Non-Provisional Utility Patent Application Filing

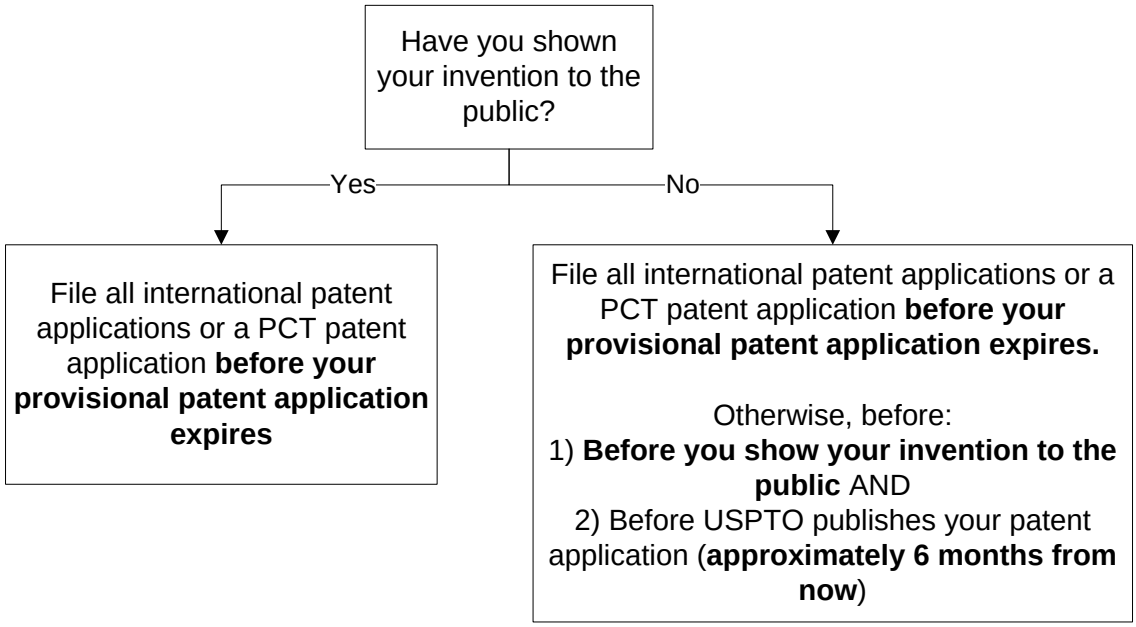
Utility Patent Application Number: **17/223,920**
Filing Date: **06-APR-2021**

WHAT'S NEXT?

1) **Filing Receipt From USPTO**
The US Patent Office will send a filing receipt in about 4-6 weeks. This comes in PDF format and when we receive it, we will email it to you. There is no need to wait for this document. The application is filed and *patent pending* as of the filing date above.
2) **Examination by USPTO**
The US Patent Office will examine your patent application and find inventions similar to yours, called prior art. If the examiner believes your invention is unique enough, the examiner may issue a notice of allowance at which time issuance fees will be due to formally grant the approved patent. If the examiner wants to discuss the similarities of your invention to other inventions the examiner has found, the examiner will issue a letter called an office action stating why the examiner thinks your invention is too similar to prior art. If this should happen, you have an opportunity to ask our attorneys to argue back for approval. On average, it may take 18-24 months before the US Patent Office examines your patent application. Hang tight, in the meantime, your invention is patent pending, and you can and should label your invention as such.

IMPORTANT DEADLINES:

1) **<u>FILE INTERNATIONAL PATENT APPLICATIONS BEFORE</u>:**



<u>Failure to file international patent applications before the deadline may result in permanent loss of the option to file internationally.</u>

- **IF YOU HAVE SHOWN YOUR INVENTION TO THE PUBLIC:** You must file all international patent applications or a PCT patent application to extend the time to file international patent apps before your provisional patent application expires.
- **IF YOU HAVE NOT YET SHOWN YOUR INVENTION TO THE PUBLIC:** You should file international patent applications or a PCT patent application to extend the time to file international patent apps before your provisional patent application expires. This gives your international patent applications the date of your US provisional patent application. If you cannot file before your US provisional patent application expires, you can still file internationally before the earlier of:
    - Before you show your invention to the public AND
    - Before the US Patent Office publishes the US patent application we just filed, which will be approximately 6 months from now. The date the US Patent Office publishes your patent application is approximate, so it is important to file international patent apps as soon as possible. Once the US Patent Office publishes your US patent application, you may lose the ability to file international patent applications. We need 8 weeks to comfortably prepare international patent apps, notify promptly.

To learn more about the PCT application: https://www.thoughtstopaper.com/blog/what-is-a-pct-patent-application/

It is your responsibility to let us know you want to file internationally, well ahead of the deadlines.

If you missed the above deadline to file internationally, you may still be able to file in some countries, but not all. Each country's patent rules are different. Ask us to review your specific scenario and countries you wish to file in.

2) **FILE DESIGN PATENT APPLICATIONS BEFORE YOU SHOW YOUR INVENTION TO THE PUBLIC**
Your patent application covers the *utility* of your invention (how your invention works). However, it does not cover the *design* of your invention (how your invention looks). If you also want to prevent others from making an invention that looks like yours, you should also apply for a design patent. Design patent applications should be filed before you show your invention to the public. After your invention is shown to the public, you lose the ability to file design patent applications in many countries. It is important to note that this patent application we just filed will be published to the public by the US Patent Office sometime in the next several months. Even if you do not show your invention to the public yourself, the US Patent Office will. Once the invention is shown to the public, you lose the ability to file design patent applications in many countries, Therefore, you should request design patent applications in all countries you want design rights in as soon as possible.

KEEP IN MIND:

1) **Let us know if your contact information changes**
As we represent you before the patent office, the patent office will send notices to us only and not directly to you. We then forward these notices to you by email. Most notices from the patent office have a strict due date for us to reply to. It is therefore important for you to update us if your email, mail, or phone number changes so that we can ensure delivery of important notifications to you. Further, it is important for you to regularly check your email and mail so as to not miss any notices which have a deadline.

2) **Let us know if you become aware of similar inventions invented before yours**
   US patent law states that you as the inventor have the obligation to report to the patent office any inventions made before yours that you are aware of or even become aware of after you have filed your patent application. Failure to do so could result in loss of patent rights. If you become aware of such similar inventions, send them to us so that we can submit them to the US Patent Office. A fee will be required.
3) **Improvements to the invention can be filed as child applications**
   Once a patent application is filed, no new information can be added to it. If you make an improvement to your invention that you wish to protect in a patent application, we need to do so by filing a second patent application to cover the new version, we call a child application. This should be done as soon as possible so that the improved version is also protected with a patent application.

Electronic Acknowledgement Receipt

EFS ID:	42383330
Application Number:	17223920
International Application Number:	
Confirmation Number:	7828
Title of Invention:	METHODS TO PREPARE NASOPHARYNGEAL AND ORAL MATERIAL FOR ORAL INOCULATION OF COVID-19
First Named Inventor/Applicant Name:	Steven Mark Hayden
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RAM confirmation Number	E202146I28373875
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The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	ADS_TUP63220.pdf	1255679 ef9911ef7afcf988ef08470c532c940cf938119e	no	8
Warnings:					
Information:					
2		spec_TUP63220.pdf	71503 2b41a644b46c6a2bbcaa17a4941f42ffd834136b	yes	17

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	10
Claims	11	16
Abstract	17	17

Warnings:					
Information:					
3	Drawings-only black and white line drawings	figs_TUP63220_emb.pdf	172699 97c6de262765e20abf9fd24a2a5968642e6edd1b	no	1
Warnings:					
Information:					
4	Oath or Declaration filed	Declaration_TUP63220.pdf	2120508 55734132f9507d449f1783d46b5d583bd11cce67	no	2
Warnings:					
Information:					
5	Power of Attorney	POA_TUP63220.pdf	2353240 1bfa13ab22c5c5faf25487478c398e129ff02323	no	2

Warnings:					
Information:					
6	Fee Worksheet (SB06)	fee-info.pdf	35435 3d53fa25cbd0263ff8d82ac1fa98b1138c2b3ac2	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	6009064	

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

METHODS TO PREPARE NASOPHARYNGEAL AND ORAL MATERIAL FOR ORAL INOCULATION OF COVID-19

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority to U.S. Provisional Application No. 63/008,145 filed April 10, 2020, which is hereby incorporated herein by reference.

FIELD OF THE INVENTION

The present disclosure relates generally to oral inoculation. More specifically, the present disclosure describes methods to prepare nasopharyngeal and oral material for oral inoculation of COVID-19.

BACKGROUND OF THE INVENTION

Current methods of reducing SARS-Co V-2 transmission include social distancing, wearing face masks, and vaccinations. However, it is becoming increasingly difficult to control SARS-CoV-2 respiratory spread. The working populations in many countries cannot afford N95 masks, expensive injections with unknown long-term side effects, nor economic and social isolation. The SARS-CoV-2 is currently reproducing in areas that are unable to control respiratory transmission, multiplication and mutation. As the transmissibility of respiratory mutants increases it become more difficult to control transmission. There exists a need in the art for solutions that address SARS-Co V-2 transmissions rates without resulting in serious side effects that are not burdensome on the economically distressed.

BRIEF DESCRIPTION OF THE DRAWINGS

Some of the embodiments will be described in detail, with reference to the following figures, wherein like designations denote like members, wherein:

FIGURE illustrates the process steps for a method to prepare material for oral inoculation of SARS-CoV-2 according to some embodiments.

Unless otherwise specifically noted, articles depicted in the drawings are not necessarily drawn to scale.

DETAIL DESCRIPTIONS OF THE INVENTION

As a preliminary matter, it will readily be understood by one having ordinary skill in the relevant art that the present disclosure has broad utility and application. As should be understood, any embodiment may incorporate only one or a plurality of the above-disclosed aspects of the disclosure and may further incorporate only one or a plurality of the above-disclosed features. Furthermore, any embodiment discussed and identified as being "preferred" is part of a best mode contemplated for carrying out the embodiments of the present disclosure. Other embodiments also may be discussed for additional illustrative purposes in providing a full and enabling disclosure. Moreover, many embodiments, such as adaptations, variations, modifications, and equivalent arrangements, will be implicitly disclosed by the embodiments described herein and fall within the scope of the present disclosure.

Accordingly, while embodiments are described herein in detail in relation to one or more embodiments, it is to be understood that this disclosure is illustrative and exemplary of the present disclosure and are made merely for the purposes of providing a full and enabling disclosure. The detailed disclosure herein of one or more embodiments is not intended, nor is to be construed, to limit the scope of patent protection afforded in any claim of a patent issuing here from, which scope is to be defined by the claims and

the equivalents thereof. It is not intended that the scope of patent protection be defined by reading into any claim a limitation found herein that does not explicitly appear in the claim itself.

Thus, for example, any sequence(s) and/or temporal order of steps of various processes or methods that are described herein are illustrative and not restrictive. Accordingly, although steps of various processes or methods may be shown and described as being in a sequence or temporal order, the steps of any such processes or methods are not limited to being carried out in any sequence or order, absent an indication otherwise. Indeed, the steps in such processes or methods generally may be carried out in various sequences and orders while still falling within the scope of the present disclosure. Accordingly, it is intended that the scope of patent protection is to be defined by the issued claim(s) rather than the description set forth herein.

Additionally, it is important to note that each term used herein refers to that which an ordinary artisan would understand such term to mean based on the contextual use of such term herein. To the extent that the meaning of a term used herein—as understood by the ordinary artisan based on the contextual use of such term—differs in any way from any dictionary definition of such term, it is intended that the meaning of the term as understood by the ordinary artisan should prevail.

Furthermore, it is important to note that, as used herein, “a” and “an” each generally denotes “at least one,” but does not exclude a plurality unless the contextual use dictates otherwise. When used herein to join a list of items, “or” denotes “at least one of the items,” but does not exclude a plurality of items of the list. Finally, when used herein to join a list of items, “and” denotes “all of the items of the list.”

The following detailed description refers to the accompanying drawings. Wherever possible, the same reference numbers are used in the drawings and the following description to refer to the same or similar elements. While many embodiments of the disclosure may be described, modifications, adaptations, and other implementations are possible. For example, substitutions, additions, or modifications may be made to the elements illustrated in the drawings, and the methods described herein may be modified by substituting, reordering, or adding stages to the disclosed methods. Accordingly, the following detailed description does not limit the disclosure. Instead, the

proper scope of the disclosure is defined by the appended claims. The present disclosure contains headers. These headers are used as references and are not to be construed as limiting upon the subjected matter disclosed under the header.

Other technical advantages may become readily apparent to one of ordinary skill in the art after review of the following figures and description. It should be understood at the outset that, although exemplary embodiments are illustrated in the figures and described below, the principles of the present disclosure may be implemented using any number of techniques, whether currently known or not. The present disclosure should in no way be limited to the exemplary implementations and techniques illustrated in the drawings and described below.

The present disclosure includes many aspects and features. Moreover, while many aspects and features relate to, and are described in the context of methods to prepare nasopharyngeal and oral material for oral inoculation of COVID-19, embodiments of the present disclosure are not limited to use only in this context.

Current methods of reducing SARS-Co V-2 transmission include social distancing, wearing face masks, and vaccinations. However, it is becoming increasingly difficult to control SARS-CoV-2 respiratory spread. The working populations in many countries cannot afford N95 masks, expensive injections with unknown long-term side effects, nor economic and social isolation. The SARS-CoV-2 is currently reproducing in areas that are unable to control respiratory transmission, multiplication and mutation. As the transmissibility of respiratory mutants increases it become more difficult to control transmission. There exists a need in the art for solutions that address SARS-Co V-2 transmissions rates without resulting in serious side effects that are not burdensome on the economically distressed.

Coronavirus infections historically are well tolerated causing only rhinitis and nasal congestion in billions of people. The entire coronavirus family infects the gastrointestinal tract usually with little or no symptoms. Coronavirus is very well tolerated in the intestines. SARS-CoV-2, a member of coronavirus family, produces a serious respiratory infection with severe symptoms. To be sure, SARS-CoV-2 only produces serious symptoms when it infects the pulmonary alveolus, which can result in serious disease and hospitalizations. If SARS-CoV-2 does not infect the alveolus there is

no serious infection or disease. For example, if SARS-CoV-2 infects the intestinal tract, the result is limited to mild to moderate intestinal cramps and loose stool as opposed to fever chills, pneumonia, and sepsis. Prior to the coronavirus pandemic, coronavirus upper respiratory infections typically did not result in fevers, chills, or severe fatigue.

Avoiding alveolar infections avoids the systemic fever chills, fatigue, hospitalizations, and serious side effects. When SARS-CoV-2 infects the pulmonary alveolus, it multiplies into many millions of virus particles in asymptomatic phase. Eventually the alveolus fills with many millions of virus particles that cause viral sepsis in the blood stream. Alveolar multiplication is necessary to create fever chills, pulmonary and other systemic complications.

Not to be limited by theory, if intestinal exposure of SARS-CoV-2 can occur without alveolar infection, then there would be no systemic side effects of fever chills and fatigue. It is also theorized that intestinal exposure can create an alveolar defense that would stop airborne transmission of virus. Thus, if the SARS -CoV-2 virus does not multiply on the alveolus, it cannot spread through the air and be transmitted. Despite millions of intestinal infections, there are almost no cases of stool to respiratory transmission. Accidental intestinal exposure occurs secondary to oral live virus being swallowed from mouth via accidental exposure. The vast majority of live oral SARS-CoV-2 is killed by stomach acid. However, often a few viruses will make it to the small intestine and establish an intestinal infection of SARS-CoV-2.

Intestinal exposure of SARS-CoV-2 results in an intestinal infection of SARS-CoV-2. When the SARS-CoV-2 intestinal infection occurs without alveolar infection there are only mild gastrointestinal ("GI") side effects and no fever chills and myalgia. SARS-CoV-2 severely depressed the world economy. Most nations responded in a traditional manner to the COVID epidemic. Many nations funded research in intramuscular vaccines, but COVID is not a traditional respiratory infection. SARS-CoV-2 spreads mostly in the asymptomatic phase and is based on multiplication at the alveolus. Speaking, singing, or making noise in the chest vibrates the alveolus and aerosolizes the virus thereby making transmittable to others.

Traditional intramuscular vaccines are injected into the muscle and create elevated serum antibodies. These serum antibodies are typically considered proof of

intramuscular vaccine effectiveness. However, serum antibodies are not effective unless they impact the multiplication of the virus in the alveolus, which means that intramuscular vaccines cannot completely eliminate the transmission of virus from the alveolus . On the other hand, intestinal infection of SARS-CoV-2 enhances alveolar defense and reduces transmission at a higher rate compared to intramuscular vaccines.

Since the arrival of SARS-CoV-2 in 2019, the virus continues to mutate thereby increasing the chance of the development of increasingly transmissible strains. For example, the virus may acquire more capacitance to increase its electrostatic charge and facilitate its escape from the same charged alveolus. Alternatively, the virus may increase its viral replication rates in the alveolus. It is true that replications in the intestines allow mutations to occur, but intestinal mutants are not spread from the intestinal tract. Reported cases of fecal spreading are rare and SARS-CoV-2 dies in the sewage system. Hence, it is safe to conclude that intestinal mutants do not promote spread of SARS-CoV-2 respiratory disease. Stool mutations die and do not lead to respiratory mutants that multiply faster or aerosolize better.

Vaxart, Inc. is an intestinal oral vaccine company that promotes oral vaccines that are based on adenovirus vector. The oral inoculation method disclosed in the instant disclosure does not use adenovirus as a vector, which distinguishes the oral live SARS-CoV-2 vaccine from vector-based oral vaccines such as disclosed by Vaxart, Inc. Vaxart Covid vaccine uses genetic code for the spike protein that is installed in adenovirus. Vaxart has never utilized coronavirus as a vector or to our knowledge even experimented with coronavirus as a vector. The safety and efficacy of one viral family as a vector does not apply across viral families.

Oral live SARS-CoV-2 result in improved alveolar defense with no significant alveolar multiplication transmission ten days after the successful intestinal infection. This occurs accidentally when naturally infected individuals receive an accidental intestinal exposure and are unable to transmit the virus ten days after intestinal exposure. Inoculation uses deliberate intentional intestinal exposure to create an intestinal infection of coronavirus that can last for weeks. This exposure allows long lasting IgA antibodies to be formed for long term defense of the alveolar surface. It is alveolar SARS-CoV-2 growth that allow for respiratory spread of the virus.

It is believed that vector-based oral vaccines fail because the adenovirus does not colonize the intestinal tract as well as SARS-CoV-2. Typically, SARS -CoV-2 remains in the intestines for up to weeks at a time and allows for the best possible antibody to antigen matching by the intestinal immune defense. Extended intestinal growth of adenovirus (e.g., up to several weeks) has not yet been established. The SARS-CoV-2 intestinal growth can be monitored by PCR and rapid antigen testing of the stool. Frequently, SARS-CoV-2 typically grows for weeks in the intestines without systemic side effects. A single active intestinal infection of SARS-Cov-2 produces 99.5 percent or more prevention of transmission. In contrast, adenovirus vector-based vaccines have not been shown to produce the same reduction in transmission.

Traditional vaccines have been developed to stop the spread of SARS-Cov-2. Aerosol transmission of SARS typically does not occur from exposure to the bloodstream. Serum antibody levels have reduced influence on viral replication that occurs on the surface of the alveolus. Current data reflects that intramuscular vaccines are only ninety (90) percent or less effective at reducing air spread of SARS-CoV-2 even when combines with best N95 masking techniques. However, intestinal SARS-CoV-2 infection typically reduces 99.5 percent or more of all respiratory transmission within ten days. This means that intestinal infection promotes reduction of alveolar multiplication of SARS-CoV-2.

Intramuscular vaccines create fever chills and local soreness in a substantial portion of the vaccinated. Intestinal exposure to SARS-CoV-2 typically creates mild gastric cramps and loose stool. Local population can disapprove of the side effects of the intramuscular vaccines and refuse vaccination. In undeveloped countries, 95 percent of the population will not typically consent to COVID vaccinations that have undesirable side effects. Unless immunization reaches 90-95 percent, the virus will continue to spread and mutate in undeveloped countries and become more transmissible and resistant to treatment.

Obviously, such mutants have developed and will continue to develop. Individuals can receive multiple doses of an intramuscular SARS-CoV-2 vaccine, which mimic a pathogenic viral attack in the bloodstream and causes fever, chills, and fatigue. Repeated immunization of intramuscular vaccines cause hypersensitivity to develop as

symptoms progressively become more severe with each repeated intramuscular dose. As a result, the incidence of severe complications and side effects goes up with the number of intramuscular SARS-CoV-2 dosages a subject receives. None of current intramuscular vaccines for SARS-CoV-2 have more than 2 doses.

However, intestinal inoculation of SARS-CoV-2 desensitizes the person to SARS-CoV-2 where each intestinal exposure produces less symptoms not more symptoms. Intestinal inoculation reduces symptoms with each subsequent dose. Hence, a patient can expose themselves daily to intestinal SARS-CoV-2 for the remainder of their life with minimal symptoms. However, daily injections of SARS-CoV-2 vaccine injections would sensitize an individual and create extreme serious progressively harmful immune symptoms that would become intolerable and disabling if not fatal. SARS-CoV-2 is likely to be present and mutate for several years, which requires the development of long-term immune therapies that can address viral mutations and be administered on a frequent basis.

The instant disclosure seeks to provide a method for oral inoculation of SARS-CoV-2. FIG. **1** depicts the process steps of a method to prepare material for oral inoculation of SARS-CoV-2. At Step **105**, SARS-CoV-2 viral particles are collected from at least one of a nasopharyngeal specimen and an oral specimen each derived from a patient infected with SARS-CoV-2 or a SARS-CoV-2 variant. At Step **110**, mammalian cells are infected with the SARS-CoV-2 viral particles to produce infected mammalian cells. For example, applicable mammalian cells include, but are not limited to, Vero cells (e.g., Vero-E6 cells and Vero-CCL81). At Step **115**, the infected mammalian cells are cultured to produce a mammalian cell culture. At Step **120**, SARS-CoV-2 viral particles are collected from the mammalian cell culture to produce isolated viral particles.

In preferred embodiments, SARS-CoV-2 viral particles are collected from the mammalian cell culture when the mammalian cell culture have about 1,000 to 10,000,000 viable SARS-CoV-2. At Step **125**, the isolated viral particles are collected to produce a frozen isolate. In preferred embodiments, the isolated vial particles mixed with gelatin (e.g., up to 10 wt%) to produce a solution, which is frozen to produce the frozen isolate. To be sure, other stabilizers that are similar to gelatin are applicable. At Step **130**, the frozen isolate is partitioned into a plurality of tablets each having a therapeutically

effective amount of the SARS-CoV-2 viral particles. The tablets can be coated. An enteric coating is a barrier that controls the location of oral medication in the digestive system where it is absorbed. The word “enteric” indicates small intestine; therefore, enteric coatings prevent release of medication before it reaches the small intestine. The enteric coated polymers remain stable at low pH, and therefore remain insoluble. But as the pH increases in the gastrointestinal tract, the acidic functional groups are capable of ionization, and the polymer (coating) swells or becomes soluble in the intestinal fluid. In certain embodiments, the method further includes Step **135**, where an enteric coating is applied to each tablet. Applicable enteric coatings include but are not limited to cellulose acetate phthalate, cellulose acetate trimellitate, poly(vinyl acetate phthalate), hydroxypropyl methylcellulose phthalate, fatty acids, waxes, shellac, plastics, and/or plant fibers.

Alternative intestinal inoculation methods are also available. For example, the rectal mucosa contains ACE2 receptors that are used for cellular attachment and entry by the COVID-19 virus. Therefore, vaccine suppository is possible. For example, stool samples are often positive for COVID-19. COVID positive stool samples of 100 gram each were collected from ten donors that are positive for COVID-19. The samples from ten donors were gently mixed and constitute 10,000 grams of stool and likely contain billions of dead and live COVID-19 virus particles. The mixture was gently blended and frozen with 10 wt% glycerol and frozen into 10,000 one milliliter stool suppositories. During administration, recipients should be closely evaluated and managed. One rectal suppository should be administered daily for the first three days, and stopped if diarrhea, fever, or complications occur. Antibody tests should be done on subjects before and after testing to confirm immunity.

The live virus in the intestines will not magically make it to the pneumocytes. Under all ordinary circumstances, stool that contains SARS-CoV-2 is flushed into toilet and not placed in a nebulizer to be inhaled.

It is pulmonary COVID-19 complications that will disable with ARDS. The IgA made by the gut can protect the bronchial epithelium. Minimize rectal inflammation and through a small inoculation over a small area with live viruses. Smaller inoculation is better since less tissue is at risk of inflammation. A large enema might expose a large

area to inflammation and disease. The inflammatory reaction may be unexpectedly strong, which is why a small dose of 1 ml suppository is initially used and gradually increased in frequency and dosage. The rectum is physically resilient organ. Rectal perforations are very rare even with mild to moderate rectal trauma during anal intercourse. The viral rectal dose should start small and increase until immunity occurs. Those sick with COVID pneumonia may benefit from frozen rectal suppositories as well after testing them for safety. A hundred stools from ten patients may treat hundreds if not thousands of patients in the simple rectal suppository. Eventually, the virus may be cultured for pure virus without any risk of other fecal contaminants. Eventually, in a year or two, a true classic live virus of known potency may use a rectal application with a known precise amount of live or dead virus. Diarrhea is expected as the most likely symptom, but it can be treated with IV fluids if the subject becomes dehydrated.

When members of the community are accidentally infected in the respiratory tract, their alveolar immunity benefits if the SARS-CoV-2 to reaches their small intestine as rapidly as possible. Infected individual with SARS-CoV-2 is already swallowing the saliva in the mouth that contains live virus. However, most of the accidentally swallowed virus is killed by stomach acid. They can put their own saliva in an enteric capsule and swallow it to prevent acid destruction. In this way more live SARS-CoV-2 virus will reach the small intestine faster to mount an immune response. The research director should swallow saliva from SARS-CoV-2 positive patients to demonstrate that the process is safe. Due to the risk of cytomegalovirus and herpes family in the donor the donors should be screened for mouth sores or presence of other viruses or bacteria. It is recommended that research director take acyclovir to reduce risk of herpes family virus when consuming saliva samples from other donors.

Although the disclosure has been explained in relation to its preferred embodiment, it is to be understood that many other possible modifications and variations can be made without departing from the spirit and scope of the disclosure.

CLAIMS

What is claimed is:

1. A method to prepare material for oral inoculation of SARS-CoV-2 comprising:

collecting severe acute respiratory syndrome coronavirus 2 ("SARS-CoV-2") viral particles from at least one of a nasopharyngeal specimen and an oral specimen each derived from a patient infected with SARS-CoV-2 or a SARS-CoV-2 variant;

infecting mammalian cells with the SARS-CoV-2 viral particles to produce infected mammalian cells;

culturing the infected mammalian cell to produce a mammalian cell culture;

collectingSARS-CoV-2 viral particles from the mammalian cell culture to produce isolated viral particles;

freezing the isolated viral particles to produce a frozen isolate; and

partition the frozen isolate into a plurality of tablets each having a therapeutically effective amount of the SARS-CoV-2 viral particles.

2. The method of claim 1, wherein

infecting the mammalian cells with the SARS-CoV-2 viral particles comprises infecting Vero cells with the SARS-CoV-2 viral particles.

3. The method of claim 2, wherein

Collecting SARS-CoV-2 viral particles from the mammalian cell culture comprises:

collecting SARS-CoV-2 viral particles from the mammalian cell culture when the mammalian cell culture comprises 1,000 to 10,000,000 viable SARS-CoV-2.

4. The method of claim 3, wherein

freezing the isolated viral particles comprises:

mixing the isolated vial particles with gelatin to produce a solution; and

freezing the solution to produce the frozen isolate.

5. The method of claim 4, wherein

mixing the isolated vial particles with gelatin comprises:

mixing the isolated vial particles with 10 wt % gelatin.

6. The method of claim 5, further comprising:

applying an enteric coating to each tablet.

7. The method of claim 6, wherein

the enteric coating comprises one or more of:

cellulose acetate phthalate;

cellulose acetate trimellitate;

poly(vinyl acetate phthalate);

hydroxypropyl methylcellulose phthalate;

fatty acids;

a wax;

shellac;

a plastic; and

a plant fiber.

8. The method of claim 7, wherein

the Vero cells comprise Vero-E6 cells.

9. The method of claim 8, wherein

the Vero Cells comprise Vero-CCL81 cells.

10. A method to prepare material for oral inoculation of SARS-CoV-2 comprising:

collecting acute respiratory syndrome coronavirus 2 ("SARS-CoV-2") viral particles from at least one of a nasopharyngeal specimen and an oral specimen each derived from a patient infected with SARS-CoV-2 or a SARS-CoV-2 variant;

infecting mammalian cells with the SARS-CoV-2 viral particles to produce infected mammalian cells, the mammalian cells comprise Vero cells;

culturing the infected mammalian cell to produce a mammalian cell culture;

collectingSARS-CoV-2 viral particles from the mammalian cell culture to produce isolated viral particles;

freezing the isolated viral particles to produce a frozen isolate; and

partition the frozen isolate into a plurality of tablets each having a therapeutically effective amount of the SARS-CoV-2 viral particles.

11. The method of claim 10, wherein

the Vero cells comprise Vero-E6 cells.

12. The method of claim 10, wherein

the Vero cells comprise Vero-CCL81 cells.

13. The method of claim 10, wherein

collecting SARS-CoV-2 viral particles from the mammalian cell culture comprises:

collecting SARS-CoV-2 viral particles from the mammalian cell culture when the mammalian cell culture comprises 1,000 to 10,000,000 viable SARS-CoV-2.

14. The method of claim 10, wherein

freezing the isolated viral particles comprises:

mixing the isolated vial particles with gelatin to produce a solution; and

freezing the solution to produce the frozen isolate.

15. The method of claim 14, wherein

mixing the isolated vial particles with gelatin comprises:

mixing the isolated vial particles with 10 wt % gelatin.

16. The method of claim 10, further comprising:

applying an enteric coating to each tablet.

17. The method of claim 16, wherein

the enteric coating comprises one or more of:

cellulose acetate phthalate;

cellulose acetate trimellitate;

poly(vinyl acetate phthalate);

hydroxypropyl methylcellulose phthalate;

fatty acids;

a wax;

shellac;

a plastic; and

a plant fiber.

18. A method to prepare material for oral inoculation of SARS-CoV-2, the method comprising:

collecting severe acute respiratory syndrome coronavirus 2 ("SARS-CoV-2") from at least one of a nasopharyngeal specimen and an oral specimen each derived from a patient infected with SARS-CoV-2 or a SARS-CoV-2 variant;

infecting mammalian cells with the SARS-CoV-2 viral particles to produce infected mammalian cells;

culturing the infected mammalian cell to produce a mammalian cell culture;

collecting SARS-CoV-2 viral particles from the mammalian cell culture when the mammalian cell culture comprises 1,000 to 10,000,000 viable SARS-CoV-2 to produce isolated viral particles;

mixing the isolated vial particles with gelatin to produce a solution;

freezing the solution to produce a frozen isolate; and

partition the frozen isolate into a plurality of tablets each having a therapeutically effective amount of the SARS-CoV-2 viral particles.

19. The method of claim 18, further comprising:

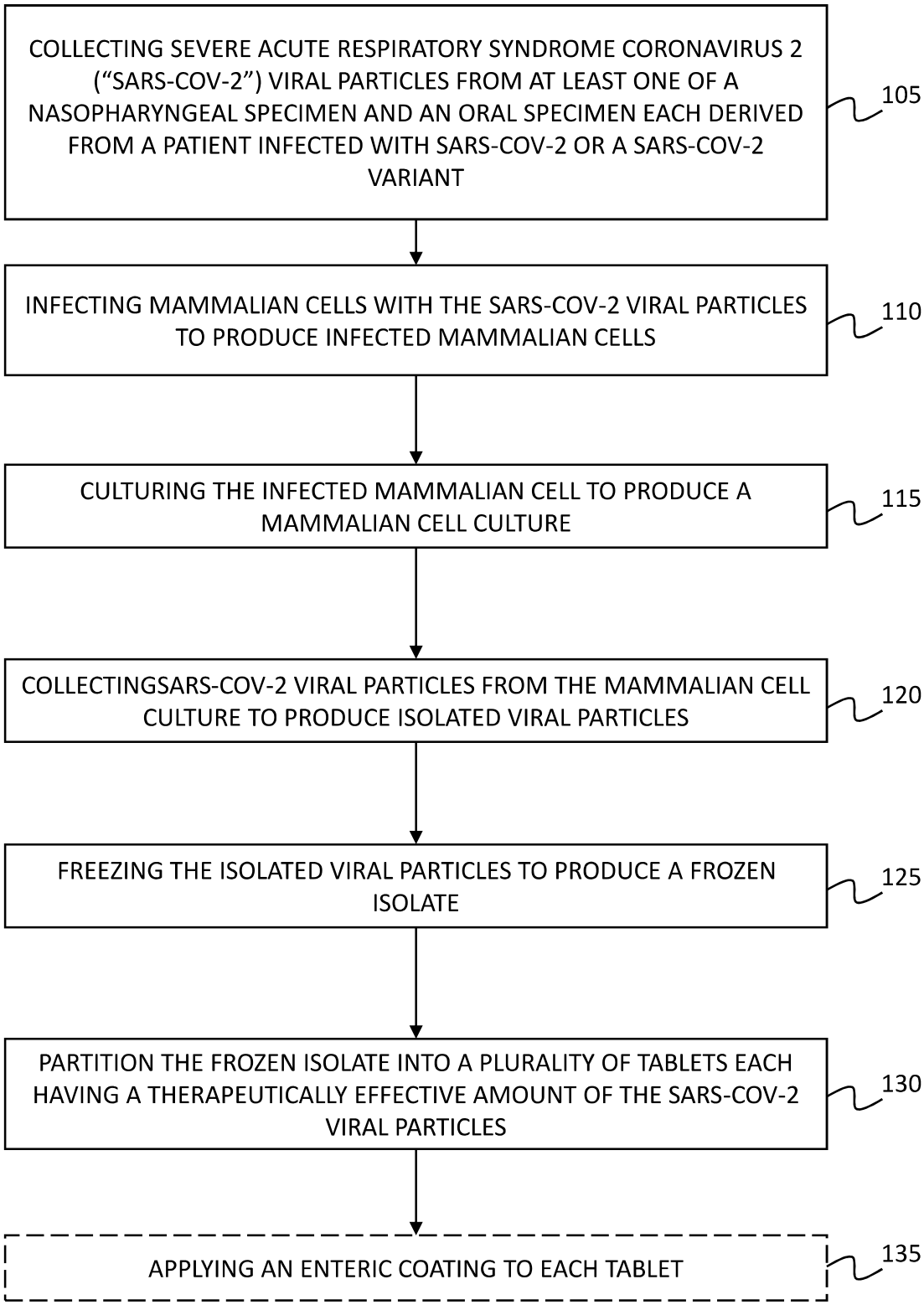
applying an enteric coating to each tablet.

20. The method of claim 19, wherein

the mammalian cells comprise one or more of Vero-E6 cell and Vero-CCL81 cells.

ABSTRACT

The instant disclosure relates generally to oral inoculation and specifically to methods to prepare nasopharyngeal and oral material for oral inoculation of COVID-19. Severe acute respiratory syndrome coronavirus 2 ("SARS-CoV-2") viral particles are collected from at least one of a nasopharyngeal specimen and an oral specimen each derived from a patient infected with SARS-CoV-2 or a SARS-CoV-2 variant. Mammalian cells (e.g., Vero-E6 and/or Vero-CCL81 cells) are infected with the SARS-CoV-2 viral particles to produce infected mammalian cells. The infected mammalian cells are cultured to produce a mammalian cell culture. SARS-CoV-2 viral particles are collected from the mammalian cell culture to produce isolated viral particles. The isolated viral particles are frozen to produce a frozen isolate. The frozen isolate is partitioned into a plurality of tablets each having a therapeutically effective amount of the SARS-CoV-2 viral particles. An enteric coating is applied to each tablet.


COLLECTING SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (“SARS-COV-2”) VIRAL PARTICLES FROM AT LEAST ONE OF A NASOPHARYNGEAL SPECIMEN AND AN ORAL SPECIMEN EACH DERIVED FROM A PATIENT INFECTED WITH SARS-COV-2 OR A SARS-COV-2 VARIANT
105
INFECTING MAMMALIAN CELLS WITH THE SARS-COV-2 VIRAL PARTICLES TO PRODUCE INFECTED MAMMALIAN CELLS
110
CULTURING THE INFECTED MAMMALIAN CELL TO PRODUCE A MAMMALIAN CELL CULTURE
115
COLLECTINGSARS-COV-2 VIRAL PARTICLES FROM THE MAMMALIAN CELL CULTURE TO PRODUCE ISOLATED VIRAL PARTICLES
120
FREEZING THE ISOLATED VIRAL PARTICLES TO PRODUCE A FROZEN ISOLATE
125
PARTITION THE FROZEN ISOLATE INTO A PLURALITY OF TABLETS EACH HAVING A THERAPEUTICALLY EFFECTIVE AMOUNT OF THE SARS-COV-2 VIRAL PARTICLES
130
APPLYING AN ENTERIC COATING TO EACH TABLET
135

FIGURE

PTO/AIA/14 (02-18)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	TUP63220
	Application Number	
Title of Invention	METHODS TO PREPARE NASOPHARYNGEAL AND ORAL MATERIAL FOR ORAL INOCULATION OF COVID-19	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	**Given Name**	**Middle Name**	**Family Name**	**Suffix**
	Steven	Mark	Hayden	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Las Vegas	**State/Province**	NV	**Country of Residence** i	US

Mailing Address of Inventor:

Address 1	76297 Tallassee Highway		
Address 2			
City	Wetumpka	**State/Province**	AL
Postal Code	36092	**Country** i	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	062439		
Email Address	patent@sinorica.com	Add Email	Remove Email

Application Information:

Title of the Invention	METHODS TO PREPARE NASOPHARYNGEAL AND ORAL MATERIAL FOR ORAL INOCULATION OF COVID-19		
Attorney Docket Number	TUP63220	**Small Entity Status Claimed**	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)		**Suggested Figure for Publication (if any)**	

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	TUP63220
	Application Number	
Title of Invention	METHODS TO PREPARE NASOPHARYNGEAL AND ORAL MATERIAL FOR ORAL INOCULATION OF COVID-19	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

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Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
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Please Select One:	◉ Customer Number	○ US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	062439		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Claims benefit of provisional	63008145	2020-04-10

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	TUP63220
	Application Number	
Title of Invention	METHODS TO PREPARE NASOPHARYNGEAL AND ORAL MATERIAL FOR ORAL INOCULATION OF COVID-19	

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

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Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button.

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	TUP63220
	Application Number	
Title of Invention	METHODS TO PREPARE NASOPHARYNGEAL AND ORAL MATERIAL FOR ORAL INOCULATION OF COVID-19	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	TUP63220
	Application Number	
Title of Invention	METHODS TO PREPARE NASOPHARYNGEAL AND ORAL MATERIAL FOR ORAL INOCULATION OF COVID-19	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

◯ Assignee ◯ Legal Representative under 35 U.S.C. 117 ◯ Joint Inventor

◯ Person to whom the inventor is obligated to assign. ◯ Person who shows sufficient proprietary interest

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Applicant:

Address 1			
Address 2			
City		**State/Province**	
Country		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button.

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	TUP63220
	Application Number	
Title of Invention	METHODS TO PREPARE NASOPHARYNGEAL AND ORAL MATERIAL FOR ORAL INOCULATION OF COVID-19	

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.

Signature:

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Trentice V. Bolar/			Date (YYYY-MM-DD)	2021-04-06
First Name	Trentice	Last Name	Bolar	Registration Number	60146

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	TUP63220
	Application Number	
Title of Invention	METHODS TO PREPARE NASOPHARYNGEAL AND ORAL MATERIAL FOR ORAL INOCULATION OF COVID-19	

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1 The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3 A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent CooperationTreaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Doc Code: Oath

Document Description: Oath or declaration filed

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☒ Declaration Submitted With Initial Filing OR ☐ Declaration Submitted After Initial Filing (surcharge (37 CFR 1.16(f)) required)

Attorney Docket Number	TUP63220
First Named Inventor	Steven Mark Hayden
COMPLETE IF KNOWN	
Application Number	
Filing Date	
Art Unit	
Examiner Name	

METHODS TO PREPARE NASOPHARYNGEAL AND ORAL MATERIAL FOR ORAL INOCULATION OF COVID-19

(Title of the Invention)

As a below named inventor, I hereby declare that:

This declaration is directed to:

☒ The attached application,

OR

☐ United States Application Number or PCT International application number _____

filed on_____.

The above-identified application was made or authorized to be made by me.

I believe I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

Direct all correspondence to: ☒ The address associated with Customer Number: 062439 **OR** ☐ Correspondence address below

Name		
Address		
City	State	Zip
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DECLARATION — Utility or Design Patent Application

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available. Petitioner/applicant is advised that documents which form the record of a patent application (such as the PTO/SB/01) are placed into the Privacy Act system of records DEPARTMENT OF COMMERCE, COMMERCE-PAT-7, System name: *Patent Application Files* . Documents not retained in an application file (such as the PTO-2038) are placed into the Privacy Act system of COMMERCE/PAT-TM-10, System name: *Deposit Accounts and Electronic Funds Transfer Profiles*.

LEGAL NAME OF SOLE OR FIRST INVENTOR:

(*E.g.,* Given Name (first and middle if any) and Family Name or Surname)

Steven Mark Hayden

Inventor's Signature	Date (Optional)
	04/03/2021

Residence: City	State	Country
Las Vegas	NV	US

Mailing Address

76297 Tallassee Highway

City	State	Zip	Country
Wetumpka	AL	36092	US

☐ Additional inventors are being named on the _____ Supplemental sheet(s) PTO/AIA/10 attached hereto

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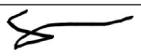
TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B or equivalent) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5. If the Power of Attorney by Applicant form is not accompanied by this transmittal form or an equivalent, the Power of Attorney will not be recognized in the application.

Application Number	
Filing Date	
First Named Inventor	Steven Mark Hayden
Title	METHODS TO PREPARE NASOPHARYNGEAL AND ORAL MATERIAL FOR ORAL INOCULATION OF COVID-19
Art Unit	
Examiner Name	
Attorney Docket Number	TUP63220

SIGNATURE of Applicant or Patent Practitioner

Signature		Date	04/03/2021
Name	Steven Mark Hayden	Telephone	
Registration Number			

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications.

☐ *Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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I hereby revoke all previous powers of attorney given in the application identified in the attached transmittal letter.

☒ I hereby appoint Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A or equivalent):

062439

OR

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SIGNATURE of Applicant for Patent

Signature		Date	04/03/2021
Name	Steven Mark Hayden	Telephone	
Title and Company			

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms for more than one signature, see below *.

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