Technology Transfer at The University of Tennessee: Patent Basics

Janet Ralbovsky, Ph.D. Lakita Cavin, J.D., Ph.D.

Technology Transfer: Health Science Center (Memphis) Office



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What is a Patent?

Intellectual property right

- granted by US Government
- to an inventor

- "to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States"
- in exchange for public disclosure of the invention when the patent is granted.
- 20 years

Right established in Article 1, Section 8 of the United States Constitution:

 "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."



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Who is Granted a Patent?

Inventor

- One who conceives of the invention
- Must contribute to conception
 - Authorship v. Inventorship
- In US (for now), first person to invent



What Can Be Patented?

- Short Answer- <u>Anything under the sun made by</u> <u>man</u>
- Any <u>new</u>, <u>useful</u>, and <u>nonobvious</u>:
 - process
 - machine
 - manufacture
 - composition of matter
 - improvement of any of the above



What Can Not Be Patented?

- Laws of nature, physical phenomena, naturally occurring manufacture/compositions, and abstract ideas.
 - E=mc²
 - New plant found in the wild
 - Human being
 - Any living subject matter that does not involve human intervention in its production.
- Mere idea or suggestion.



Basic Requirements for Obtaining a Patent

1. Utility

- Useful for some purpose
- Must have specific utility
- Credible utility
- Must be operative/Work for intended purposes(produce claimed result); reduced to practice
- Describe invention, disclose best mode for making or using
- Violation of utility requirement means claimed invention is totally incapable of achieving a useful result
 - **No requirements for safety or efficacy in humans**



Basic Requirements for Obtaining a Patent

2. Novelty

- Invention must be new.
- Assess prior art. No patent if:
 - The invention is patented or described in a printed publication anywhere, including posters.
 - The invention was known or used by others in this country

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- The inventor uses the invention publicly
- The inventor places the invention on sale
- Time period: No patent if above activities take place more than <u>one year</u> before the invention or the application for patent (US only). Patent rights in foreign countries are immediately lost.

Basic Requirements for Obtaining a Patent

3. Nonobviousness

- Even if the subject matter not exactly shown by the prior art, a patent will not be granted if the differences are obvious or trivial.
- Combination of references can make the claimed invention obvious.
- Subject matter sought to be patented must be sufficiently different from prior art.
- Standard is whether person having skill in the art would think invention is obvious.

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Types of Patents

- <u>Utility patents</u> any new and useful process, machine, article of manufacture, or composition of matter, or any new and useful improvement thereof
 - Patent term 20 years from filing date
- <u>Design patents</u> a new, original, and ornamental design for an article of manufacture
 - Patent term is 14 years from grant
- Plant patents asexually reproduced any distinct and new variety of plant.
 - Patent term 20 years from filing date

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Types of Patent Applications

Provisional

- Typically what is filed first for the invention.
- Establishes a filing date for claimed invention.
- Gives right to file regular application 1 year later; establishes priority date.
- Automatically abandoned after 1 year.
- No formal patent claim required.
- Not examined.
- Never issued.

Nonprovisional (Regular)

- Filed for all types of patents sought (utility, design, plant)
- Must be filed 1 year later to establish earlier priority date to the provisional
- Initiates the examination process.
- Must include a specification, including a claim or claims; drawings, when necessary; an oath or declaration; and the prescribed filing fee



Continuing Applications

Offsprings of the "Parent" Nonprovisional • Continuation

 a second application for the same invention claimed in a prior nonprovisional application and filed during the pendency of first application. Same inventive entity.

Continuation in Part (CIP)

 an application filed during pendency of an earlier nonprovisional application, which may contain some substantial portion the earlier nonprovisional application and add new matter not disclosed in the earlier nonprovisional application. Does not have to name same inventive entity.

Divisional

 an application for an independent and distinct invention that was disclosed in the earlier application and is now carved out.



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Examination of Applications

- Applications are assigned for examination to appropriate examiner.
- The examination of the application consists of a study of the application
 - for compliance with the legal requirements
 - search through prior art (U.S. patents, publications of patent applications, foreign patent documents, and other publications); to assess invention for novelty, utility, and nonobviousness.
 - Determine if more than one invention is claimed in a single application



Office Action

- The method by which applicant is notified of the examiner's decision
- States the reasons for any adverse action
- States any objection, rejection, or requirement. Some reasons for rejections:
 - Unpatentable subject matter
 - Requirements of novelty, utility, or nonobviousness not met.
- Possible that all claims are rejected on first office action.
- Information given in office action useful for applicant to determine how to continue with prosecution.



Applicant's Reply (Attorney)

- Must request reconsideration in writing.
- Must distinctly and specifically point out the supposed errors in the examiner's Office action.
- Must reply to every ground of objection and rejection in the prior Office action.
- Can amend the application in reply to a rejection, but the applicant must clearly point out why the amended claims are patentable over any prior art cited by examiner.
- Must be made within a prescribed time limit.



Second Office Action(or Allowance)

- Response to Applicant's Reply; previous arguments not convincing
- May be final
- Claims may be allowed

Final Office Action (or Allowance)

Final rejection

- Applicant can appeal or petition examiner's findings.
- Claims may be allowed



Typical Time Line





International Application (PCT)

- The Patent Cooperation Treaty (PCT) allows applicant to file one application.
- It provides a unified procedure for simultaneously filing patent applications for inventions in each member country
- Typically filed at same time as nonprovisional.
- Then applicant pursues patents in national patent offices(national stage) of the countries in which he/she wants to obtain them.



Typical Time Line(with PCT)





Anatomy of a Patent Application

Title

- Field of Invention
- Background of Invention
- Summary of the Invention
- Brief Description of the Drawings
- Detailed Description of the Invention
 - Includes experimental examples
- What is claimed (a list of Claims)



How to search, find and download Patents?

- United States Patent and Trademark Office (USPTO) database
 - www.**uspto**.gov
 - Good for searching whether a patent is issued or published
 - Good for searching a particular inventor
 - Public PAIR patent application information retrieval
 - provides status of patent applications
- Google patents
 - www.google.com/patents
 - Great for downloading pdf versions of patents
- Patent Lens
 - www.Patentlens.net
 - Great for downloading pdf versions of patents



Patent numbers

Application Number:

- Given to a patent application when filed in U.S.
- 99999999 or 99/999999

Patent Number:

- Given to a patent application upon issuance in U.S.
- 9,999,999

Publication Number:

- Given to a patent when published
- US YYYY-9999999 A9 or 9999-9999999

PCT Number:

- Given to a patent application when filed as a PCT
- PCT/CCYY/99999 or PCT/CCYYYY/999999

WO (PCT) Number:

- Given to a PCT patent application when published
- WOYYYYUS99999





US 20090286824A1

(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2009/0286824 A1

Moore, II et al.

Nov. 19, 2009 (43) **Pub. Date:**

- (54) PYRIDINE CLASSICAL CANNABINOID **COMPOUNDS AND RELATED METHODS OF** USE
- Bob M. Moore, II, Nesbit, MS (76)Inventors: (US); Steven Gurley, Memphis, TN (US); Suni Mustafa, Memphis, TN (US)

Correspondence Address: **REINHART BOERNER VAN DEUREN S.C.** ATTN: LINDA KASULKE, DOCKET COORDI-NATOR 1000 NORTH WATER STREET, SUITE 2100 MILWAUKEE, WI 53202 (US)

- Appl. No.: 12/468,773 (21)
- (22)Filed: May 19, 2009

Related U.S. Application Data

(60) Provisional application No. 61/128,160, filed on May 19, 2008.

Publication Classification

(51)	Int. Cl.	
	A61K 31/436	(2006.01)
	C07D 491/052	(2006.01)
	A61P 35/00	(2006.01)
(52)	U.S. Cl	514/291 ; 546/89

ABSTRACT (57)

Disclosed are compounds of the formula I:



wherein R₁, R₂, V, W, X, Y and Z can be as defined herein. The compounds can be used in the treatment of disorders mediated by the cannabinoid receptors.



U.S. Patent Classification System

- The Index to the U.S. Patent Classification System is an annual publication from the USPTO.
- There are over 400 classes in the U.S. Patent Classification System, each having a title descriptive of its subject matter and each being identified by a class number.
- Each class is subdivided into a number of subclasses. Each subclass bears a descriptive title and is identified by a subclass number.
- A complete identification of a subclass requires both the class and subclass number and any alpha or decimal designations; e.g., 417/161.1A identifies Class 417, Subclass 161.1A.

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(12) United States Patent Shukla et al.

(54) VEHICLES FOR DELIVERY OF BIOLOGICALLY ACTIVE SUBSTANCES

- (75) Inventors: Atul J. Shukla, Cordova, TN (US); James R. Johnson, Germantown, TN (US); Yichun Sun, Germantown, TN (US); Robert Cooper, Starkville, MS (US); Gregg Boring, Starkville, MS (US); Dan Scruggs, Starkville, MS (US)
- (73) Assignce: University of Tennessee Research Foundation, Knoxville, TN (US)
- (*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 420 days.
- (21) Appl. No.: 10/143,144
- (22) Filed: May 9, 2002

(65) Prior Publication Data

US 2003/0211123 A1 Nov. 13, 2003

- (51) Int. Cl.⁷ A61K 9/02; A61K 9/08; A61K 9/70; A61K 13/02; A61F 2/02
- (58) Field of Search 424/400, 423, 424/443, 434, 78.04, 437

(56) References Cited

U.S. PATENT DOCUMENTS

4,297,353 A	10/1981	Maulding
5,047,166 A	9/1991	Weil
5,204,121 A	4/1993	Bucheler
5,352,662 A	10/1994	Brooks
5,591,727 A	1/1997	Bencsits
5,635,190 A	6/1997	Cheetham
5,747,058 A	5/1998	Tipton

(10) Patent No.: US 6,960,346 B2
(45) Date of Patent: Nov. 1, 2005

5,958,937 A	9/1999	Hausheer
6,001,822 A	12/1999	Wicks
6,117,857 A	9/2000	Carlsson

OTHER PUBLICATIONS

MORFLEX, INC., Technical Bulletin 102, "Citrate Esters as Plasticizers for Aqueous Based Pharmaceutical Coatings" (1993).

MORFLEX, INC., Technical Bulletin 103, "Medical Grade Citroflex® Plasticizers" (1993).

MORFLEX, INC., "Permanence of Plasticizers in Polymeric Films" (1993).

MORFLEX, INC., Pharmaceutical Coatings Bulletin 102–1, "Influence of Citrate Ester Plasticizers on the Properties of Acrylic Resin Polymers" (1993).

MORFLEX, INC., Pharmaceutical Coatings Bulletin 102–2, "Physical and Mechanical Properties of Acrylic and Cellulosic Polymers Plasticized with Citrate Esters" (1994).

MORFLEX, INC., Pharmaceutical Coatings Bulletin 102–3, "Influence of Plasticizers on the Dissolution and Physical Properties of Ethyl Cellulose Films and Coated Beads" (1995).

Kennedy, SW, "Triethyl Citrate", in Kibbe, AH (ed.), Handbook of Pharmaceutical Exciplents, 3rd ed., pp. 574–575, American Pharmaceutical Association (2000).

USP 23 NF 18 (United States Pharmacopoeia/National Formulary), "Pharmaceutical Dosage Forms", pp. 1944–1949 (1995).

Primary Examiner—Carlos A. Azpuru (74) Attorney, Agent, or Firm—Howard Eisenberg, Esq.

ABSTRACT

(57)

A formulation containing one or more biologically active substances dissolved, dispersed, emulsified, or suspended within a vehicle of one or more citric acid esters and/or citric acid ethers. Methods for making and using are disclosed, as are kits for administration of the pharmaceutical formulation.

80 Claims, 1 Drawing Sheet

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Contacts

Richard Magid, Ph.D. <u>rmagid1@uthsc.edu</u> (901) 448-1562

Lakita Cavin, J.D., Ph.D. Icavin@uthsc.edu (901) 448-7827

Janet Ralbovsky, Ph.D. jralbovs@uthsc.edu (901) 448-1146

http://utrf.tennessee.edu



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