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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/095,430	11/11/2020	Andrew R. CHADEAYNE	205.0001-US01	1807

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EXAMINER	
ANDERSON, JAMES D	

ART UNIT	PAPER NUMBER
1629	

NOTIFICATION DATE	DELIVERY MODE
05/23/2023	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):

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Office Action Summary	Application No. 17/095,430	Applicant(s) CHADEAYNE, Andrew R.	
	Examiner JAMES D ANDERSON	Art Unit 1629	AIA (FITF) Status Yes

-- 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 03/06/2023.

☐ 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) 19-22,24-25 and 27-32 is/are pending in the application.

5a) Of the above claim(s) 25 is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 19-22,24 and 27-32 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: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Claim Status

Applicants' response and amendments to the claims, filed 03/06/2023, are acknowledged and entered. Claims 23 and 26 have been cancelled by Applicant. Claims 19-22, 24-25, and 27-32 are pending. Claim 25 remains withdrawn from consideration as being directed to a non-elected species of psilocybin derivative. Applicant elected the species psilocybin in the response filed 09/27/2022.

Status of Rejections Set Forth in the November 19, 2021 Non-Final Office Action

In reply to the rejection of claims 19-22 and 26-32 under 35 U.S.C. §112, 2nd Paragraph as being indefinite for their recitation of "a purified psilocybin derivative", as set forth at p.4-5 of the previous Office Action dated November 7, 2022, Applicant now amends claim 19 to recite a definite Markush group listing from which the claimed purified psilocybin derivative is selected. Accordingly, the rejection is withdrawn.

In reply to the rejection of claim 27 under 35 U.S.C. §112, 2nd Paragraph as being indefinite for its recitation of "comprising administering an excipient, as set forth at p.5-6 of the previous Office Action dated November 7, 2022, Applicant now amends claim 27 to recite "wherein the composition further comprises an excipient". Accordingly, the rejection is withdrawn.

In reply to the rejection of claims 29 and 31 under 35 U.S.C. §112, 2nd Paragraph as being indefinite for their recitation of the purified psilocybin and/or the serotonergic drug is "crystalline", as set forth at p.6 of the previous Office Action dated November 7, 2022, Applicant now amends claims 29 and 31 to recite that the purified psilocybin and/or the serotonergic drug are "in crystalline form". Accordingly, the rejection is withdrawn.

In reply to the rejection of claims 29 and 31 under 35 U.S.C. §112, 1st Paragraph as failing to comply with the written description requirement for their recitation of the purified psilocybin and/or the serotonergic drug being "crystalline", as set forth at p.6-9 of the previous Office Action dated November 7, 2022, Applicant now amends claims 29 and 31 to recite that the purified psilocybin and/or the serotonergic drug are "in crystalline form". Applicants additionally cite to, inter alia, ¶¶ [0039], [0041], [0042], [0045], and [0052], for support for "a dried powder is composed of particles with a crystalline structure", that "a dried powder is composed of pure crystals", and that the term "purified" refers to a compound or composition that has been crystallized. Accordingly, the rejection is withdrawn.

Applicants' arguments pertaining to the 35 U.S.C. 103 rejection over the prior art references Griffiths, Carhart-Harris 2016, Shirota, and GB '696 in view of US '255 and Carhart-Harris 2017, as set forth at p.9-15 of the previous Office Action dated November 7, 2022, have been fully considered but they are not deemed to be persuasive. Applicants' arguments are addressed below.

The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

Applicant's Information Disclosure Statement filed 05/02/2023 has been received and entered into the present application. As reflected by the attached, completed copy of form PTO-1449, the Examiner has considered the cited references to the extent that they comply with the provisions of 37 C.F.R. §1.97, §1.98 and MPEP §609.

Claim Rejections - 35 USC § 103

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

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

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-22, 24, and 27-32 remain rejected under 35 U.S.C. 103(a) as being unpatentable over **GRIFFITHS ET AL.** (Journal of Psychopharmacology, 2016, vol. 30, no. 12, pages 1181-1197), **CARHART-HARRIS ET AL.** (Lancet Psychiatry, 2016, vol. 3, pages 619-627), **SHIROTA ET AL.** (J. Nat. Prod., 2003, vol. 66, pages 885-887), and **GB 2571696 B** (Published May 27, 2020; *Filed Oct. 9, 2017*) in view of **US 2005/0137255 A1** (Published June 23, 2005) and **CARHART-HARRIS ET AL.** (Neuropsychopharmacology, 2017, vol. 42, pages 2105-2113) (*Published Online May 17, 2017*).

The amended claims are drawn to treating a psychological disorder[1] comprising administering a serotonergic drug[2] and a purified psilocybin derivative[3] to a subject in need thereof.

As will be established by the following prior art, all of the claimed elements were known in the art prior to the filing of Applicant's application and it would have been *prima facie* obvious to a person of ordinary skill in the art to combine these elements to arrive at the claimed invention.

The Examiner first cites evidence of the common knowledge in the art that psilocybin was known to be therapeutically effective in the treatment of depression.

Griffiths *et al.* teach that psilocybin produces substantial and sustained decreases in depression and anxiety in patients with life-threatening cancer. *See* Abstract ("[t]he effects of psilocybin were studied in 51 cancer patients with life-threatening diagnoses and symptoms of depression and/or anxiety…[h]igh-dose psilocybin produced large decreases in clinician- and self-rated measures of depressed mood and anxiety, along with increases in quality of life, life meaning, and optimism, and decreases in death anxiety.") They cite Carhart-Harris *et al.*, 2016, for teaching that administration of psilocybin reduced depressive symptoms in patients with treatment-resistant depression. *See* p.1182, left column, 2nd full paragraph ("[a]lso relevant, a recent open-label pilot study in 12 patients with treatment-resistant depression showed marked reductions in depressive symptoms 1 week and 3 months after administration of 10 and 25 mg of psilocybin in two sessions separated by 7 days (Carhart-Harris et al., 2016).")

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[1] Applicant elected a depressive disorder as the species of psychological disorder.
[2] Applicant elected the SSRI escitalopram as the species of serotonergic drug.
[3] Applicant elected psilocybin as the species of psilocybin derivative.

Carhart-Harris *et al.*, cited by Griffiths *et al. supra*, teach administering two oral doses of psilocybin (10 mg and 25 mg, 7 days apart) to patients with treatment-resistant depression. *See* Summary ("…12 patients (six men, six women) with moderate-to-severe, unipolar, treatment-resistant major depression received two oral doses of psilocybin (10 mg and 25 mg, 7 days apart) in a supportive setting.") They teach psilocybin was clinically effective in treating depression. *See* Summary ("[r]elative to baseline, depressive symptoms were markedly reduced 1 week…and 3 months…after high-dose treatment.") They conclude this study provides preliminary support for the safety and efficacy of psilocybin for treatment-resistant depression and motivates further trials. *See* Summary. Also see p.627, left column ("[p]silocybin has a novel pharmacological action in comparison with currently available treatments for depression (ie, 5-HT2A receptor agonism) and thus could constitute a useful addition to available therapies for the treatment of depression.")

While Griffiths *et al.* and Carhart-Harris *et al.* do not expressly disclose that the psilocybin administered therein was "purified", purified psilocybin, specifically highly purified crystalline psilocybin was known in the art. It would be obvious to a person of ordinary skill in the art that a therapeutic agent intended to be administered to subjects should be as pure as possible. Factors to be considered in determining whether a purified form of an old product is obvious over the prior art include whether the claimed chemical compound or composition has the same utility as closely related materials in the prior art, and whether the prior art suggests the particular form or structure of the claimed material or suitable methods of obtaining that form or structure. *In re Cofer*, 354 F.2d 664, 148 USPQ 268 (CCPA 1966). Here, Applicant does not even claim any particular form or structure of the claimed "purified psilocybin".

Shirota *et al.* teach large-scale synthesis of psilocybin that does not require chromatographic purification. *See* Abstract ("[t]he concise large-scale syntheses of psilocin (1) and psilocybin (2), the principal hallucinogenic constituents of "magic mushroom", were achieved without chromatographic purification.") Specifically, they teach that obtained psilocybin as a white needle crystalline powder without any chromatographic purification (p.885, right column; p.887, paragraph bridging left and right columns).

GB '696 also teaches the large-scale synthesis production of psilocybin, specifically for use in medicine. *See* [0001] ("[t]his invention relates to the large-scale production of psilocybin for use in medicine.") They in fact specifically teach it for use in the treatment of treatment resistant depression ([0003]). Also see [0030] ("[i]t is yet a further object of the invention to formulate the psilocybin of the invention in a form suitable for administration to human subjects and use it in medicine…in the treatment of depression…particularly…drug resistant depression…".) Regarding claims 28-30, the psilocybin is a crystalline powder with a chemical purity of greater than 97%. *See* [0037] ("[t]he high purity, crystalline psilocybin…is a white to off white solid…has a chemical purity of greater than 97%…".) The psilocybin is provided in pharmaceutical formulation together with one or more excipients ([0049]). The pharmaceutical formulation is an oral dosage form such as a tablet or capsule ([0053]-[0054]). Summarizing the express teachings of GB '696, the Examiner refers to [0059]:

> **[0059]** In another embodiment there is provided a method of treating drug resistant depression comprising administering to a subject in need thereof an effective dose of a high purity, crystalline psilocybin - polymorph A.

The combined teachings of Griffiths et al., Carhart-Harris et al., Shirota et al., and GB '696 differ from the instant claims only in so far as they do not disclose administering purified psilocybin in combination with a serotonergic drug to treat depression. As evidenced by the

following prior art, the SSRI escitalopram was a well-known, clinically effective anti-depressive agent, available in a highly purified crystalline form, at the time the application was filed.

US '255 teaches crystalline escitalopram hydrobromide, a novel crystalline form of escitalopram hydrobromide referred to as Form I (Abstract). It teaches citalopram is a well known antidepressant drug that has been widely sold for many years ([0003]). It teaches a pharmaceutical composition comprising crystalline escitalopram hydrobromide (such as Form I escitalopram hydrobromide) and, optionally, a pharmaceutically acceptable excipient ([0011]). It a method of treating a subject (such as a mammal (e.g., human)) having an escitalopram-treatable disorder comprising administering a therapeutically effective amount of a pharmaceutical composition comprising crystalline escitalopram hydrobromide or crystalline Form I of escitalopram hydrobromide ([0012]). It teaches escitalopram-treatable disorders include, *inter alia*, depression (e.g., major depression disorder and treatment of patients which failed to respond to initial treatment with conventional selective serotonin reuptake inhibitors (SSRIs) ([0034]). It teaches the crystalline escitalopram hydrobromide is 90-100% pure ([0050]).

The claimed invention, *i.e.*, treatment of depression comprising administering a first serotonergic drug (*e.g.*, the SSRI escitalopram) and a purified psilocybin derivative (*e.g.*, psilocybin), is the result of combining equivalents known for the same purpose, *i.e.*, combining two therapeutics having anti-depressant activity. See MPEP 2144.06. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). A person of ordinary skill in the art would have had a reasonable expectation that administering purified psilocybin as

taught in Griffiths et al., Carhart-Harris et al., Shirota et al., and GB '696 in combination with the SSRI escitalopram as taught in US '255 to a depressed subject would provide a therapeutic benefit to the subject, e.g., reduced depressive symptoms. As both psilocybin and escitalopram were known to reduce depressive symptoms when administered individually, when combined they would also be expected to reduce depressive symptoms.

The Examiner acknowledges that the prior art questions whether administration of an SSRI should be discontinued before administering psilocybin to a depressed subject. Carhart-Harris *et al.* (2017) discuss the therapeutic potential of psychedelic drugs, specifically psilocybin in the treatment of depression. They specifically address the differential serotonergic actions of SSRIs and psychedelics in the treatment of depression (Figure 1). They acknowledge that a significant number of patients with treatment-resistant depression treated first line with either an SSRI or CBT fail to respond adequately (paragraph bridging p.2109-2110). They agree that treatment-resistant depression represents a valid point in the treatment pathway, where a single psychedelic intervention might find a place (*Id.*). Carhart-Harris ("RLC-H"), however, questions whether patients must wait until their depression is significantly stamped-in before psilocybin can be considered (*Id.*). They teach that it seems reasonable to ask whether early intervention with psilocybin could be prophylactic, while acknowledging "there is also the issue of SSRIs obstructing the potential therapeutic action of psilocybin" (*Id.*). This is, however, based on "anecdotal evidence" that psychedelic effects are largely attenuated by ongoing treatment with SSRIs (p.2110, left column, first full paragraph). They teach that any trial would "ideally" be conducted in patients withdrawn from such drugs for at least 2 weeks or so, but they also acknowledge that "this is not always straightforward" (*Id.*).

A totality of the evidence weighs in favor of obviousness of the claimed invention, despite the "anecdotal" evidence that SSRIs might potentially attenuate "psychedelic effects". Notably, Carhart-Harris *et al.* (2017) point to "psychedelic effects" being attenuated, not anti-depressant effects. Further, the suggestion to administer both an SSRI and psilocybin in Carhart-Harris outweighs the largely unanswered question whether an SSRI would actually interfere with the anti-depressant activity of psilocybin. While they teach that "ideally" trials of psilocybin in patients being administered with another antidepressant such as an SSRI would be conducted in patients withdrawn from the antidepressant for at least 2 weeks, they admit that such might not be practical. Further, even if the evidence were in equipoise, equally balancing the obviousness of combining two known drugs having anti-depressant activity with the unanswered question whether administration of an SSRI would interfere with the anti-depressant activity of psilocybin, Applicant did not actually administer psilocybin and an SSRI to any subjects. In fact, Applicant's disclosure is purely hypothetical, having no working examples whatsoever. Thus, there is a preponderance of evidence showing that the combined teachings of the cited prior art would have provided at least a reasonable expectation of success in treating depression with a combination of escitalopram and psilocybin.

Response to Arguments

Applicant's arguments have been fully and carefully considered but they are not deemed persuasive to overcome the prima facie case of obviousness set forth *infra*.

First, Applicant argues that neither Griffiths nor Carhart-Harris 2016 teach or suggest administering a purified psilocybin derivative.

As addressed by the Examiner in the rejection, purified, crystallized psilocybin was known in the art as evidenced by both Shirota et al. and GB '696. As expressly taught in GB '696:

> **[0059]** In another embodiment there is provided a method of treating drug resistant depression comprising administering to a subject in need thereof an effective dose of a high purity, crystalline psilocybin - polymorph A.

A person of ordinary skill in the art utilizing psilocybin as a therapeutic drug would most certainly use a "purified" form of psilocybin to avoid potential unwanted side effects from impurities. Such is routine and commonplace in the art of pharmaceuticals as evidenced by the cited prior art. While it is true that Griffiths and Carhart-Harris 2016 do not use the word "purified" to describe the psilocybin administered therein, there is also nothing in either of these references to suggest that the psilocybin was not "purified". For example, Carhart-Harris 2016 teaches psilocybin was obtained from THC-pharm and formulated into the investigational medicinal product (5 mg psilocybin in size 0 capsules) (p.621, left column).

Next, Applicant argues that Carhart-Harris 2016 teaches away from administering a composition comprising a first serotonergic drug and a purified psilocybin derivative.

In response, the Examiner already acknowledged and addressed this issue in the rejection. Specifically, this was based on "anecdotal evidence" that psychedelic effects are largely attenuated by ongoing treatment with SSRIs (p.2110, left column, first full paragraph). While they teach that any trial would "ideally" be conducted in patients withdrawn from such drugs for at least 2 weeks or so, they also acknowledge that "this is not always straightforward" (*Id.*). There is nothing in the cited prior art that suggests an effective antidepressant effect would not be achieved if psilocybin were administered with a serotonergic drug because psilocybin was effective in treating patients who previously took an SSRI.

Next, Applicant again argues that it would not have been obvious to administer a "purified" psilocybin. Citing the Specification, Applicant argues that at the time of the invention, "[d]espite a handful of studies utilizing purified psilocybin as a single active pharmaceutical ingredient, virtually no work has been done formulating psilocybin into drug products for treating mental disorders"; "[a]side from a few studies on purified psilocybin, no efforts [had] been made to modulate its properties with formulating agents or other ingredients"; and "no efforts [had] been made to formulate particular combinations or doses of psilocybin derivatives or combinations with other active molecules." See Specification (as-filed) at ¶[0008].

In response, that those skilled in the art chose not to expend substantial resources and money developing a **Schedule I controlled substance** for use as a therapeutic agent does not render its administration to patients with depression any less obvious as i) the prior art already administered psilocybin to patients with depression and ii) psilocybin was already demonstrated in the art to have antidepressant effects.

Applicant next addresses the teachings of Shirota and GB '696, arguing that the references do not teach or suggest administering a composition comprising a first serotonergic drug and a purified psilocybin derivative.

In response, Shirota and GB '696 were cited as factual evidence that "purified" and "crystalline" psilocybin was known in the art. It is the combined teachings of the cited prior art that render *prima facie* obvious the claimed invention, not Shirota and/or GB '696 alone.

Applicant next addresses the teachings of US '255, arguing that it does not even mention psilocybin, let alone purified psilocybin derivatives.

In response, US '255 was cited as factual evidence that "purified" and "crystalline" escitalopram hydrobromide was known in the art and taught to be useful in the treatment of

depression. It is the combined teachings of the cited prior art that render *prima facie* obvious the claimed invention, not US '255 alone.

Applicant next argues that Carhart-Harris 2017 also "teaches away" from administering a serotonergic drug with a psilocybin derivative. Applicant argues the teachings of Carhart-Harris 2017 imply that treating medication-heavy, treatment-resistant depressed patients with psilocybin will be especially challenging.

In response, the claims are not limited to treating "medication-heavy, treatment-resistant depressed patients". That *chronic* antidepressant medication may *potentially* have a muting effect on psilocybin's acute and putative antidepressant effects only suggests that psilocybin might not be as effective in patients already taking antidepressant medications. Further, that the art suggests that treatment of a specific patient population might be "challenging" is not an express "teaching away".

Finally, Applicant argues that even assuming *arguendo* that the cited references individually teach administering either a purified psilocybin derivative or a serotonergic drug to treat a psychological disorder, none of the cited references teach or suggest, let alone motivate, the person of ordinary skill in the art to administer a composition comprising ***both*** a purified psilocybin derivative and a serotonergic drug to treat a psychological disorder (Emphasis Applicant's).

In response, the Examiner submits that two drugs being used for the same purpose and being administered to the same patient can only be administered one of two ways – in different compositions or in the same composition. The selection of either of these means of administering the drugs to the same patient would have been *prima facie* obvious to a person of ordinary skill in the art at the time the application was filed. Given the known efficacy of

psilocybin and SSRIs to treat depression as evidenced by the cited prior art, there combined administration to patients with depression is prima facie obvious for the reasons discussed *infra*.

At bottom, the prior art teaches psilocybin administration is effective in treating depression in patients who previously took SSRIs for their depression. As SSRIs are commonly and routinely administered to depressed patients as evidenced by the cited prior art, a person of ordinary skill in the art would have a reasonable expectation that combining psilocybin with an SSRI such as escitalopram would provide a beneficial therapeutic effect in patients with depression. Additionally, if the art of combining psilocybin and an SSRI for the treatment of depression were so fraught with uncertainty as alleged by Applicant, the Examiner would have rejected Applicant's claims as lacking enablement as he provides no objective evidence in the as filed disclosure that a composition comprising a psilocybin and an SSRI has therapeutic efficacy in the treatment of depression.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant is requested to specifically point out the support for any amendments made to the disclosure in response to this Office action, including the claims (M.P.E.P. §§ 714.02 and 2163.06). In doing so, applicant is requested to refer to pages and line (or paragraph) numbers (if available) in the as-filed specification, not the published application. Due to the procedure outlined in M.P.E.P. § 2163.06 for interpreting claims, 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.

Applicant is reminded that MPEP §2001.06(b) clearly states that "[t]he individuals covered by 37 C.F.R. 1.56 have a duty to bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications which are "material to patentability" of the application in question." See *Armour & Co. v. Swift & Co.*, 466 F.2d 767, 779, 175 USPQ 70, 79 (7th Cir. 1972). MPEP §2001.06(b) clearly indicates that "if a particular inventor has different applications pending in which similar subject matter but patentably indistinct claims are present that fact must be disclosed to the examiner of each of the involved applications." See *Dayco Prod. Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1365-69, 66 USPQ2d 1801, 1806-08 (Fed. Cir. 2003).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES D ANDERSON whose telephone number is (571)272-9038. The examiner can normally be reached on Monday-Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Lundgren can be reached on 571-272-5541. 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.

/James D. Anderson/
Primary Examiner, Art Unit 1629

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