chimeric protein with the 1:1 ratio of subunits did not produce neutralizing antibodies. RefB's highly generalized teachings that chimeric outer membrane proteins from bacteria can be a suitable strategy to develop anti-bacterial vaccines would not have motivated the skilled person to specifically modify RefA to reach the specifically claimed subject matter of claim 5. Since RefB does not specifically teach or suggest modifying a OspA protein with two subunits of OspB, and this result was surprising and not predictable, the skilled person would also not have had a reasonable expectation of success in reaching the claimed subject matter of claim 5 by combining RefA and RefB.

Docket No.: 1111/2636-US0

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Tom Morrow

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.

Docket No.: 1111/2636-US0

AMENDMENTS TO THE CLAIMS

In the claims:

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

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

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

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,

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; and

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

2. (Canceled)

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. (Currently Amended) 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 wherein the herd database includes records stored on a blockchain;

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.

Docket No.: 1111/2636-US0

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.

Applicant has amended independent claim 1 and independent claim 7. More particularly, claim 1 has been amended to include features of original dependent claim 2, which is canceled herein. Claim 7 has been amended to include features of original claim 6.

The Office concludes that the claims recite the abstract idea of performing an evaluation, and that the claims are not drawn to eligible subject matter. Claim 1 has been amended to recite, "automatically [sending] 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." Applicant respectfully submits that these additional features, in combination with the remaining features of claim 1, do not merely link the judicial exception to a technical field, but instead add meaningful limitations in that applicant's system, as currently claimed, can employ the information provided by the judicial exception, including to cause the feed dispenser to operate in response to the "control signal." Moreover, the combination of features of amended claim 1 enables the control of appropriate farm equipment based on the automatic detection of grass tetany, which goes beyond merely automating the abstract idea.

Still further, applicant respectfully submits that independent claim 1, as amended, includes non-computer physical elements to the claim, which changes state in response to the calculations performed by the computer. Applicant maintains that the combination of features set forth in amended independent claim 1 transform the invention as originally claimed into one that meets the requirements of § 101.

Moreover, applicant respectfully submits that amended independent claim 1 is analogous to Supreme Court and Federal Circuit case law regarding the law of nature and natural phenomena exceptions. More particularly and in view of *Mayo v. Prometheus* and its progeny, claim 1, as amended, effectively includes treatment features, administering a medicine by dispensing a "therapeutically effective amount of supplemental salt and minerals mixed with feed." In that light, applicant submits that claim 1 recites a combination of features that define patent-eligible subject matter.

Moreover, each of claims 2-6 depends directly or indirectly from independent claim 1, and is patentable for at least the same reasons, including in connection with the combination of features set forth in each of the claims with the features set forth in the base claim(s) from which it depends. Applicant respectfully submits that any one or more independent claim(s) is not representative of the limitations set forth in the dependent claims, and that the limitations of the dependent claims may also bear on patentability, including subject matter eligibility.

Applicant's independent claim 7 has been amended to recite "the herd database includes records stored on a blockchain." Applicant respectfully submits that this feature, in combination with the remaining features set forth amended claim 7 recite patent eligible under 35 U.S.C. § 101.

To the extent that the invention as currently claimed in amended claim 7 includes an abstract idea, Applicant respectfully submits that the invention as currently claimed in claim 7 integrates the judicial exception into a practical application that will apply, rely on, or use the judicial exception in a manner that imposes a meaningful limit on the judicial exception. Thus, the combination of features in amended claim 7, for example, go far beyond a monopoly on a judicial exception. Furthermore applicant submits that the steps and features set forth in amended claim 7 cannot practically be performed mentally, nor define mental processes.

Applicant respectfully directs the Office to the Patent Office's October 2019 Update: Subject Matter Eligibility guidance. Applicant respectfully submits that, pursuant to the October 2019 Update, the amended independent claims include limitations that are indicative of integration of the abstract idea into a practical application. Moreover, the specificity of the claim

features, in particular with regard to implementing a database vis-à-vis blockchain technology, is indicative of the use of a particular machine and particular transformation, which goes far beyond mere instructions to apply a judicial exception (e.g., an abstract idea).

-Accordingly, for the foregoing reasons, applicant respectfully submits that the ordered and interrelated combination of features set forth in applicant's amended claim 7 define patent-eligible subject matter.

Further, applicant submits that even assuming, *arguendo*, that claim 7 is directed to a judicial exception (as the Office concludes), applicant respectfully submits that the combination of features recited in amended independent claim 7 provides technological features additional elements that are sufficient to amount to significantly more than the judicial exception. For example, and for the reasons set forth herein, the claims "improve upon an existing technological process" and are submitted to be patent-eligible.

Accordingly, reconsideration and withdrawal of the rejection of claims 1-8 under 35 U.S.C. § 101 is respectfully requested.

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

SAMPLE PATENT

For use by jurors viewing

An Introduction to the Patent System

FJC videotape # 4342-V/02

Produced by the Federal Judicial Center
2002

(12) **United States Patent**
PUBLIC et al.

(10) **Patent Number: 6,543,210 B1**
(45) **Date of Patent: Dec. 6, 2016**

(54) **PORTABLE APPARATUS FOR SITTING**

(75) Inventors: **John Q. Public, Jane B. Doe,** both of New York, NY

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(21) Appl. No.: **09/876,543**

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(52) **U.S. Cl.** .297/452.1
(58) **Field of Search** .297/452.1,440.2

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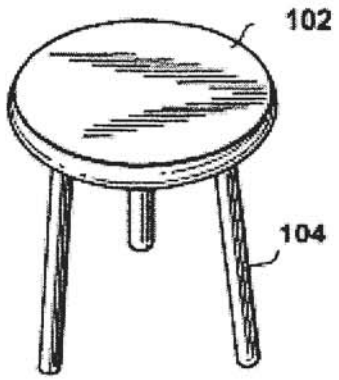
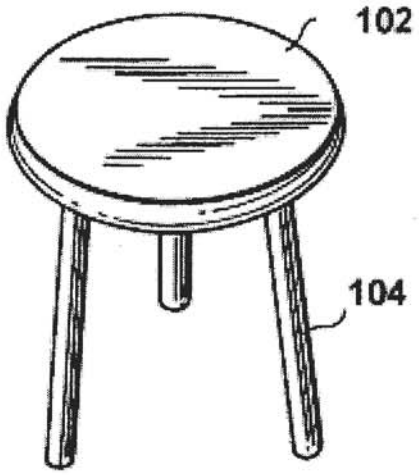
(57) **ABSTRACT**

A portable apparatus for use while sitting. The apparatus includes a planar surface or seat with at least three elongate members or legs attached to one side of the planar surface or seat. The elongate members or legs are generally parallel to each other and below the planar surface or seat in use. The apparatus may include a support member or back that is attached to the opposite side of the planar surface or seat and extends upward in use.

7 Claims, 2 Drawing Sheets





100

FIG. 1

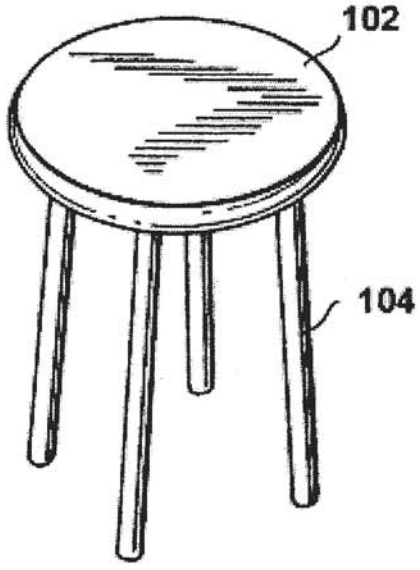


FIG. 2

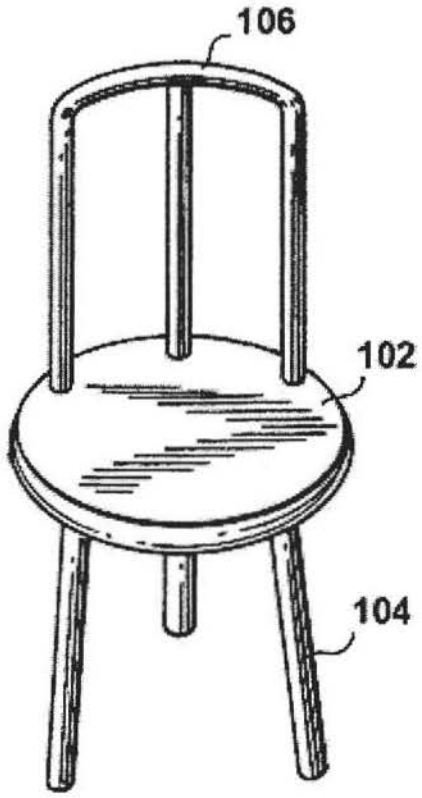


FIG.3

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.

2. 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 area 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.

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 104 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.

As illustrated in FIGs. 1 and 2, apparatus 100 includes at least three elongate members. When fewer than three elongate members were tried, it was found that apparatus 100 was not particularly stable and resting was therefore difficult. With three elongate members, as illustrated in FIG. 1, 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 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 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 104 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 as the 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 limitation. 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.

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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