**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Barrow, Robert Confirmation No.: 4638
Serial No.: 17/835051 Group No.:
Filing or 371(c) Date: June 08, 2022 Examiner:
Entitled: 18-MC for Treating Obesity

**THIRD-PARTY PRE-ISSUANCE SUBMISSION**

Examiner:

The following documents, which are also identified in the Form PTO/SB/429 filed herewith, are submitted for your consideration as being of potential relevance to the examination of the present application:

1. TARASCHENKO (2008) "18-Methoxycornaridine: a potential new treatment for obesity in rats?" Vol. 201: 339-350. Psychopharmacology.
2. GLICK (2000) "18-Methoxycornaridine (18-MC) and Ibogaine: Comparison of Antiaddictive Efficacy, Toxicity, and Mechanisms of Action" Vol. 914(1): 369-386. Annals of the New York Academy of Science.
3. ClinicalTrials.gov, "A Study to Assess 18-Methoxycoronaridine (18-MC HCl) in Healthy Volunteers." March 3, 2020. https://clinicaltrials.gov/ct2/show/NCT04292197

Attached hereto is a claim chart providing a concise description of the relevance of each reference in the document list to the elements of the presently pending claims.

| U.S.S.N. 17/835,051 Pending Claims | References |
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| **1**. A method of treating obesity, including the steps of: administering an effective amount of a composition chosen from the group consisting of 18-methoxycoronaridine (18-MC), salts thereof, tartrates thereof, solvates thereof, isomers thereof, analogs thereof, homologues thereof, | 1. TARASCHENKO (2008) "18-Methoxycornaridine: a potential new treatment for obesity in rats?" Vol. 201: 339-350. Psychopharmacology.<br><br>From abstract: "Acute administration of **18-MC** (10–40 mg/kg i.p.) reduced operant responding for sucrose and decreased ad libitum ingestion of sucrose, saccharin, and saline. The highest dose of 18-MC also reduced consumption of water when palatable fluids were not available. In rats having unlimited access to sucrose (30%), chronic treatment with 18-MC (20 mg/kg i.p.) prevented sucrose-induced increases in body weight, **decreased fat deposition**, and reduced consumption of sucrose while not altering food intake." |

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| and deuterated forms thereof to an individual; and<br>treating obesity. | 3. ClinicalTrials.gov, "A Study to Assess 18-Methoxycoronaridine (18-MC HCl) in Healthy Volunteers. March 3, 2020. https://clinicaltrials.gov/ct2/show/NCT04292197<br><br>From Study Description: "The primary objective of this study is to assess the safety and tolerability of a **single day dosing and a separate multiple day dosing of 18-MC HCl** administered orally, each part of the study having a different set of healthy male and female volunteers." |
| **2**. The method of claim 1, wherein the composition is administered in a dose of 0.01-10 mg/kg. | 1. TARASCHENKO (2008) "18-Methoxycornaridine: a potential new treatment for obesity in rats?" Vol. 201: 339-350. Psychopharmacology.<br><br>From abstract: "Acute administration of **18-MC (10–40 mg/kg i.p.)** reduced operant responding for sucrose and decreased ad libitum ingestion of sucrose, saccharin, and saline. The highest dose of 18-MC also reduced consumption of water when palatable fluids were not available. In rats having unlimited access to sucrose (30%), chronic treatment with 18-MC (20 mg/kg i.p.) prevented sucrose-induced increases in body weight, decreased fat deposition, and reduced consumption of sucrose while not altering food intake." |
| **3**. The method of claim 1, wherein the composition is administered as a single dose. | 1. TARASCHENKO (2008) "18-Methoxycornaridine: a potential new treatment for obesity in rats?" Vol. 201: 339-350. Psychopharmacology.<br><br>From abstract: "**Acute administration of 18-MC** (10–40 mg/kg i.p.) reduced operant responding for sucrose and decreased ad libitum ingestion of sucrose, saccharin, and saline. The highest dose of 18-MC also reduced consumption of water when palatable fluids were not available. In rats having unlimited access to sucrose (30%), chronic treatment with 18-MC (20 mg/kg i.p.) prevented sucrose-induced increases in body weight, decreased fat deposition, and reduced consumption of sucrose while not altering food intake." |
| **4**. The method of claim 1, wherein the composition is administered as a repeat dose over a time period chosen from the group consisting of days, weeks, months, and years. | 3. ClinicalTrials.gov, "A Study to Assess 18-Methoxycoronaridine (18-MC HCl) in Healthy Volunteers. March 3, 2020. https://clinicaltrials.gov/ct2/show/NCT04292197<br><br>From Study Description: "The primary objective of this study is to assess the safety and tolerability of a single day dosing and a **separate multiple day dosing of 18-MC HCl** administered orally, each part of the study having a different set of healthy male and female volunteers." |

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| **5**. The method of claim 1, wherein said treating step further includes the steps of reducing craving for food and reducing weight gain in the individual. | 1. TARASCHENKO (2008) "18-Methoxycornaridine: a potential new treatment for obesity in rats?" Vol. 201: 339-350. Psychopharmacology.<br><br>From abstract: "**Acute administration of 18-MC** (10–40 mg/kg i.p.) reduced operant responding for sucrose and **decreased ad libitum ingestion of sucrose, saccharin, and saline**. The highest dose of 18-MC also reduced consumption of water when palatable fluids were not available. In rats having unlimited access to sucrose (30%), **chronic treatment with 18-MC (20 mg/kg i.p.) prevented sucrose-induced increases in body weight, decreased fat deposition, and reduced consumption of sucrose while not altering food intake**." |
| **6**. A method of treating binge eating, including the steps of: administering an effective amount of a composition chosen from the group consisting of 18-methoxycoronaridine (18-MC), salts thereof, tartrates thereof, solvates thereof, isomers thereof, analogs thereof, homologues thereof, and deuterated forms thereof to an individual; and treating binge eating. | 1. TARASCHENKO (2008) "18-Methoxycornaridine: a potential new treatment for obesity in rats?" Vol. 201: 339-350. Psychopharmacology.<br><br>From abstract: "**Acute administration of 18-MC** (10–40 mg/kg i.p.) reduced operant responding for sucrose and **decreased ad libitum ingestion of sucrose, saccharin, and saline**. The highest dose of 18-MC also reduced consumption of water when palatable fluids were not available. In rats having unlimited access to sucrose (30%), **chronic treatment with 18-MC (20 mg/kg i.p.) prevented sucrose-induced increases in body weight, decreased fat deposition, and reduced consumption of sucrose while not altering food intake**." |
| **7**. The method of claim 6, wherein the composition is administered in a dose of 0.01-10 mg/kg. | 1. TARASCHENKO (2008) "18-Methoxycornaridine: a potential new treatment for obesity in rats?" Vol. 201: 339-350. Psychopharmacology.<br><br>From abstract: "**Acute administration of 18-MC (10–40 mg/kg i.p.)** reduced operant responding for sucrose and decreased ad libitum ingestion of sucrose, saccharin, and saline. The highest dose of 18-MC also reduced consumption of water when palatable fluids were not available. In rats having unlimited access to sucrose (30%), chronic treatment with 18-MC (20 mg/kg i.p.) prevented sucrose-induced |

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| | increases in body weight, decreased fat deposition, and reduced consumption of sucrose while not altering food intake." |
| **8**. The method of claim 6, wherein the composition is administered as a single dose. | 1. TARASCHENKO (2008) "18-Methoxycornaridine: a potential new treatment for obesity in rats?" Vol. 201: 339-350. Psychopharmacology.<br><br>From abstract: "**Acute administration of 18-MC** (10–40 mg/kg i.p.) reduced operant responding for sucrose and decreased ad libitum ingestion of sucrose, saccharin, and saline. The highest dose of 18-MC also reduced consumption of water when palatable fluids were not available. In rats having unlimited access to sucrose (30%), chronic treatment with 18-MC (20 mg/kg i.p.) prevented sucrose-induced increases in body weight, decreased fat deposition, and reduced consumption of sucrose while not altering food intake." |
| **9**. The method of claim 6, wherein the composition is administered as a repeat dose over a time period chosen from the group consisting of days, weeks, months, and years. | 3. ClinicalTrials.gov, "A Study to Assess 18-Methoxycoronaridine (18-MC HCl) in Healthy Volunteers. March 3, 2020. https://clinicaltrials.gov/ct2/show/NCT04292197<br><br>From Study Description: "The primary objective of this study is to assess the safety and tolerability of a single day dosing and a **separate multiple day dosing of 18-MC HCl** administered orally, each part of the study having a different set of healthy male and female volunteers." |
| **10**. The method of claim 6, wherein said treating step further includes the step of reducing craving for food in the individual. | 1. TARASCHENKO (2008) "18-Methoxycornaridine: a potential new treatment for obesity in rats?" Vol. 201: 339-350. Psychopharmacology.<br><br>From abstract: "**Acute administration of 18-MC** (10–40 mg/kg i.p.) reduced operant responding for sucrose and **decreased ad libitum ingestion of sucrose, saccharin, and saline**. The highest dose of 18-MC also reduced consumption of water when palatable fluids were not available. In rats having unlimited access to sucrose (30%), **chronic treatment with 18-MC (20 mg/kg i.p.) prevented sucrose-induced increases in body weight, decreased fat deposition, and reduced consumption of sucrose while not altering food intake**." |
| **11**. A method of treating behavioral addictions, including the steps of: administering an | 1. TARASCHENKO (2008) "18-Methoxycornaridine: a potential new treatment for obesity in rats?" Vol. 201: 339-350. Psychopharmacology. |

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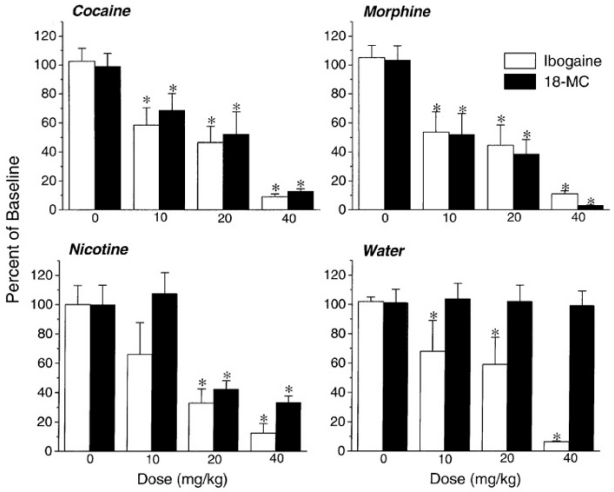
| effective amount of a composition chosen from the group consisting of 18-methoxycoronaridine (18-MC), salts thereof, tartrates thereof, solvates thereof, isomers thereof, analogs thereof, homologues thereof, and deuterated forms thereof to an individual; and treating the behavioral addiction. | From abstract: "**Acute administration of 18-MC** (10–40 mg/kg i.p.) reduced operant responding for sucrose and **decreased ad libitum ingestion of sucrose, saccharin, and saline**. The highest dose of 18-MC also reduced consumption of water when palatable fluids were not available. In rats having unlimited access to sucrose (30%), **chronic treatment with 18-MC (20 mg/kg i.p.) prevented sucrose-induced increases in body weight, decreased fat deposition, and reduced consumption of sucrose while not altering food intake**."<br><br>2. GLICK (2000) "18-Methoxycornaridine (18-MC) and Ibogaine: Comparison of Antiaddictive Efficacy, Toxicity, and Mechanisms of Action" Vol. 914(1): 369-386. Annals of the New York Academy of Science.<br><br>From page 371: "The acute intraperitoneal (ip) administration of either ibogaine or **18-MC**, 15 min prior to testing, **dose-dependently decreased the self-administration of morphine, cocaine, nicotine, and alcohol in rats**."<br><br>From page 372:<br>  <br><br>**FIGURE 2.** Comparison of the dose-response effects of intraperitoneally administered ibogaine and 18-MC (40 mg/kg, ip, 30 min earlier) on the self-administration of cocaine (top, left), morphine (top, right), nicotine (bottom, left), and water (bottom, right). Each bar represents the mean (±SEM) of at least 6 rats. *Asterisks* indicate significant differences ($p < 0.05$) from vehicle (0 mg/kg). |
| **12**. The method of claim 11, wherein the behavioral addiction is chosen from the group consisting of gambling, sex, food, plastic | 2. GLICK (2000) "18-Methoxycornaridine (18-MC) and Ibogaine: Comparison of Antiaddictive Efficacy, Toxicity, and Mechanisms of Action" Vol. 914(1): 369-386. Annals of the New York Academy of Science. |

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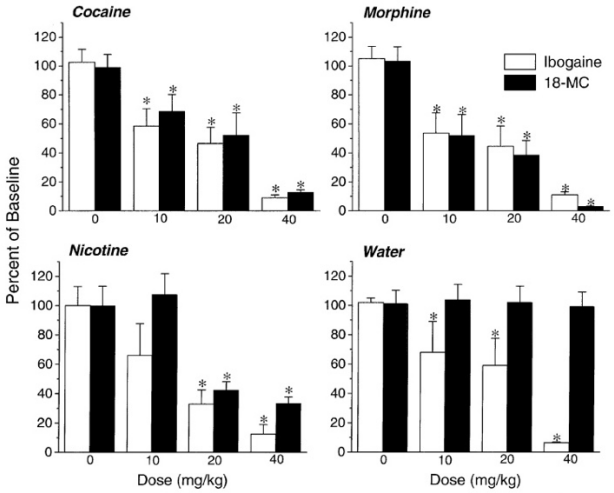
| surgery, social media, internet, risks, shopping, and pornography. | From page 371: "The acute intraperitoneal (ip) administration of either ibogaine or **18-MC**, 15 min prior to testing, **dose-dependently decreased the self-administration of morphine, cocaine, nicotine, and alcohol in rats**."<br><br>From page 372:<br>  <br><br>**FIGURE 2.** Comparison of the dose-response effects of intraperitoneally administered ibogaine and 18-MC (40 mg/kg, ip, 30 min earlier) on the self-administration of cocaine (top, left), morphine (top, right), nicotine (bottom, left), and water (bottom, right). Each bar represents the mean (±SEM) of at least 6 rats. *Asterisks* indicate significant differences ($p < 0.05$) from vehicle (0 mg/kg). |
| **13**. The method of claim 11, wherein said treating step further includes the steps of reducing and/or eliminating a need to do behaviors relating to the behavioral addiction. | 2. GLICK (2000) "18-Methoxycornaridine (18-MC) and Ibogaine: Comparison of Antiaddictive Efficacy, Toxicity, and Mechanisms of Action" Vol. 914(1): 369-386. Annals of the New York Academy of Science.<br><br>From page 371: "The acute intraperitoneal (ip) administration of either ibogaine or **18-MC**, 15 min prior to testing, **dose-dependently decreased the self-administration of morphine, cocaine, nicotine, and alcohol in rats**."<br><br>From page 372: |

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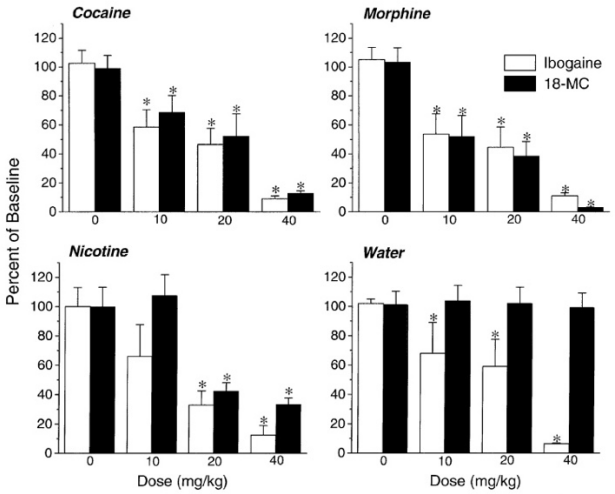
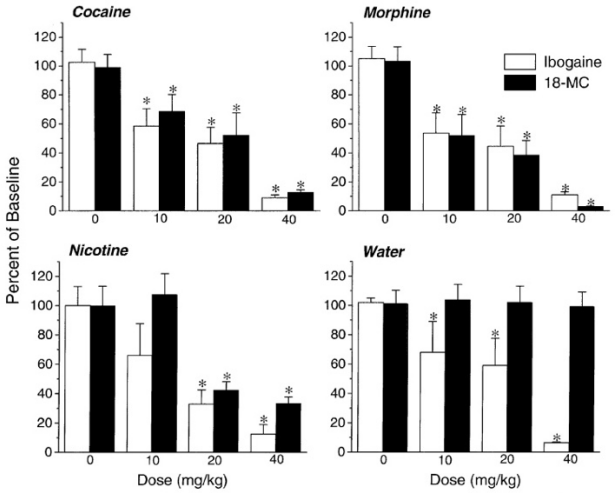
| |  <br>**FIGURE 2.** Comparison of the dose-response effects of intraperitoneally administered ibogaine and 18-MC (40 mg/kg, ip, 30 min earlier) on the self-administration of cocaine (top, left), morphine (top, right), nicotine (bottom, left), and water (bottom, right). Each bar represents the mean (±SEM) of at least 6 rats. *Asterisks* indicate significant differences ($p < 0.05$) from vehicle (0 mg/kg). |
| **14**. The method of claim 11, wherein the composition is administered in a dose of 0.01-10 mg/kg. | 2. GLICK (2000) "18-Methoxycornaridine (18-MC) and Ibogaine: Comparison of Antiaddictive Efficacy, Toxicity, and Mechanisms of Action" Vol. 914(1): 369-386. Annals of the New York Academy of Science.<br><br>From page 372:<br>  <br>**FIGURE 2.** Comparison of the dose-response effects of intraperitoneally administered ibogaine and 18-MC (40 mg/kg, ip, 30 min earlier) on the self-administration of cocaine (top, left), morphine (top, right), nicotine (bottom, left), and water (bottom, right). Each bar represents the mean (±SEM) of at least 6 rats. *Asterisks* indicate significant differences ($p < 0.05$) from vehicle (0 mg/kg). |
| **15**. The method of claim 11, wherein the composition is | 2. GLICK (2000) "18-Methoxycornaridine (18-MC) and Ibogaine: Comparison of Antiaddictive Efficacy, Toxicity, and Mechanisms of |

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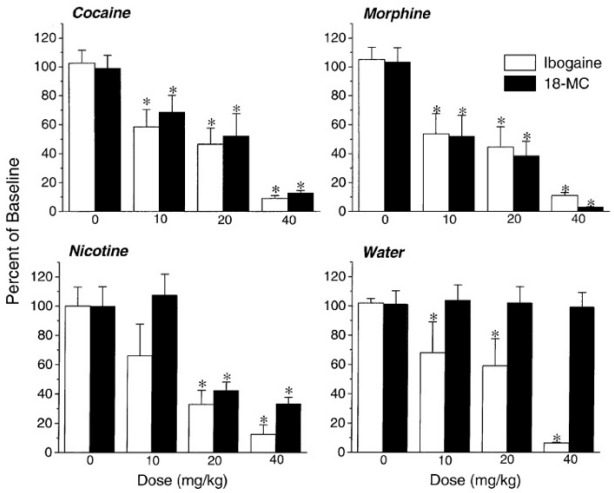
| administered as a single dose. | Action" Vol. 914(1): 369-386. Annals of the New York Academy of Science.<br><br>From page 371: "The acute intraperitoneal (ip) administration of either ibogaine or **18-MC**, 15 min prior to testing, dose-dependently decreased the self-administration of morphine, cocaine, nicotine, and alcohol in rats."<br><br>From page 372:<br>  <br><br>**FIGURE 2.** Comparison of the dose-response effects of intraperitoneally administered ibogaine and 18-MC (40 mg/kg, ip, 30 min earlier) on the self-administration of cocaine (top, left), morphine (top, right), nicotine (bottom, left), and water (bottom, right). Each bar represents the mean (±SEM) of at least 6 rats. *Asterisks* indicate significant differences ($p < 0.05$) from vehicle (0 mg/kg). |
| **16**. The method of claim 11, wherein the composition is administered as a repeat dose over a time period chosen from the group consisting of days, weeks, months, and years. | 3. ClinicalTrials.gov, "A Study to Assess 18-Methoxycoronaridine (18-MC HCl) in Healthy Volunteers. March 3, 2020. https://clinicaltrials.gov/ct2/show/NCT04292197<br><br>From Study Description: "The primary objective of this study is to assess the safety and tolerability of a single day dosing and a **separate multiple day dosing of 18-MC HCl** administered orally, each part of the study having a different set of healthy male and female volunteers." |

# Electronic Acknowledgement Receipt

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| **EFS ID:** | 48108599 |
| **Application Number:** | 17835051 |
| **International Application Number:** | |
| **Confirmation Number:** | 4638 |
| **Title of Invention:** | 18-MC FOR TREATING OBESITY |
| **First Named Inventor/Applicant Name:** | Robert BARROW |
| **Customer Number:** | 48924 |
| **Filer:** | Kurtzweil Taylor |
| **Filer Authorized By:** | |
| **Attorney Docket Number:** | 0614.00146 |
| **Receipt Date:** | 06-JUN-2023 |
| **Filing Date:** | 08-JUN-2022 |
| **Time Stamp:** | 14:04:52 |
| **Application Type:** | |

## Payment information:

| | |
|---|---|
| Submitted with Payment | no |

## File Listing:

| Document Number | Document Description | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl.) |
|---|---|---|---|---|---|
| 1 | Concise Description of Relevance | Concise-description-generated.pdf | 37344<br>f22618ace0b37c7ddaa11711d5a8078023ccdbef | no | 4 |

**Warnings:**

| | | | | | |
|---|---|---|---|---|---|
| **Information:** | | | | | |
| 2 | Third-Party Submission Under 37 CFR 1.290 | Third-party-preissuance-submission.pdf | 58868<br>a827c04a9bcc32c7fe548e28e69a1d4e3eeb0781 | no | 3 |
| **Warnings:** | | | | | |
| **Information:** | | | | | |
| 3 | Request for Notification of Non-compliant Third-Party Submission | Third-party-notification-request.pdf | 23739<br>eed4432c2eb729987ed53b18c2f389c4c80379b4 | no | 1 |
| **Warnings:** | | | | | |
| **Information:** | | | | | |
| 4 | Evidence of Publication | Taraschenko2008.pdf | 296518<br>5f1d697bf52df1c53f8b26f64eac4c483be86543 | no | 12 |
| **Warnings:** | | | | | |
| **Information:** | | | | | |
| 5 | Evidence of Publication | Glick2000.pdf | 4949737<br>f9772c2e3588a5e181bc6d2f6d63ed5ea916eb49 | no | 18 |
| **Warnings:** | | | | | |
| **Information:** | | | | | |
| 6 | Concise Description of Relevance | US20220409628_Claims_Chart.pdf | 315739<br>d9f9e7688d1608e73db26c7f16c1eaeb714f98ba | no | 8 |
| **Warnings:** | | | | | |
| **Information:** | | | | | |
| | | | **Total Files Size (in bytes):** | 5681945 | |

**This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.**

**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.**