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Application Number: 15467631 Document Date: 03/23/2017

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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	**SYPA-009/C03US**
First Inventor	**Stephen COMISKEY**
Title	**FORMULATIONS OF GUANYLATE CYCLASE C AGONISTS AND METHODS OF USE**
Express Mail Label No.	

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. ☐ **Fee Transmittal Form** (PTO/SB/17 or equivalent)
2. ☒ **Applicant asserts small entity status.** See 37 CFR 1.27.
3. ☐ **Applicant certifies micro entity status.** See 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent.
4. ☒ **Specification** [*Total Pages* 152] Both the claims and abstract must start on a new page. *(See MPEP § 608.01(a) for information on the preferred arrangement)*
5. ☒ **Drawing(s).** (*35 U.S.C. 113*) [*Total Sheets* 6]
6. **Inventor's Oath or Declaration** [*Total Sheets* ___] *(including substitute statements under 37 CFR 1.64 and assignments serving as an oath or declaration under 37 CFR 1.63(e))*
   a. ☐ Newly executed (original or copy)
   b. ☐ A copy from a prior application (37 CFR 1.63(d))
7. ☒ **Application Data Sheet** **See Note below.* See 37 CFR 1.76 (PTO/AIA/14 or equivalent)
8. ☐ **CD-ROM or CD-R** in duplicate, large table or Computer Program *(Appendix)*
   ☐ Landscape Table on CD
9. **Nucleotide and/or Amino Acid Sequence Submission** *(if applicable, items a. – c. are required)*
   a. ☒ Computer Readable Form (CRF)
   b. ☐ Specification Sequence Listing on:
      i. ☐ CD-ROM or CD-R (2 copies); or
      ii. ☐ Paper
   c. ☐ Statements verifying identity of above copies

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ACCOMPANYING APPLICATION PARTS

10. ☐ **Assignment Papers** (cover sheet & document(s))
    Name of Assignee _____
11. ☐ **37 CFR 3.73(c) Statement** ☐ **Power of Attorney** *(when there is an assignee)*
12. ☐ **English Translation Document** *(if applicable)*
13. ☐ **Information Disclosure Statement** (PTO/SB/08 or PTO-1449)
    ☐ Copies of citations attached
14. ☒ **Preliminary Amendment**
15. ☐ **Return Receipt Postcard** *(MPEP § 503) (Should be specifically itemized)*
16. ☐ **Certified Copy of Priority Document(s)** *(if foreign priority is claimed)*
17. ☐ **Nonpublication Request** Under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent.
18. ☐ **Other:**

***Note**: (1) Benefit claims under 37 CFR 1.78 and foreign priority claims under 1.55 **must** be included in an Application Data Sheet (ADS).
(2) For applications filed under 35 U.S.C. 111, the application must contain an ADS specifying the applicant if the applicant is an assignee, person to whom the inventor is under an obligation to assign, or person who otherwise shows sufficient proprietary interest in the matter. See 37 CFR 1.46(b).

19. CORRESPONDENCE ADDRESS

☒ The address associated with Customer Number: **58249** **OR** ☐ Correspondence address below

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Signature	/Anne E. Fleckenstein/	Date	March 23, 2017
Name (Print/Type)	Anne E. Fleckenstein	Registration No. (Attorney/Agent)	62,951

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: Comiskey et al.		Confirmation No.:	*To Be Assigned*
Serial No.: *To Be Assigned* *(Continuation of U.S. Appl. No. 13/421,769)*		Group Art Unit:	*To Be Assigned*
Filed:	*herewith*	Examiner:	*To Be Assigned*

FOR: **FORMULATIONS OF GUANYLATE CYCLASE C AGONISTS AND METHODS OF USE**

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
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PRELIMINARY AMENDMENT

Prior to examination of the above-identified application, please amend the above-captioned application as follows:

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims begin on page 3 of this paper.

Remarks begin on page 5 of this paper.

IN THE SPECIFICATION:

Please replace the paragraph under the heading "Related Applications" with the paragraph below. The amendments are indicated by strikethrough and underlining.

This application is a continuation of U.S. Application No. 13/421,769, filed March 15, 2012, which is a continuation-in-part of PCT/US2011/051805 filed on September 15, 2011, which claims the benefit of priority to U.S. Provisional Application No. 61/383,156 filed on September 15, 2010, U.S. Provisional Application No. 61/387,636 filed on September 29, 2010, and U.S. Provisional Application No. 61/392,186 filed on October 12, 2010, the contents of which are incorporated by reference in their entireties.

Please insert the paragraph below at page 1, after the "Related Applications" section and before the "Field of Invention" section:

INCORPORATION OF SEQUENCE LISTING

The contents of the text file named "SYPA_009_C03US_SeqList_ST25.txt", which was created on March 23, 2017 and is 113 KB in size, are hereby incorporated by reference in their entirety.

IN THE CLAIMS:

1-42. (Cancelled)

43. (New) An oral dosage formulation of a Guanylate Cyclase-C (GCC) agonist peptide consisting of SEQ ID NO:1, wherein said peptide is a (4,12; 7,15) bicycle, an inert low moisture carrier and a lubricant, wherein the peptide has a chromatographic purity of no less than 91% after storage for at least three months.

44. (New) The oral dosage formulation of claim 43, wherein the GCC agonist peptide has a chromatographic purity of no less than 92% to 95%.

45. (New) The oral dosage formulation of claim 43, wherein the formulation contains less than 0.2% inorganic acids and carboxylic acids.

46. (New) The oral dosage formulation of claim 43, wherein the formulation is a solid formulation and the unit dose is a powder, granule, sachet, troche, tablet, or capsule.

47. (New) The oral dosage formulation of claim 43, wherein the GCC agonist peptide is stabilized against degradation for a period of at least 18 months at 30 °C and 65% relative humidity, or at least 18 months at 25 °C and 60% relative humidity, or at least 18 months at 2-8 °C.

48. (New) The oral dosage formulation of claim 43, wherein the formulation is in the form of a capsule or tablet.

49. (New) The oral dosage formulation of claim 48, wherein the capsule or tablet is in a blister pack or strip.

50. (New) The oral dosage formulation of claim 43, wherein the lubricant is magnesium stearate.

51. (New) The oral dosage formulation of claim 43, wherein the lubricant is at 0.25% (w/w).

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