

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number

<b>Provisional Application for Patent Cover Sheet</b>					
This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c)					
<b>Inventor(s)</b>					
Inventor 1					Remove
Given Name	Middle Name	Family Name	City	State	Country <sub>i</sub>
Herriot		Tabuteau	New York	NY	US
All Inventors Must Be Listed – Additional Inventor Information blocks may be generated within this form by selecting the <b>Add</b> button.					<input type="button" value="Add"/>
<b>Title of Invention</b>		USE OF PAMIDRONATE, OLPADRONATE AND RELATED COMPOUNDS FOR THE TREATMENT OF PAIN			
Attorney Docket Number (if applicable)					
<b>Correspondence Address</b>					
Direct all correspondence to (select one):					
<input type="radio"/> The address corresponding to Customer Number			<input checked="" type="radio"/> Firm or Individual Name		
Firm or Individual Name 1			Herriot Tabuteau		
Firm or Individual Name 2					
<b>Mailing Address of Applicant:</b>					
Address 1	401 East 64th Street, Apt. 4D				
Address 2					
City	New York	State/Province	NY		
Postal Code	10065	Country <sub>i</sub>	US		
Phone	1-646-688-2824				

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.	
<input checked="" type="radio"/> No.	
<input type="radio"/> Yes, the name of the U.S. Government agency and the Government contract number are:	

<b>Entity Status</b>					
Applicant claims small entity status under 37 CFR 1.27					
<input checked="" type="radio"/> Yes, applicant qualifies for small entity status under 37 CFR 1.27 <input type="radio"/> No					
<b>Warning</b>					
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 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.					
<b>Signature</b>					
Please see 37 CFR 1.4(d) for the form of the signature.					
Signature	/Herriot Tabuteau/			Date (YYYY-MM-DD)	2012-05-15
First Name	Herriot	Last Name	Tabuteau	Registration Number (If appropriate)	
This collection of information is required by 37 CFR 1.51. 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 8 hours 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. <b>DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. This form can only be used when in conjunction with EFS-Web. If this form is mailed to the USPTO, it may cause delays in handling the provisional application.</b>					

## Privacy Act Statement

**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 disclosure of these records is required by the Freedom of Information Act.
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.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
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 Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to a n other 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 inspection 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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Utility Patent Application (Provisional)

**USE OF PAMIDRONATE, OLPADRONATE AND RELATED COMPOUNDS FOR THE TREATMENT OF PAIN**

Inventor: **Herriot Tabuteau**

Correspondence Address:

**Herriot Tabuteau**

**401 East 64th Street, Apt. 4D**

**New York, NY 10065**

BACKGROUND OF THE INVENTION

Complex regional pain syndrome type I (CRPS-I), also known as reflex sympathetic dystrophy (RSD), and complex regional pain syndrome type II (CRPS-II), also known as causalgia, are debilitating pain syndromes. They are characterized by severe pain in a limb accompanied by allodynia, hyperalgesia, edema, changes in skin blood flow and abnormal sudomotor activity.

These disorders are often difficult to treat and there exists a need for additional therapeutic options.

DESCRIPTION OF THE INVENTION

Disclosed are pharmaceutical compositions and methods for the treatment of any type of pain including, but not limited to, postoperative pain, cancer pain, arthritic pain, lumbosacral pain, musculoskeletal pain, neuropathic pain, chronic pain, etc.

Disclosed are pharmaceutical compositions and methods for the treatment of complex regional pain syndrome type I and type II (CRPS-I and CRPS-II).

One embodiment is a pharmaceutical composition comprising pamidronate, neridronate, olpadronate, alendronate, ibandronate, risedronate, zoledronate or another bisphosphonate compound for the treatment of pain.

Another embodiment is a pharmaceutical composition comprising pamidronate, neridronate, olpadronate, alendronate, ibandronate, risedronate, zoledronate or another bisphosphonate compound for the treatment of CRPS-I and CRPS-II.

The terms pamidronate, neridronate, olpadronate, alendronate, ibandronate, risedronate, zoledronate, or another bisphosphonate compound, as used in this application refer to these compounds or their pharmaceutically acceptable salts, and any of their polymorphic forms.

Other names for pamidronate, neridronate, olpadronate, alendronate, ibandronate, risedronate, and zoledronate may include but are not limited to pamidronic acid, neridronic acid, olpadronic acid, alendronic acid, ibandronic acid, risedronic acid, and zoledronic acid, respectively.

Another embodiment is a method for the treatment of treatment of pain comprising administering to an individual pamidronate, neridronate, olpadronate, alendronate, ibandronate, risedronate, zoledronate or another bisphosphonate compound.

Yet another embodiment is a method for the treatment of treatment of CRPS-I and CRPS-II comprising administering to an individual pamidronate, neridronate, olpadronate, alendronate, ibandronate, risedronate, zoledronate or another bisphosphonate compound.

Any suitable route of administration may be employed for providing an individual with an effective dosage of the pamidronate, neridronate, olpadronate, alendronate, ibandronate, risedronate, zoledronate or another bisphosphonate compound. For example, oral, rectal, parenteral, transdermal, sublingual, subcutaneous, intrathecal, intramuscular and the like may be employed as appropriate.

Dosage forms for the pamidronate, neridronate, olpadronate, alendronate, ibandronate, risedronate, zoledronate or another bisphosphonate compound in the present embodiments include but are not limited to tablets, coated tablets, cachets, capsules, caplets, troches, dispersions, sustained release formulations, suspensions, solutions, patches and the like.

In addition to the common dosage forms set forth above, the pamidronate, neridronate, olpadronate, alendronate, ibandronate, risedronate, zoledronate or another bisphosphonate compound may also be administered by controlled release or sustained release means and/or delivery devices.

The effective amount of pamidronate, neridronate, olpadronate, alendronate, ibandronate, risedronate, zoledronate or another bisphosphonate compound in the treatment of pain, CRPS-I and CRPS-II will vary depending on various factors known to the treating physicians, such as the severity of the condition to be treated, route of administration, formulation and dosage forms, physical characters of the pamidronate, neridronate, olpadronate, alendronate, ibandronate, risedronate, zoledronate or another bisphosphonate compound used, and age, weight and response of the individual patients.

In some embodiments the daily oral dose of pamidronate is about 10 mg to about 1,000 mg, about 50 mg to about 500 mg, about 100 mg to about 500 mg, or about 150 mg to about 300 mg. In some embodiments the parenteral dose of pamidronate is about 5 mg to about 500 mg, about 5 mg to about 200 mg, or about 10 mg to about 150 mg.

In some embodiments the daily oral dose of neridronate is about 10 mg to about 1,000 mg, about 50 mg to about 500 mg, about 100 mg to about 500 mg, or about 150 mg to about 300 mg. In some embodiments the parenteral dose of neridronate is about 5 mg to about 500 mg, about 5 mg to about 200 mg, or about 10 mg to about 150 mg.

In some embodiments the daily oral dose of alendronate is about 0.5 mg to about 200 mg, about 1 mg to about 100 mg, about 5 mg to about 100 mg, or about 2 mg to about 50 mg. In some embodiments the parenteral dose of alendronate is about 1 mg to about 100 mg, about 1 mg to about 40 mg, or about 2 mg to about 30 mg.

In some embodiments the daily oral dose of olpadronate is about 0.5 mg to about 200 mg, about 1 mg to about 100 mg, about 5 mg to about 100 mg, or about 2 mg to about 50 mg. In some embodiments the parenteral dose of olpadronate is about 1 mg to about 100 mg, about 1 mg to about 40 mg, or about 2 mg to about 30 mg.

In some embodiments the daily oral dose of ibandronate is about 0.25 mg to about 100 mg, about 0.5 mg to about 50 mg, about 2.5 mg to about 50 mg, or about 1 mg to about 25 mg. In some embodiments the parenteral dose of ibandronate is about 0.5 mg to about 50 mg, about 0.5 mg to about 20 mg, or about 1 mg to about 15 mg.

In some embodiments the daily oral dose of risedronate is about 0.25 mg to about 100 mg, about 0.5 mg to about 50 mg, about 2.5 mg to about 50 mg, or about 1 mg to about 25 mg. In some embodiments the parenteral dose of risedronate is about 0.25 mg to about 25 mg, about 0.25 mg to about 10 mg, or about 0.5 mg to about 7.5 mg.

In some embodiments the daily oral dose of zoledronate is about 0.005 mg to about 20 mg, about 0.1 mg to about 10 mg, about 0.5 mg to about 10 mg, or about 0.2 mg to about 5 mg. In some embodiments the parenteral dose of zoledronate is about 0.25 mg to about 25 mg, about 0.25 mg to about 10 mg, or about 0.5 mg to about 7.5 mg.

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.