UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/095,415	12/03/2013	Aaron J. Peoples	122733-00103	1094

86738 7590 09/08/2014

MCCARTER & ENGLISH, LLP BOSTON
265 Franklin Street
Boston, MA 02110

EXAMINER	
HEARD, THOMAS SWEENEY	
ART UNIT	PAPER NUMBER
1675	

NOTIFICATION DATE	DELIVERY MODE
09/08/2014	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@mccarter.com

Office Action Summary	Application No. 14/095,415	Applicant(s) PEOPLES ET AL.	
	Examiner THOMAS S. HEARD	Art Unit 1675	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *1-8,10-12,14-17,20-23,25-33,36,38,40,43,45,46,48,50 and 52* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-8, 10-12, 14-17, 20-23, 25-33, 36, 38, 40, 43, 45, 46, 48, 50, and 52* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

The present application is being examined under the pre-AIA first to invent provisions.

Status of the Claims

First Action on the Merits

Claim(s) 1-8, 10-12, 14-17, 20-23, 25-33, 36, 38, 40, 43, 45, 46, 48, 50, and 52 and are hereby examined on the merits.

Information Disclosure Statement

No information disclosure statement has been submitted.

Specification

The title is objected to for the word “novel.”

Claim Rejections - 35 USC § 101

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, 10-12, 14 and 15 are rejected under 35 U.S.C. 101 because the claimed compound is drawn to a naturally occurring product, given the broadest reasonable interpretation of Claim 1 and its dependent claims.

On their face, the claims do not contain any limitations that clearly permit the examiner to determine that the composition is non-naturally occurring. A review of the

specification reveals that the product is an isolated compound from nature which is not sufficient to be patent eligible. As such, factor (a) is not satisfied because the composition of Claim 1 initially appears to be a natural product, but there is no evidence on the record that demonstrates that the claimed product's structure differs materially from naturally occurring compounds found within the bacterial cell from which it was isolated. Factor (g) is satisfied because the claimed compound appear to be a natural product. Factors (b)-(f) and (h)-(l) are not relevant, because the claim does not include any elements in addition to the natural product. On balance, the factors weigh against a significant difference, and claims do not qualify as eligible subject matter. *See Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116, 106 USPQ2d 1972 (2013); *Mayo Collaborative Svcs. v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 101 USPQ2d 1961 (2012). See also Guidance for Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products, available at http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf ("Natural Products Guidance").

Claims 14-17 and 20 are rejected under 35 U.S.C. 101 because the claimed invention is not directed to patent eligible subject matter. An analysis with respect to the claims as a whole reveals that they do not recite something significantly different than the judicial subject-matter eligibility exception of natural products.

See Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116, 106 USPQ2d 1972 (2013); *Mayo Collaborative Svcs. v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 101 USPQ2d 1961 (2012). See also Guidance for Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products, available at

http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf ("Natural Products Guidance").

Analysis of subject-matter eligibility under 35 U.S.C. § 101 requires consideration of three issues:

(1) whether the claim is directed to one of the four categories recited in §101;

(2) whether the claim recites or involves a judicial exception (i.e., a law of nature, natural phenomenon, or natural product);

(3) whether the claim as a whole recites something significantly different than the judicial exception. In this case, the claims are directed to a method of making (isolating) a natural product. Therefore, they must each be considered to determine whether, given their broadest reasonable interpretation, they are significantly different compared to the natural product.

There are twelve factors to consider in the "significantly different" analysis.

The six factors that **weigh toward subject-matter eligibility** are:

(a) the claim is a product claim reciting something that initially appears to be a natural product, but after analysis is determined to be non-naturally occurring and markedly different in structure from naturally occurring products. This factor is not relevant.

(b) the claim recites elements/steps in addition to the judicial exception that impose meaningful limits on claim scope (i.e., the elements/steps narrow the scope of the claim so that others are not substantially foreclosed from using the judicial exception). Elements and steps do not impose any meaningful limitation.

(c) the claim recites elements/steps in addition to the judicial exception that relate to the judicial exception in a significant way (i.e., the elements/steps are more than nominally, insignificantly, or tangentially related to the judicial exception). This factor is not satisfied.

(d) the claim recites elements/steps in addition to the judicial exception that do more than describe the judicial exception with general instructions to apply or use the judicial exception. This step is not satisfied as the steps are generic and general in the field.

(e) the claim recites elements/steps in addition to the judicial exception that include a particular machine or transformation of a particular article, where the particular machine/transformation implements one or more judicial exception(s) or integrates the judicial exception(s) into a particular practical application. This does not appear to be relevant.

(f) the claim recites one or more elements/steps in addition to the judicial exception that add a feature that is more than well-understood, purely conventional or routine in the relevant field. This step is not satisfied as the steps and features are generic, applicable to other compounds.

The six factors that **weigh against subject-matter eligibility** are:

(g) the claim is a product claim reciting something that appears to be a natural product that is not markedly different in structure from naturally occurring products. This factor is not relevant.

(h) the claim recites elements/steps in addition to the judicial exception at a high level of generality such that substantially all practical applications of the judicial exception are covered. This factor is applicable as the steps are generic.

(i) the claim recites elements/steps in addition to the judicial exception that must be used/taken by others to apply the judicial exception. This factor weights against as the elements and steps to not add limitation to the already generic steps.

(j) the claim recites elements/steps in addition to the judicial exception that are well-understood, purely conventional, or routine in the relevant field. The factor weights against patentability.

(k) the claim recites elements/steps in addition to the judicial exception that are insignificant extrasolution activity (i.e., are merely appended to the judicial exception). Does not appear to be relevant.

(l) the claim recites elements/steps in addition to the judicial exception that amount to nothing more than a mere field of use. This factor weighs against patentability as the methods is generic to the intended outcome of isolating the compound, which can isolate other unrelated compounds.

On balance, if the totality of the relevant factors weighs toward eligibility, the claim qualifies as eligible subject matter. If the totality of the relevant factors weighs against eligibility, the claim should be rejected. The examiner has considered every relevant factor and related evidence in rejecting the claims under §101 and the

invention as claimed is not found to be patent eligible. The method of making (isolating) is not patent eligible.

Claim21-23, 25-33, 36, 38, 40, 43, 46, 48, 50 and 52 are rejected under 35 U.S.C. 101 because the claimed invention is not directed to patent eligible subject matter. An analysis with respect to the claims as a whole reveals that they do not recite something significantly different than the judicial subject-matter eligibility exception of natural products.

See Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116, 106 USPQ2d 1972 (2013); *Mayo Collaborative Svcs. v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 101 USPQ2d 1961 (2012). See also Guidance for Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products, available at http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf ("Natural Products Guidance").

Analysis of subject-matter eligibility under 35 U.S.C. § 101 requires consideration of three issues:

(1) whether the claim is directed to one of the four categories recited in §101;

(2) whether the claim recites or involves a judicial exception (i.e., a law of nature, natural phenomenon, or natural product);

(3) whether the claim as a whole recites something significantly different than the judicial exception. In this case, the claims are directed to a method of treating an undisclosed disorder a natural product. Therefore, they must each be considered to determine whether, given their broadest reasonable interpretation, they are significantly different compared to the natural product.

There are twelve factors to consider in the "significantly different" analysis.

The six factors that **weigh toward subject-matter eligibility** are:

(a) the claim is a product claim reciting something that initially appears to be a natural product, but after analysis is determined to be non-naturally occurring and markedly different in structure from naturally occurring products. This factor is not applicable.

(b) the claim recites elements/steps in addition to the judicial exception that impose meaningful limits on claim scope (i.e., the elements/steps narrow the scope of the claim so that others are not substantially foreclosed from using the judicial exception). This factor is not satisfied. Claims are drawn to disorders which does not impose any limitation.

(c) the claim recites elements/steps in addition to the judicial exception that relate to the judicial exception in a significant way (i.e., the elements/steps are more than nominally, insignificantly, or tangentially related to the judicial exception). This is also not satisfied as the claims are a broad application in treating.

(d) the claim recites elements/steps in addition to the judicial exception that do more than describe the judicial exception with general instructions to apply or use the judicial exception. This is not satisfied as the claims are a broad brush application for treatment.

(e) the claim recites elements/steps in addition to the judicial exception that include a particular machine or transformation of a particular article, where the particular machine/transformation implements one or more judicial exception(s) or integrates the judicial exception(s) into a particular practical application. This factor is not applicable.

(f) the claim recites one or more elements/steps in addition to the judicial exception that add a feature that is more than well-understood, purely conventional or routine in the relevant field. This is not satisfied as the steps are simply a generic administration.

The six factors that **weigh against subject-matter eligibility** are:

(g) the claim is a product claim reciting something that appears to be a natural product that is not markedly different in structure from naturally occurring products. This is not relevant as the claims are to a method of treating.

(h) the claim recites elements/steps in addition to the judicial exception at a high level of generality such that substantially all practical applications of the judicial exception are covered. The generality of the method weighs against eligibility.

(i) the claim recites elements/steps in addition to the judicial exception that must be used/taken by others to apply the judicial exception. The generalities weight against.

(j) the claim recites elements/steps in addition to the judicial exception that are well-understood, purely conventional, or routine in the relevant field. Generic

administration of compounds for treatment is well-understood and conventional and weights against patentability.

(k) the claim recites elements/steps in addition to the judicial exception that are insignificant extrasolution activity (i.e., are merely appended to the judicial exception). Appears not to be relevant.

(l) the claim recites elements/steps in addition to the judicial exception that amount to nothing more than a mere field of use. The general administration for generic treatment is nothing more than a mere field of use against a myriad of unrelated organisms.

On balance, if the totality of the relevant factors weighs toward eligibility, the claim qualifies as eligible subject matter. If the totality of the relevant factors weighs against eligibility, the claim should be rejected. The examiner has considered every relevant factor and related evidence in rejecting the claims under §101 and the invention as claimed is not found to be patent eligible. The invention is not patent eligible.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 5-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolating the compound of Fomula (II), for example (Claim 4), is not enabled for the compound of Formula (I). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (Wands, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (Wands, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the relative skill of those in the art; (5) the predictability or unpredictability of the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to a compounds of Formula (I) but the compound of Formrula (II) is what is actually isolated and used in the treatments

(3) The state of the prior art:

The prior art is full of methodologies for isolating compounds from organisms as this is but routine for one of skill in the art.

(4) The relative skill of those in the art:

The relative skill of those in the art is high.

(5) The predictability or unpredictability of the art:

Since the other stereoisomers claimed remains largely unsolved and not found, means for isolating the other compound is highly unpredictable.

(6) The amount of direction or guidance presented and (7) The presence or absence of working examples:

The specification has provided structural data for a single isolate, but has not provided information on any other isolate that would have any other stereochemistry that that found.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by factors above, and the high unpredictability and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to isolate any other compound with a different stereochemistry and treat with that compound.

It is the examiner's position that one skilled in the art could not practice the invention commensurate in the scope of the claims without undue experimentation.

Claim Rejections - 35 USC § 112

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

(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), first paragraph:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-23, 25-33, 36, 38, 40, 43, 46, 48, 50 and 52 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for pre-AIA the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed. The courts have stated, for example:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, no that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163.

The factors considered in the Written Description requirement are:

(1) level of skill and knowledge in the art,

(2) partial structure,

(3) physical and/or chemical properties,

(4) functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and

(5) the method of making the claimed invention.

In the instant case, the claims are drawn to treatment of disorders from unrelated organisms/pathogens, see Claim 20 and Claim 25 for the meaning of pathogen.

(1) Level of skill and knowledge in the art:

The level of skill to practice the art of the instantly claimed invention is high.

(2) Partial structure: (3) Physical and/or chemical properties: and/or (4) Functional characteristics:

The properties of the compound is that of, at least, antibacterial, which by property ascribes some functional characteristic.

(5) Method of making the claimed invention:

Isolation from a bacterial isolate.

As stated supra, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that Claim 20, for example, is a broad generic, with respect to all possible disorders encompassed by the claims, as well as the myriad of different unrelated bacteria, virus, etc… that are embraced by these separate categories.

While having written description for a few bacterium, the specification is simply void of describing the various disorders that one can treat. A disorder from a undisclosed virus reads on Ebola, HCV, yellow fever, etc… the specificity of the compound being nearly a magic bullet for any disorder from any microbial infection. Treating a bacterial infection is described, but the disorders are not.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.")

Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Conclusion

No claims are allowed. Note that the compound of Claim 4 is found to be free of prior art.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (**MPEP 714.02 and 2163.06**). Due to the procedure outlined in **MPEP § 2163.06** for interpreting claims, it is noted that other art may be applicable under **35 U.S.C. § 102 or 35 U.S.C. § 103(a**) once the aforementioned issue(s) is/are addressed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Prior art contained in the reference of record can be applied in the next office action.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to THOMAS S. HEARD whose telephone number is (571) 272-2064. The examiner can normally be reached from 12:30 – 9:00 pm, Central Standard Time.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, James Henry Alstrum-Acevedo can be reached on (517) 272-5548. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thomas S Heard Ph.D.
Primary Examiner
Art Unit 1654

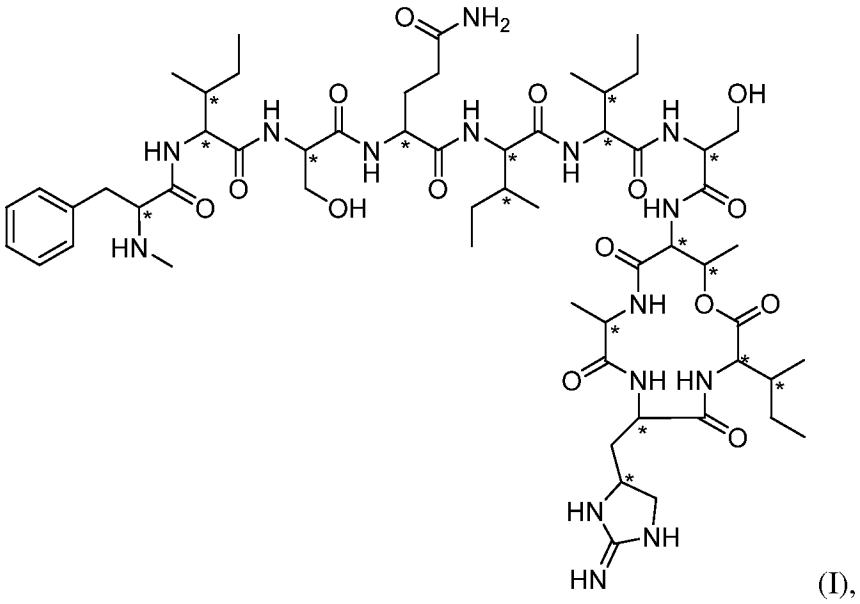
/Thomas S Heard/
Primary Examiner, Art Unit 1654

AMENDMENTS

This listing of claims will replace all prior versions, and listings, of claims in the application.

What is claimed is:

1. (Original) An isolated compound of Formula (I):



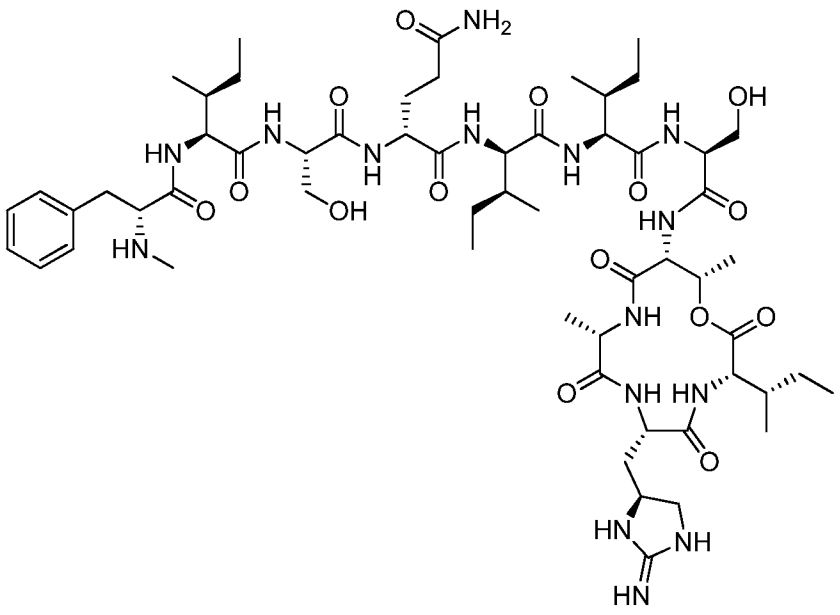
(I),

or an enantiomer, diastereomer, tautomer, or pharmaceutically-acceptable salt thereof, wherein each stereocenter (indicated with an "*") can be either the R or S configuration.

2. (Original) The compound of claim 1, wherein the compound is a natural product of bacterial isolate IS01862.

3. (Original) The compound of claim 1, wherein the compound is producible from bacterial isolate ISO1862.

4. (Original) An isolated compound of Formula (II):



(II),

or tautomer or pharmaceutically-acceptable salt thereof.

5. (Original) The compound of claim 1, wherein the compound is characterized by at least ten ^{13}C nuclear magnetic resonance peaks at chemical shifts in DMSO-d_6 selected from 36.3 ppm, 36.5 ppm, 36.9 ppm, 37.4 ppm, 52.1 ppm, 52.2 ppm, 52.7 ppm, 53.5 ppm, 55.7 ppm, 56.1 ppm, 56.4 ppm, 56.7 ppm, 57.3 ppm, 57.8 ppm, 57.9 ppm, 61.8 ppm, and 71.1 ppm.

6. (Original) The compound of claim 1, wherein the compound is characterized by ^{13}C nuclear magnetic resonance peaks at chemical shifts in DMSO-d_6 of 36.3 ppm, 36.5 ppm, 36.9 ppm, 37.4 ppm, 52.1 ppm, 52.2 ppm, 52.7 ppm, 53.5 ppm, 55.7 ppm, 56.1 ppm, 56.4 ppm, 56.7 ppm, 57.3 ppm, 57.8 ppm, 57.9 ppm, 61.8 ppm, and 71.1 ppm.

7. (Original) A compound of claim 1, wherein the compound is characterized by at least one of:

(a) a molecular weight of about 1242.47 g/mol;

(b) a proton nuclear magnetic resonance spectrum substantially the same as that shown in FIG. 1;

(c) a carbon 13 nuclear magnetic resonance spectrum substantially the same as that shown in FIG. 2;

(d) a COSY nuclear magnetic resonance spectrum substantially the same as that shown in FIG. 3;

(e) a DEPT-135 nuclear magnetic resonance spectrum substantially the same as that shown in FIG. 4;

(f) a HSQC nuclear magnetic resonance spectrum substantially the same as that shown in FIG. 5; and

(e) a HMBC nuclear magnetic resonance spectrum substantially the same as that shown in FIG. 6.

8. (Original) A compound of claim 1, wherein the compound is characterized by:

(a) a molecular weight of about 1242.47 g/mol;

(b) a proton nuclear magnetic resonance spectrum substantially the same as that shown in FIG. 1;

(c) a carbon 13 nuclear magnetic resonance spectrum substantially the same as that shown in FIG. 2;

(d) a COSY nuclear magnetic resonance spectrum substantially the same as that shown in FIG. 3;

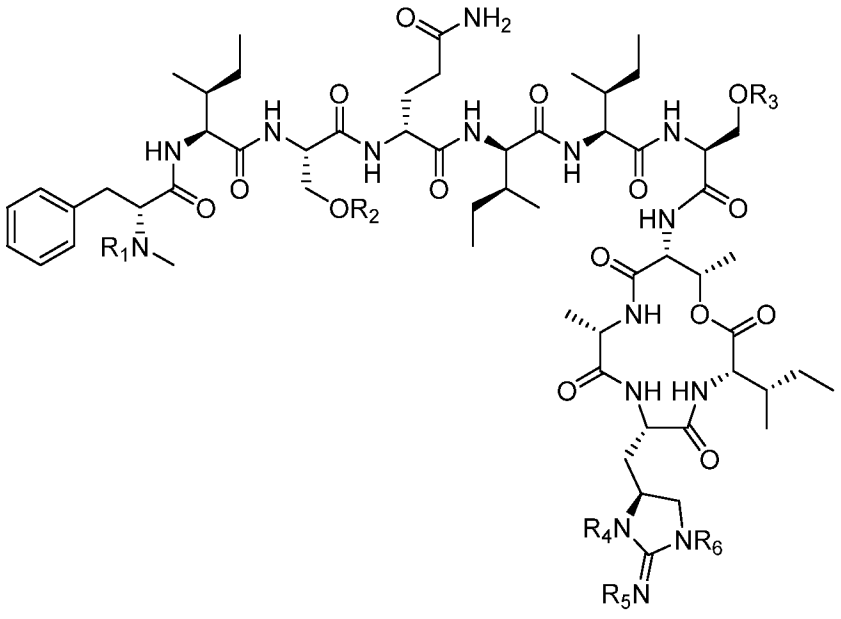
(e) a DEPT-135 nuclear magnetic resonance spectrum substantially the same as that shown in FIG. 4;

(f) a HSQC nuclear magnetic resonance spectrum substantially the same as that shown in FIG. 5; and

(e) a HMBC nuclear magnetic resonance spectrum substantially the same as that shown in FIG. 6.

9. (Cancelled)

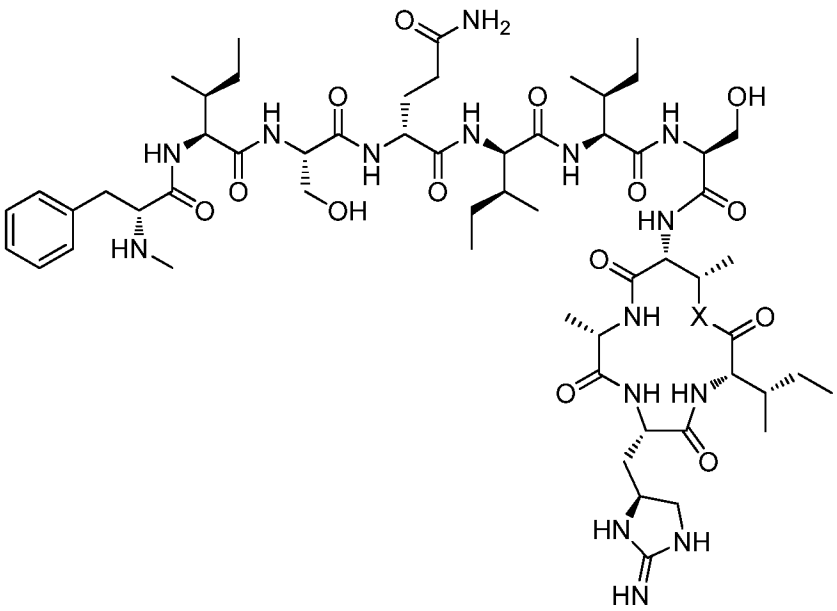
10. (Original) An isolated compound of Formula (III):



(III),

or a tautomer or pharmaceutically-acceptable salt thereof; wherein each $R_1 - R_6$ is independently selected from hydrogen, alkyl, alkenyl, alkynyl, cycloalkyl, cycloalkenyl, aryl, $C(=O)R_a$ and $S(=O)_2R_b$; each R_a is independently hydrogen, alkyl, alkenyl, alkynyl, cycloalkyl, cycloalkenyl, or aryl; and each R_b is independently alkyl, alkenyl, alkynyl, cycloalkyl, cycloalkenyl, or aryl.

11. (Original) An isolated compound of Formula (IV):

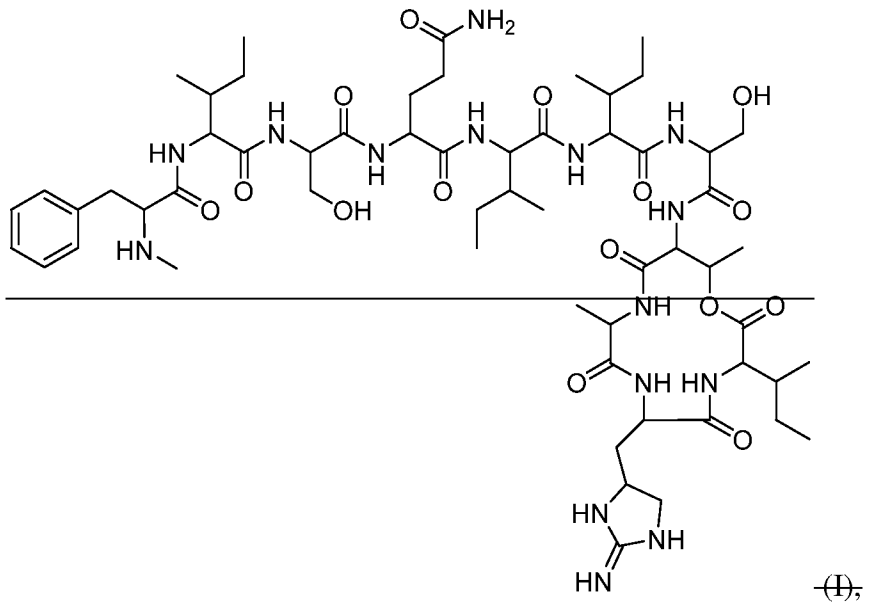


(IV), wherein X is NH, O or S; or a tautomer or pharmaceutically-acceptable salt thereof.

12. (Currently Amended) A pharmaceutical composition comprising the compound of claim [[1,]] 4[[, 10 or 11]] and a pharmaceutically-acceptable excipient, carrier, or diluent.

13. (Cancelled)

14. (Currently Amended) A method for producing a compound of Formula (I) of claim 1,



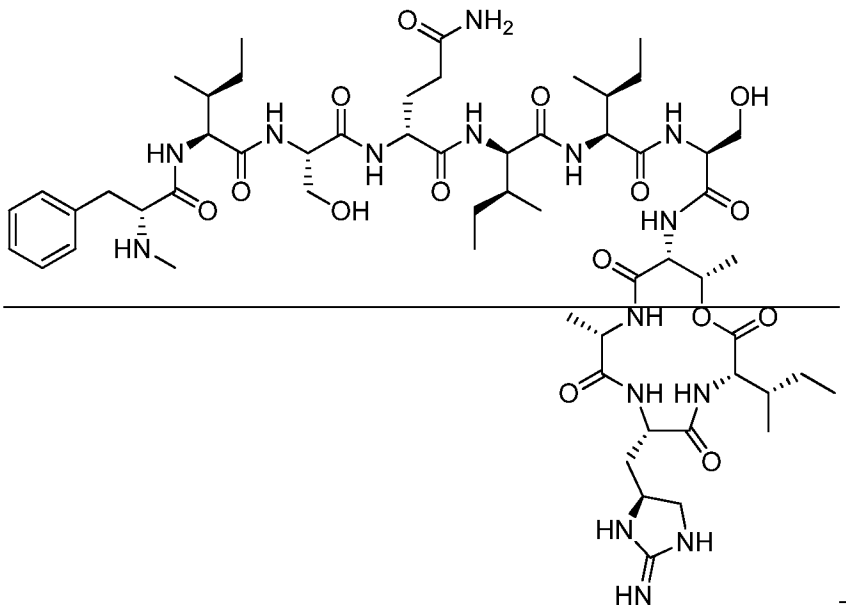
~~(I),~~

~~or an enantiomer, diastereomer, tautomer, or pharmaceutically acceptable salt thereof,~~ the method comprising:

cultivating a bacterial isolate ISO18629 in a culture medium, the culture medium comprising assimilable sources of carbon, nitrogen, and inorganic salts under aerobic conditions;

thereby producing a compound of Formula (I).

15. (Currently Amended) A method for producing a compound of Formula (II) of claim 4,~~:~~



~~(II),~~

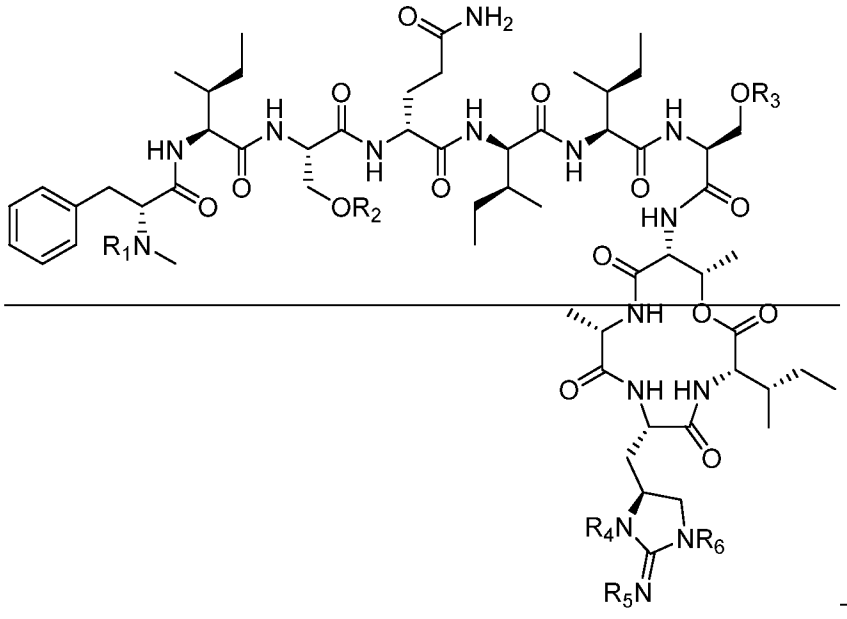
~~or tautomer or pharmaceutically acceptable salt thereof,~~

the method comprising:

cultivating a bacterial isolate ISO18629 in a culture medium, the culture medium comprising assimilable sources of carbon, nitrogen, and inorganic salts under aerobic conditions;

thereby producing a compound of Formula (II).

16. (Currently Amended) A method for producing a compound of Formula (III) of claim 10~~:~~



~~(III),~~

~~or a tautomer or pharmaceutically acceptable salt thereof, wherein~~

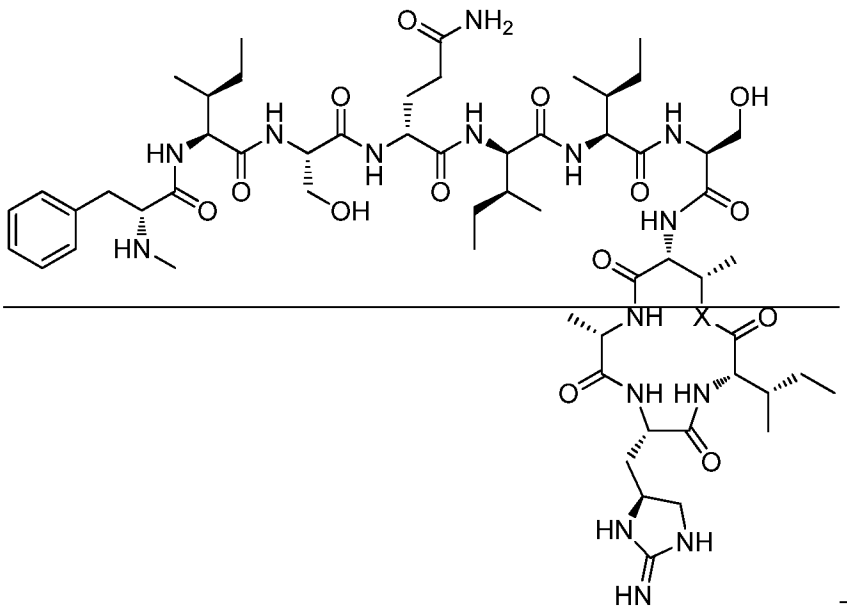
~~each R_1 — R_6 is independently selected from hydrogen, alkyl, alkenyl, alkynyl, cycloalkyl, cycloalkenyl, aryl, $C(=O)R_a$ and $S(=O)_2R_b$; each R_a is independently hydrogen, alkyl, alkenyl, alkynyl, cycloalkyl, cycloalkenyl, or aryl; and each R_b is independently alkyl, alkenyl, alkynyl, cycloalkyl, cycloalkenyl, or aryl;~~

the method comprising:

cultivating a bacterial isolate ISO18629 in a culture medium, the culture medium comprising assimilable sources of carbon, nitrogen, and inorganic salts under aerobic conditions;

thereby producing a compound of Formula (III).

17. (Currently Amended) A method for producing a compound of Formula (IV) of claim 11,~~:~~



~~(IV), wherein X is NH, O or S; or a tautomer or pharmaceutically-acceptable salt thereof;~~

the method comprising:

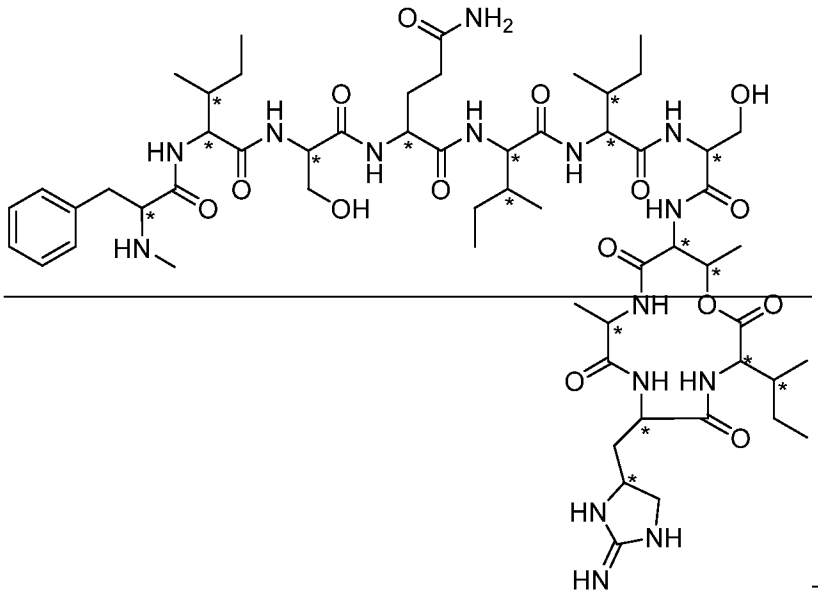
cultivating a bacterial isolate ISO18629 in a culture medium, the culture medium comprising assimilable sources of carbon, nitrogen, and inorganic salts under aerobic conditions;

thereby producing a compound of Formula (IV).

18. (Cancelled)

19. (Cancelled)

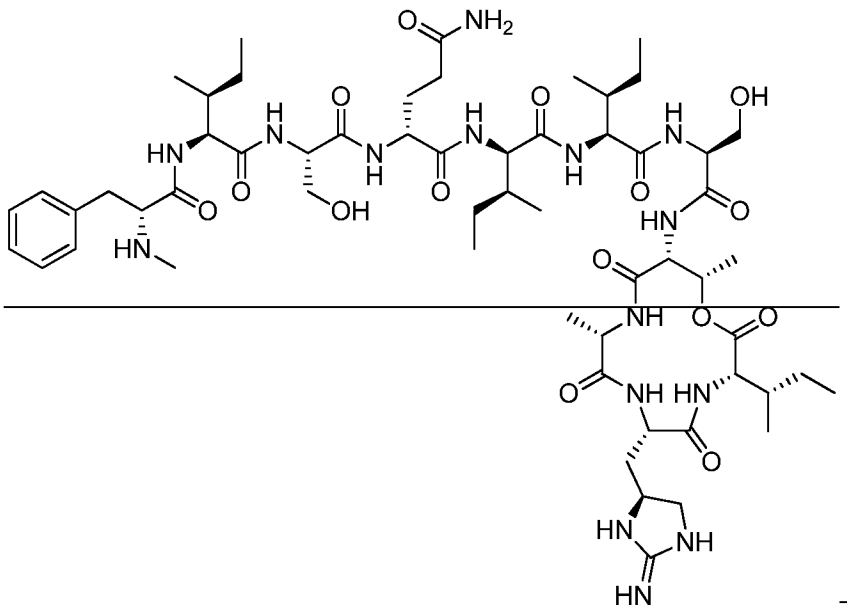
20. (Currently Amended) A method of treating a disorder in a subject in need thereof, the method comprising administering to the subject an effective amount of a compound of Formula (I) of claim 1~~,~~



~~(I)~~

~~or an enantiomer, diastereomer, tautomer, or pharmaceutically-acceptable salt thereof, wherein each stereocenter (indicated with an "*") can be either the R or S configuration,~~ thereby treating the disorder in said subject.

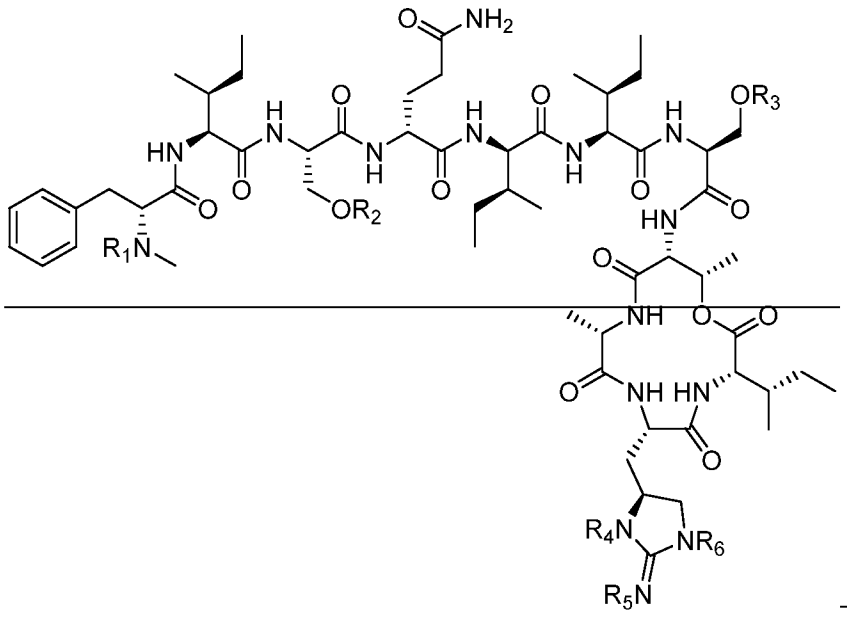
21. (Currently Amended) A method of treating a disorder in a subject in need thereof, the method comprising administering to the subject an effective amount of a compound of Formula (II) of claim 4,



~~(II),~~

~~or a tautomer or pharmaceutically acceptable salt thereof,~~ thereby treating the disorder in said subject.

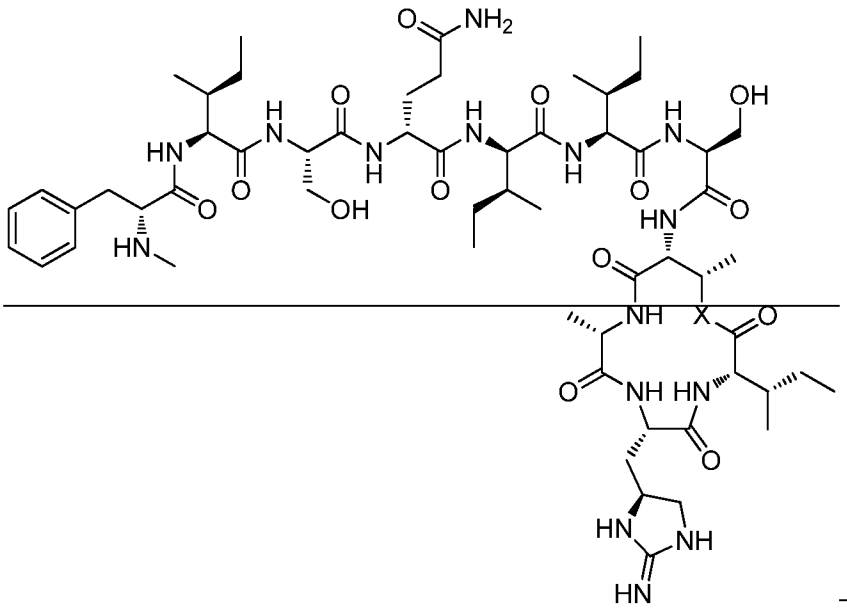
22. (Currently Amended) A method of treating a disorder in a subject in need thereof, the method comprising administering to the subject an effective amount of a compound of Formula (III) of claim 10,~~:~~



~~(III),~~

~~or a tautomer or pharmaceutically acceptable salt thereof, wherein each R_1 – R_6 is independently selected from hydrogen, alkyl, alkenyl, alkynyl, cycloalkyl, cycloalkenyl, aryl, C(=O)Ra and $S(=O)_2R_b$; each R_a is independently hydrogen, alkyl, alkenyl, alkynyl, cycloalkyl, cycloalkenyl, or aryl; and each R_b is independently alkyl, alkenyl, alkynyl, cycloalkyl, cycloalkenyl, or aryl,~~ thereby treating the disorder in said subject.

23. (Currently Amended) A method of treating a disorder in a subject in need thereof, the method comprising administering to the subject an effective amount of a compound of Formula (IV) of claim 11,



~~(IV),~~

~~wherein X is NH, O or S; or a tautomer or pharmaceutically acceptable salt thereof,~~ thereby treating the disorder in said subject.

24. (Cancelled)

25. (Currently Amended) The method of claim ~~20,~~ 21~~, 22 or 23~~, wherein the disorder is caused by a pathogen selected from the group consisting of a bacterium, a fungus, a virus, a protozoan, a helminth, a parasite, and combinations thereof.

26. (Original) The method of claim 25, wherein the pathogen is a bacterium.

27. (Original) The method of claim 26, wherein the bacterium is a Gram-positive bacterium.

28. (Original) The method of claim 27, wherein the Gram-positive bacterium is selected from the group consisting of *Streptococcus*, *Staphylococcus*, *Enterococcus*, *Corynebacteria*, *Listeria*, *Bacillus*, *Erysipelothrix*, *Mycobacterium*, *Clostridium,* and *Actinomycetales*.

29. (Original) The method of claim 27, wherein the Gram-positive bacterium is selected from the group consisting of methicillin-susceptible and methicillin-resistant staphylococci (including *Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus haemolyticus, Staphylococcus hominis, Staphylococcus saprophyticus*, and coagulase-negative staphylococci), glycopeptide intermediate-susceptible *Staphylococcus aureus* (GISA), penicillin-susceptible and penicillin-resistant streptococci (including *Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus avium, Streptococcus bovis, Streptococcus lactis, Streptococcus sangius, Streptococcus anginosus, Streptococcus intermedius, Streptococcus constellatus* and Streptococci Group C, Streptococci Group G and V*iridans streptococci*), enterococci (including vancomycin-susceptible and vancomycin-resistant strains such as *Enterococcus faecalis* and *Enterococcus faecium*), *Clostridium difficile, Clostridium clostridiiforme, Clostridium innocuum, Clostridium perfringens, Clostridium tetani , Mycobacterium tuberculosis, Mycobacterium avium, Mycobacterium intracellulare, Mycobacterium kansaii, Mycobacterium gordonae, Mycobacteria sporozoites, Listeria monocytogenes , Bacillus subtilis, Bacillus anthracis, Corynebacterium diphtheriae, Corynebacterium jeikeium, Corynebacterium sporozoites, Erysipelothrix rhusiopathiae, and Actinomyces israelli.*

30. (Original) The method of claim 25, wherein the disorder is caused by infection with *Bacillus anthracis.*

31. (Original) The method of claim 26, wherein the bacterium is a Gram-negative bacterium.

32. (Original) The method of claim 31, wherein the Gram-negative bacterium is selected from the group consisting of *Helicobacter pylori, Legionella pneumophilia , Neisseria gonorrhoeae, Neisseria meningitidis,* pathogenic *Campylobacter sporozoites, Haemophilus influenzae, Pseudomonas aeruginosa, Enterobacter aerogenes, Enterobacter cloacae, Klebsiella pneumoniae, Klebsiella oxytoca, Pasteurella multocida, Bacteroides sporozoites, Bacteriodes fragilis, Bacteriodes thetaiotaomicron, Bacteriodes*

uniformis, Bacteriodes vulgatus Fusobacterium nucleatum, Streptobacillus moniliformis, Leptospira, Escherichia coli, Salmonella enterica, Salmonella salamae, Salmonella arizonae, Salmonella diarizonae, Salmonella houtenae, Salmonella bongori, Salmonella indica, Salmonella Enteritidis, Salmonella typhi, and *Citrobacter freundii*.

33. (Original) The method of claim 25, wherein the pathogen is a virus.

34. (Cancelled)

35. (Cancelled)

36. (Original) The method of claim 25, wherein the pathogen is a protozoan.

37. (Cancelled)

38. (Original) The method of claim 25, wherein the pathogen is a helminth.

39. (Cancelled)

40. (Original) The method of claim 25, wherein the pathogen is a parasite.

41. (Cancelled)

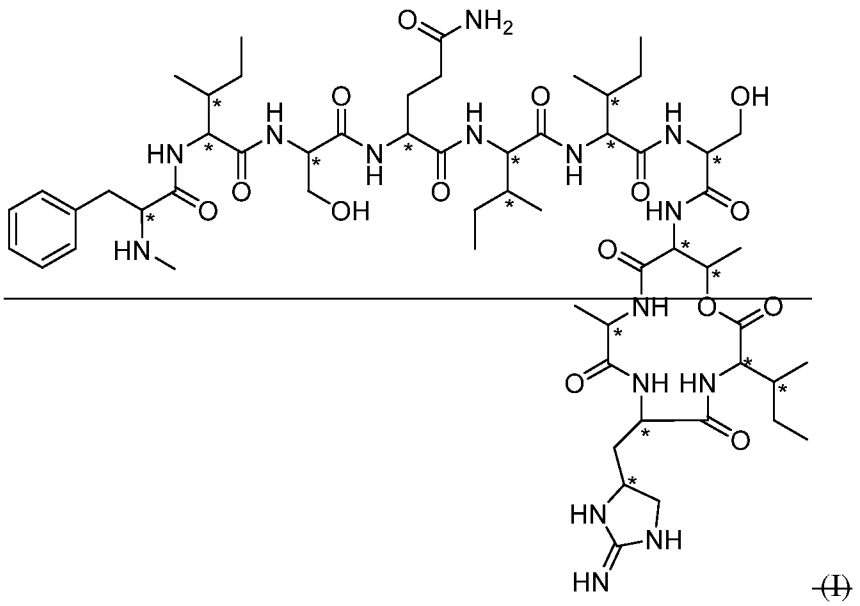
42. (Cancelled)

43. (Original) The method of claim 25, wherein the pathogen is a fungus.

44. (Cancelled)

45. (Original) An isolated culture comprising a bacterial species, having the identifying characteristics of a ISO18629 isolate.

46. (Currently Amended) A method of inhibiting the growth of an infectious agent, the method comprising contacting the agent with a compound of Formula (I) of claim 1~~:~~

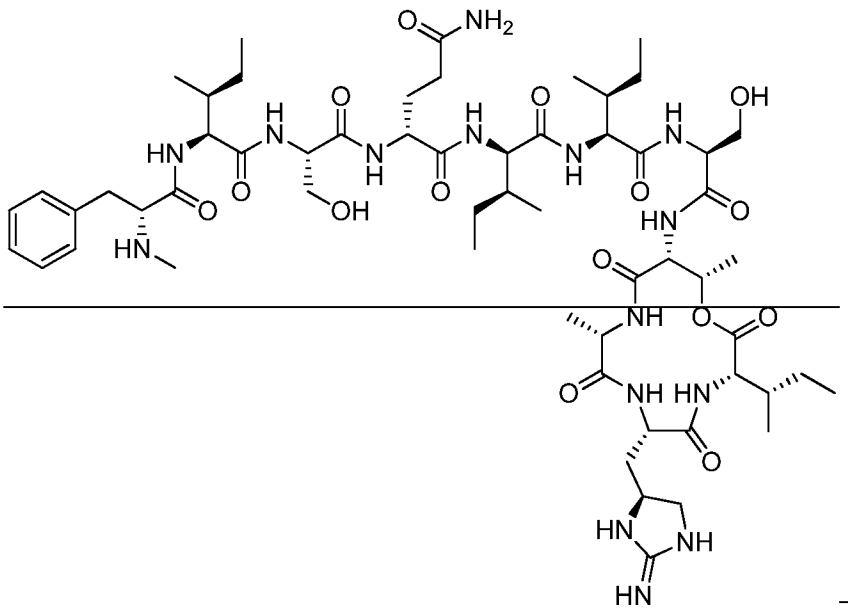


~~(I)~~

~~or an enantiomer, diastereomer, tautomer, or pharmaceutically acceptable salt thereof, wherein each stereocenter (indicated with an "*") can be either the R or S configuration,~~ thereby inhibiting the growth of the infectious agent.

47. (Cancelled)

48. (Currently Amended) A method of inhibiting the growth of an infectious agent, the method comprising contacting the agent with a compound of Formula (II) of claim 4~~:~~

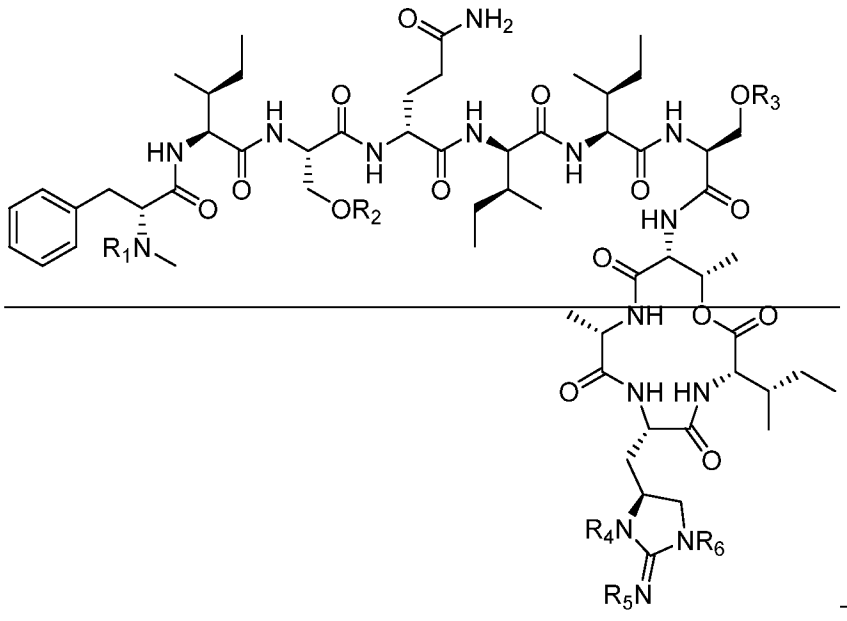


~~(II),~~

~~or tautomer or pharmaceutically acceptable salt thereof,~~ thereby inhibiting the growth of the infectious agent.

49. (Cancelled)

50. (Currently Amended) A method of inhibiting the growth of an infectious agent, the method comprising contacting the agent with a compound of Formula (III) of claim 10,~~:~~



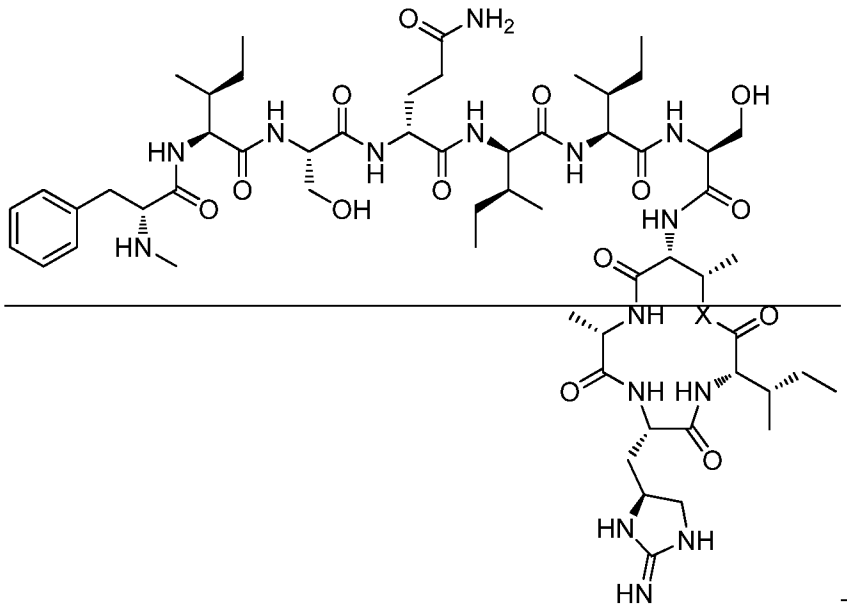
~~(III),~~

~~or a tautomer or pharmaceutically acceptable salt thereof, wherein~~

~~each R_1 – R_6 is independently selected from hydrogen, alkyl, alkenyl, alkynyl, cycloalkyl, cycloalkenyl, aryl, $C(=O)R_a$ and $S(=O)_2R_b$; each R_a is independently hydrogen, alkyl, alkenyl, alkynyl, cycloalkyl, cycloalkenyl, or aryl; and each R_b is independently alkyl, alkenyl, alkynyl, cycloalkyl, cycloalkenyl, or aryl;~~ thereby inhibiting the growth of the infectious agent.

51. (Cancelled)

52. (Currently Amended) A method of inhibiting the growth of an infectious agent, the method comprising contacting the agent with a compound of Formula (IV) of claim 11~~:~~



~~(IV), wherein X is NH, O or S; or a tautomer or pharmaceutically-acceptable salt thereof,~~ thereby inhibiting the growth of the infectious agent.

53. (Cancelled)