

PROFESSOR MARGO A. BAGLEY

ASA GRIGGS SANDLER PROFESSOR OF LAW

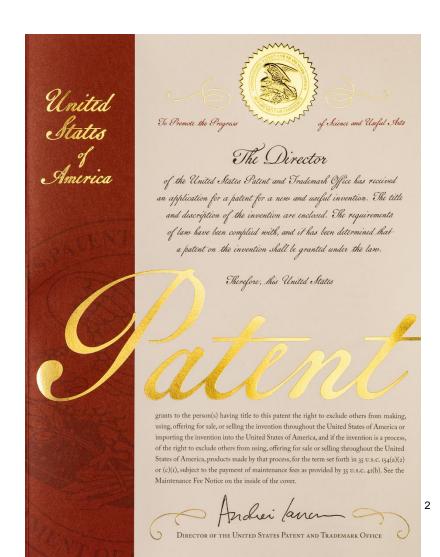
EMORY UNIVERSITY SCHOOL OF LAW

PATENT FEATURES

What is a patent? A property right

- Nature of the property right?
 - Negative right to exclude others from making, using, selling, or offering to sell invention;
 - Territorial: must obtain patent in every country where protection is desired
 - Personal property: can be bought, sold, licensed, bequeathed, etc.

Limited term: ~20 years



NO GLOBAL PATENT

Patent rights
are territorial
(must be
obtained and
enforced in
each
country/region)

Rules vary by country
International treaties
facilitate multi-country
filings



TYPES OF PATENTS

(NOT AVAILABLE IN ALL COUNTRIES)

<u>Utility/Invention</u> <u>Patents (longest term)</u>:

 For machines, processes, articles of manufacture or compositions

<u>Design</u> <u>Patents/Industrial</u> <u>Design Rights</u>:

 For ornamental or aesthetically pleasing designs

Utility Models (not U.S.):

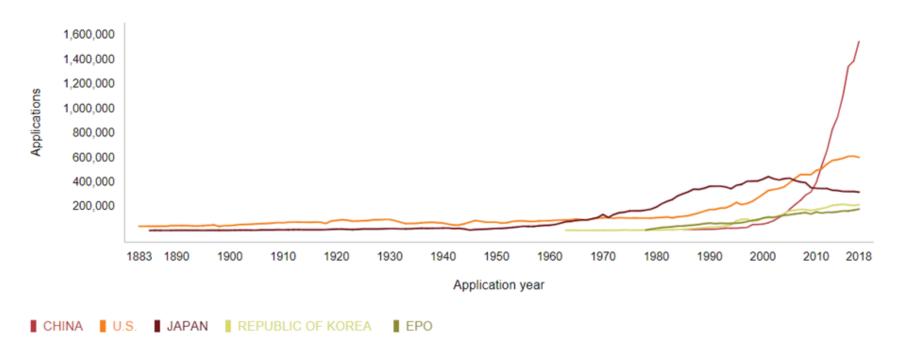
 Relating to form or structure of a product

Plant Patents:

For asexually reproducible plants

PATENT APPLICATION TRENDS (WIPO)

Trend in patent applications for the top five offices, 1883-2018



Note: The IP office of the Soviet Union, not represented in this figure, was the leading office in the world in terms of filings from 1964 to 1969. Like Japan and the U.S., the office of the Soviet Union saw stable application numbers until the early 1960s, after which it recorded rapid growth in the number of applications filed.

Source: Figure A7.

PATENT OPPORTUNITIES

- Expand Knowledge/MAKE MONEY
 - Monopoly pricing potential (single source)
 - Licensing patents (revenue stream)
 - Sale/auction (cash infusion)
 - Leverage (cross-licensing, settle litigation)
 - Enforcement (patent infringement damages)
 - Investment (venture capital funds)
 - Recognition (inventor/community contribution)

IMPORTANCE OF PATENTS FOR STARTUPS (AND IPLCS!)

Patents facilitate venture capital investment

Patents can help a startup defend itself

Patents may help a startup stop theft of its innovations by larger rivals

Patents can help a startup increase market share

Patents can increase the chances that a startup will be acquired

Startups with IP achieve greater long-term success

PATENTABILITY REQUIREMENTS

- (Utility Patents):
- **Type** (machine, composition of matter, article of manufacture, process)
- **Utility/Industrial Applicability** useful, functional
- **Novelty** –new, not before known
- Nonobviousness/Inventive Step —to person of ordinary skill in the art
- **Proper Description (enabling disclosure)**



(10) Patent No.:

(45) Date of Patent:

(12) United States Patent Semple et al.

(54) ANTI-INFLAMMATORY COMPOUNDS

(75) Inventors: Susan J. Semple, Mylor (AU); Bradley S. Simpson, Highbury (AU); Ross Allan McKinnon, Eden Hills (AU); David Claudie, Caims (AU): Jacobus P. Gerber, Eden Valley (AU); Jiping Wang, Felixstow (AU); George Moreton, Sr., Cairns (AU)

(73) Assignces: University of South Australia, Adelaide, S.A. (AU): Chuulangun Aboriginal Corporation, Queensland

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1120 days.

13/509,194 (21) Appl. No.:

(22) PCT Filed: Nov. 10, 2010

(86) PCT No.: PCT/AU2010/001502 § 371 (c)(1). (2), (4) Date: Aug. 6, 2012

(87) PCT Pub. No.: WO2011/057332 PCT Pub. Date: May 19, 2011

Prior Publication Data US 2013/0053437 A1 Feb. 28, 2013

Nov. 10, 2009 (AU)

Foreign Application Priority Data

(51) Int. Cl. C07D 307/42 (2006.01) (2006.01) C07D 307/54

CPC C07D 307/42 (2013.01); C07D 307/54

(58) Field of Classification Search

See application file for complete search history.

References Cited

U.S. PATENT DOCUMENTS

6,143,303 A 11/2000 Janakiram et al.

FOREIGN PATENT DOCUMENTS

2011/057327 A1 5/2011

OTHER PUBLICATIONS

Banker, Gilbert, Modern Pharmaceutics 3rd ed. Marcel Dekker, Inc. New York, 1996.*

Nordqvist, Christian. "Inflammation: Causes, Symptoms and Treatment." Medical News Today. Medil.exicon, Intl., Sep. 16, 2015. Web. http://www.medicalnewstoday.com/articles/248423.php.*

Hardard Health Publications: Harvard Medical School "Foods that fight inflammation". Jul. 1, 2014. Web http://www.health.harvard. edu/staying-healthy/foods-that-fight-inflammation>.*

US 9,403,786 B2

Aug. 2, 2016

Lee, D.Y.W. et al., New Neoclerodane Diterpenoids Isolated From the Leaves of Salvia Divinorum and Their Binding Affinities for Human k Opioid Receptors, Bioorganic & Medicinal Chemistry 13,

Bigham, A.K. et al., Divinatorins A-C, New Neoclerodane Diterpenoids from the Controlled Sage Salvia Divinorum, J. Nat. Prod. 66, 1242-1244 (2003).

Medana, C. et al., Determination of Salvinorins and Divinatorins in Salvia Divinorum Leaves by Liquid Chromatography/Multistage Mass Spectrometry, Rapid Communications in Mass Spectrometry 20, 131-136 (2006).

Venkateswarlu, K. et al., A Benzofuranoid and Two Clerodane Diterpenoids from Pulicaria Wightlana, Helvetica Chimica Acta 91: 2081-2088 (2008).

Jefferies, P.R. et al., Structure Elucidation of Some Ent-Clerodane Diterpenes From Dodonaea Boroniaefolia and Cyanostegia Angustifolia, Australian Journal of Chemistry 26 (10), 2199-2211 (1973).

Jefferies, P.R. et al., Diterpenes of the Cascarillin Group From Dodonaea SPP., Tetrahedron Letters (48) 4777-4782 (1967).

Payne, T.G. et al., The Chemistry of Dodonaea SPP-IV. Diterpene and Flavonoid Components of D. attenuata, Tetrahedron 29, 2575-

Anis, I., et al., Thrombin Inhibitory Constituents from Duranta Repens, Helvetica Chimica Acta, vol. 84, 649-655, (2001).

Bigham, A.K. et al., Divinatorins A-C, New Neoclerodane Diterpenoids from the Controlled Sage Salvia divinorum, Journal of Natural Products, vol. 66, (9), 1242-1244, (2003).

Jolad, S.D. et al., Diterpenoids of Conyza Coulteri, Phytochemistry, vol. 27 (4), 1211-1212 (1988).

Lee, D.Y.W. et al., New Neoclerodane Diterpenoids Isolated from the Leaves of Salvia Divinorum and their Binding Affinities for Human Kappa Opioid Receptors, Bioorganic & Medicinal Chemistry, vol. 13 (19), 5635-5639 (2005).

Munro, T.A. et al., Autoxidation of Salvinorin a Under Basic Conditions, The Journal of Organic Chemistry, vol. 70, (24) 10057-10061,

Pandey, U.C. et al., Stereochemistry of Strictic Acid and Related Furano-Diterpenes from Conyza Japonica and Grangea Maderaspatana, Phytochemistry, vol. 23 (2), 391-397, (1984).

Simpson, B.S., Chemical and Pharmacological Investigation of Dodonaea Polyandra, Ph.D. Thesis, Division of Health Science, School of Pharmacy and Medical Sciences, University of South Australia (2011).

Wilson, S.R. et al., The Chemistry of the Euphorbiaceae. A New Diterpene from Croton Californicus, Journal of the American Chemical Society, vol. 98 (12), 3669-3674, (1976).

Zdero, C. et al., Clerodane Derivatives From Diplostephium, Phytochemistry, vol. 31 (1), 213-216, (1992).

* cited by examiner

Primary Examiner - Golam M M Shameem Assistant Examiner - Laura Daniel (74) Attorney, Agent, or Firm - Olson & Cepuritis, Ltd.

ABSTRACT

New clerodane compounds isolated from plant material from Dodonaea polyandra are disclosed. The compounds have anti-inflammatory activity. Pharmaceutical and cosmetic compositions containing the compounds, as well as methods of treating inflammation using the compounds, are also dis-

17 Claims, 16 Drawing Sheets

PATENTABILITY REQUIREMENTS

- (Utility Patents):
- **Type** (machine, composition of matter, article of manufacture, process)
- **Utility/Industrial Applicability** useful, functional
- **Novelty** –new, not before known
- Nonobviousness/Inventive Step —to person of ordinary skill in the art
- **Proper Description (enabling disclosure)**

US 9,403,786 B2

$$\mathbb{R}^4$$
 \mathbb{R}^5
 \mathbb{R}^5
 \mathbb{R}^5
 \mathbb{R}^5
 \mathbb{R}^5

In various embodiments R9 is optionally substituted C6-C18 arvl. In some embodiments R9 is phenyl. In some embodiments only one of R5 and R6 is (CH2)mOC(O)R9. In some embodiments m is selected from the group consisting of

In some embodiments T is a double bond

In some embodiments n is 1.

In various embodiments Ar is selected from the group consisting of: optionally substituted furan, optionally substituted thiophene, optionally substituted pyrrole, optionally substituted phenyl, and optionally substituted pyridine. In some embodiments Ar is furan.

In various embodiments R1 is COOR7. In some embodi-

In some embodiments R2 is optionally substituted C1-C12 alkyl.

In some embodiments R2 is methyl

In some embodiments R3 is H.

C1-C12 alkyl. In some embodiments R4 is methyl.

From the foregoing, it will be evident that in some embodiments the present invention provides compounds of formula

$$\mathbb{R}^{\underline{c}} \xrightarrow{H_{J}C} \mathbb{R}^{\underline{c}}$$

$$\mathbb{C}_{CQ,\mathbb{R}^{3}}$$

or a pharmaceutically acceptable salt or prodrug thereof; wherein R5, R6, and R7 are as defined above.

In various embodiments R5 is (CH2)mOC(O)R9 and R6 is selected from the group consisting of H and OH.

In various embodiments R⁶ is (CH₂)mOC(O)R⁹ and R⁵ is 65 optionally substituted C1-C12 alkyl. In some embodiments

In another aspect, the present invention provides a composition comprising a compound as described herein. The composition may be a pharmaceutical composition or a cosmetic

In a further aspect, the present invention provides a method of treating or preventing inflammation in a subject, the method comprising administering to the subject a therapeutically effective amount of a compound as described herein.

In another aspect, the present invention provides a method (Ib) 10 of treating or preventing inflammation in a subject, the method comprising administering to the subject a therapeutically effective amount of a composition as described herein.

In another aspect, the present invention provides a method of treating a disease or condition characterised by or associ-15 ated with inflammation, the method comprising administering to a subject in need of such treatment a therapeutically effective amount of a compound as described herein.

In a further aspect, the present invention provides a method of treating a disease or condition characterised by or associated with inflammation, the method comprising administering to a subject in need of such treatment a therapeutically effective amount of a composition as described herein.

In various embodiments the subject is a mammal. In some embodiments the subject is a human

The present invention also provides for the use of a comnound as described herein in the treatment of a disease or condition characterised by or associated with inflammation.

Furthermore, the present invention provides for the use of a compound as described herein in the preparation of a medicament for the treatment or prevention of inflammation.

DESCRIPTION OF EXEMPLARY

It is to be understood that the following description is for the purpose of describing particular embodiments only, and is not intended to be limiting with respect to the above descrip-

In this specification a number of terms are used which are In various embodiments R4 is optionally substituted 40 well known to a skilled addressee. Nevertheless for the purposes of clarity a number of terms will be defined.

The term "unsubstituted" as used throughout the specification means that there is no substituent or that the only substituents are hydrogen.

The term "optionally substituted" as used throughout the specification denotes that the group may or may not be further substituted or fused (so as to form a condensed polycyclic system), with one or more non-hydrogen substituent groups. In certain embodiments the substituent groups are one or 50 more groups independently selected from the group consisting of halogen, =O, =S, -CN, -NO₂, -CF₃, -OCF₃, alkyl, alkenyl, alkynyl, haloalkyl, haloalkenyl, haloalkynyl, heteroalkyl, cycloalkyl, cycloalkenyl, heterocycloalkyl, heterocycloalkenyl, aryl, heteroaryl, cycloalkylalkyl, heterocy-55 cloalkylalkyl, heteroarylalkyl, arylalkyl, cycloalkylalkenyl, heterocycloalkylalkenyl, arylalkenyl, heteroarylalkenyl, cycloalkylheteroalkyl, heterocycloalkylheteroalkyl, arylheteroalkyl, heteroarylheteroalkyl, hydroxy, hydroxyalkyl, alkyloxy, alkyloxyalkyl, alkyloxycycloalkyl, alkyloxyhet-60 erocycloalkyl, alkyloxyaryl, alkyloxyheteroaryl, alkyloxycarbonyl, alkylaminocarbonyl, alkenyloxy, alkynyloxy, cycloalkyloxy, cycloalkenyloxy, heterocycloalkyloxy, heterocycloalkenyloxy, aryloxy, phenoxy, benzyloxy, heteroaryloxy, arylalkyloxy, amino, alkylamino, acylamino, aminoalkyl, arylamino, sulfonylamino, sulfinylamino, sulfonyl, alkylsulfonyl, arylsulfonyl, aminosulfonyl, sulfinyl, alkylsulfinyl, arylsulfinyl, aminosulfinylaminoalkyl, -C(=O)

PATENTABILITY REQUIREMENTS

(Utility Patents):

- Type (machine, composition of matter, article of manufacture, process)
- Utility/Industrial Applicability useful, functional
- Novelty –new, not before known
- Nonobviousness/Inventive Step —to person of ordinary skill in the art
- Proper Description (enabling disclosure)

A composition comprising a compound according to claim 1 and a pharmaceutically acceptable carrier.

- 16. A method of treating inflammation in a subject, the method comprising administering to the Subject a therapeutically effective amount of a compound according to claim 1.
- 17. A method of treating inflammation, the method comprising administering to a subject in need of such treatment a therapeutically effective amount of an extract according to claim 13.

NOVELTY/INVENTIVE STEP REQUIREMENTS MAY NOT BE BARRIERS FOR NEW TK

- All TK is not old. Modifications of old knowledge may be protectible by patent if displays an inventive step over the original publicly known knowledge
- "Knowledge is not 'traditional' because of its object, nor its subject matter or content, nor its **age or antiquity**, nor its aesthetic qualities. What makes it traditional is **the way it has been preserved and transmitted between generations within a community**: 'its nature relates to **the manner [in which] it develops rather than to its antiquity**'. . . . The essential characteristics of traditional knowledge are its **linkage with a traditional community as such and its dynamic, intergenerational quality**." Antony Taubman and Matthias Leister, *Analysis of Different Areas of Indigenous Resources: Traditional Knowledge (2008)*

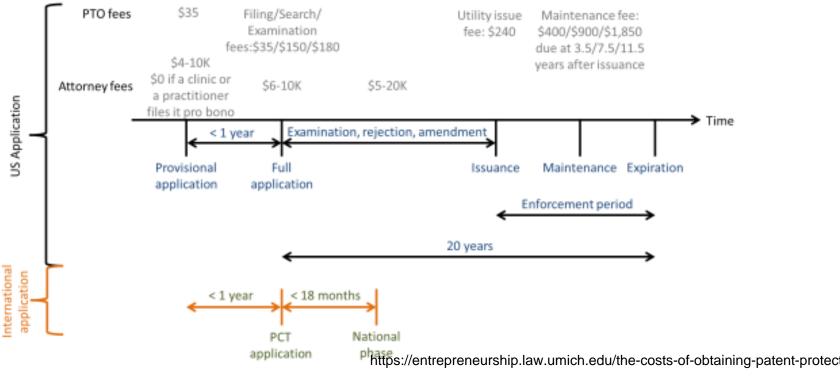
WHO CAN OBTAIN A PATENT?

AN INVENTOR OR OWNER (ASSIGNEE)

- To be an inventor, a person must contribute to the conception (mental part of invention) of at least part of one claim in a patent
- Joint inventors must have some collaboration or connection even if they did not work together or at the same time
- Patents have the attributes of personal property so they can be bought, sold, inherited, etc.
- IPLC Community can be the owner, member(s) who conceive of the invention would be the inventors

HOW MUCH DOES PATENT PROTECTION COST?

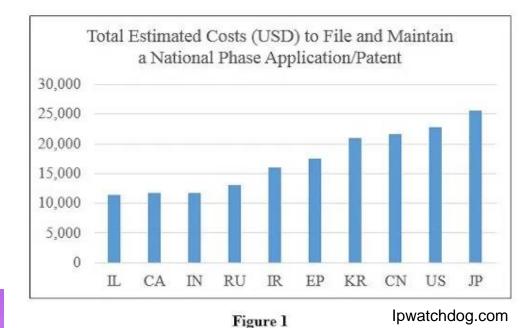
Estimated Cost



 The cost for patent protection varies based on a number of factors including the type of patent you seek to obtain and in how many countries.

Some countries have reduced filing fees for small entity inventors, but the bulk of the costs tends to be attorney fees. Also, costs do not stop at obtaining the patent.

- You may need to be able to work the patent in the countries where you have protection
- You should be able to afford to enforce your patent



COSTS OF KEEPING A PATENT IN FORCE

Table 1: Total Estimated Patent Maintenance Fees in USD

timated Patent Maintenance Fees
880
33
95
65
95
159
33
080

PRO BONO ASSISTANCE TO AN INDIGENOUS INVENTOR

- Lucas Tyree, environmental scientist, member of the Monacan tribe of Virginia
- Assisted pro bono by Jorge Goldstein, cofounder, Sterne, Kessler, Goldstein, and Fox patent law firm
- Invention on foliar hydroponic feeding formulations that allow the growth of vegetables at lower cost. Lucas's invention is currently being used to grow food in his Native American community, where healthy, inexpensive food can be scarce.



- (19) United States
- (12) Patent Application Publication (10) Pub. No.: US 2019/0127286 A1 TYREE
- May 2, 2019 (43) Pub. Date:
- (54) FOLIAR FEEDING FORMULATION AND METHODS OF USE
- (71) Applicant: Lucas TYREE, Lexington, VA (US)
- Inventor: Lucas TYREE, Lexington, VA (US)

(21) Appl. No.: 15/755,422

(22) PCT Filed: Aug. 30, 2016

(86) PCT No.: PCT/US16/49416

§ 371 (c)(1),

(2) Date: Feb. 26, 2018

Related U.S. Application Data

(60) Provisional application No. 62/212,358, filed on Aug. 31, 2015, provisional application No. 62/339,329, filed on May 20, 2016.

Publication Classification

(51)	Int. Cl.	
	C05B 7/00	(2006.01)
	C05G 3/06	(2006.01)
	C05G 3/00	(2006.01)
	A01G 7/00	(2006.01)
	A01G 31/00	(2006.01)
	A01G 22/15	(2006.01)

(52) U.S. Cl.

(2013.01); **C05G 3/0076** (2013.01); A01G 24/15 (2018.02); **A01G** 31/00 (2013.01); A01G 22/15 (2018.02); A01G 7/00 (2013.01)

(57)ABSTRACT

Described is a hydroponic system wherein a feed formulation comprising a plant's nutritionally required mineral nutrients is applied to the foliage of the plant and the roots of the plant are in contact with an incomplete water solution that may comprise only hydrogen and oxygen. The feed formulation, methods of feeding a plant or plant seed, and plants produced thereby are also described.

IP Services

Policy

Cooperation

Resources

About IP

About WIPO

Media

Meetings

Search WIPO

Contact Us

IP Portal

English -

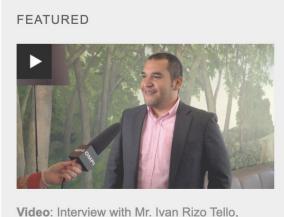
Home > About IP > Patents > Inventor Assistance Program

On this page ▼

Inventor Assistance Program

The Inventor Assistance Program (IAP) – a WIPO initiative in cooperation with the World Economic Forum – is the first global program to match developing country inventors and small businesses with limited financial means with patent attorneys. These experts provide pro bono legal assistance to help inventors secure patent protection.

Participating countries - Colombia, Ecuador, Morocco, Peru, the Philippines, South Africa.



Video: Interview with Mr. Ivan Rizo Tello, awarded inventor under the IAP.

Get involved



Pro bono attorneys - Work with the IAP

Through the IAP, pro bono attorneys and patent specialists can provide a free kickstart to the use and development of the patent system in developing countries. Their work helps spur innovation at the grassroots level and also allows them to develop their professional skills in new, rewarding ways.

- ▶ Who can apply?
- ► How can I apply?

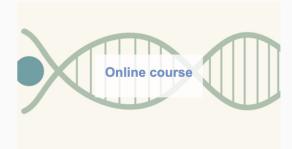


Inventors - Benefit from IAP help

Inventors working in any technological field can benefit from expert support to help them use the patent system.

A patent allows inventors/companies to gain valuable exclusivity over a new product or process. In developing countries however, few local inventors venture into the world of patents and those who do so without legal support often fail at the first steps due to formal errors.

- ▶ Who can apply?
- ► How can I apply?



Online self-check course for inventors

WIPO has developed a dedicated online course to help first-time inventors decide whether their invention fulfills patentability requirements. The course is free of charge and anyone who wishes can take it.

For inventors without a pending patent application, passing the online course is a prerequisite for working jointly with a probono patent attorney through the IAP.

Read our FAQs on the IAP for more information.

COLLABORATIONS WITH ACADEMIC, GOVERNMENT, OR NGOS TO VALORIZE TK AND TCE INNOVATIONS



US009403786B2

(12) United States Patent Semple et al.

(10) Patent No.: US 9,403,786 B2

(45) Date of Patent:

Aug. 2, 2016

(54) ANTI-INFLAMMATORY COMPOUNDS

(75) Inventors: Susan J. Semple, Mylor (AU); Bradley S. Simpson, Highbury (AU); Ross Allan McKinnon, Eden Hills (AU); David Claudie, Caims (AU); Jacobus P. Gerber, Eden Valley (AU); Jiping Wang, Felixstow (AU); George Moreton, Sr., Cairns (AU)

(73) Assignees: University of South Australia, Adelaide, S.A. (AU); Chuulangun Aboriginal Corporation, Queensland

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35

U.S.C. 154(b) by 1120 days.

(21) Appl. No.: 13/509,194

(22) PCT Filed: Nov. 10, 2010

(86) PCT No.: PCT/AU2010/001502

§ 371 (c)(1),

(2), (4) Date: Aug. 6, 2012

(87) PCT Pub. No.: WO2011/057332 PCT Pub. Date: May 19, 2011

65) Prior Publication Data

US 2013/0053437 A1 Feb. 28, 2013

(30) Foreign Application Priority Data

Nov. 10, 2009 (AU) 2009905498

(51) Int. Cl. C07D 307/42

C07D 307/42 (2006.01) C07D 307/54 (2006.01)

(52) U.S. CL. CPC C07D 307/42 (2013.01); C07D 307/54 (2013.01)

(58) Field of Classification Search None See application file for complete search history.

(56) References Cited

U.S. PATENT DOCUMENTS

6,143,303 A 11/2000 Janakiram et al.

FOREIGN PATENT DOCUMENTS

WO 2011/057327 A1 5/2011

OTHER PUBLICATIONS

Banker, Gilbert, Modern Pharmaceutics 3rd ed. Marcel Dekker, Inc. New York, 1996.**

Nordqvist, Christian. "Inflammation: Causes, Symptoms and Treatment." Medical News Today. Medil.exicon, Intl., Sep. 16, 2015. Web. http://www.medicalnewstoday.com/articles/248423.php.* Hardard Health Publications: Harvard Medical School "Foods that fight inflammation". Jul. 1, 2014. Web http://www.health.harvard.edu/staying-healthy/foods-that-fight-inflammation.

Lee, D.Y.W. et al., New Neoclerodane Diterpenoids Isolated From the Leaves of Salvia Divinorum and Their Binding Affinities for Human k Opioid Receptors, Bioorganic & Medicinal Chemistry 13, 5635-5639 (2005).

Bigham, A.K. et al., Divinatorins A-C, New Neoclerodane Diterpenoids from the Controlled Sage Salvia Divinorum, J. Nat. Prod. 66, 1242-1244 (2003).

Medana, C. et al., Determination of Salvinorins and Divinatorins in Salvia Divinorum Leaves by Liquid Chromatography/Multistage Mass Spectrometry, Rapid Communications in Mass Spectrometry 20, 131-136 (2006).

Venkateswarlu, K. et al., A Benzofuranoid and Two Clerodane Diterpenoids from Pulicaria Wightlana, Helvetica Chimica Acta 91: 2081-2088 (2008).

Jefferies, P.R. et al., Structure Elucidation of Some Ent-Clerodane Diterpenes From Dodonaea Boroniaefolia and Cyanostegia Angustifolia, Australian Journal of Chemistry 26 (10), 2199-2211 (1973).

Jefferies, P.R. et al., Diterpenes of the Cascarillin Group From Dodonaea SPP, Tetrahedron Letters (48) 4777-4782 (1967).

Payne, T.G. et al., The Chemistry of *Dodonaea* SPP-IV. Diterpene and Flavonoid Components of *D. attenuata*, Tetrahedron 29, 2575-2583 (1973).

Anis, I., et al., Thrombin Inhibitory Constituents from Duranta Repens, Helvetica Chimica Acta, vol. 84, 649-655, (2001).

Bigham, A.K. et al., Divinatorins A-C, New Neoclerodane Diterpenoids from the Controlled Sage Salvia divinorum, Journal of Natural Products, vol. 66, (9), 1242-1244, (2003).

Jolad, S.D. et al., Diterpenoids of Conyza Coulteri, Phytochemistry, vol. 27 (4), 1211-1212 (1988).

Lee, D.Y.W. et al., New Neoclerodane Diterpenoids Isolated from the Leaves of Salvia Divinorum and their Binding Affinities for Human Kappa Opioid Receptors, Bioorganic & Medicinal Chemistry, vol. 13 (19), 5635-5639 (2005).

Munro, T.A. et al., Autoxidation of Salvinorin a Under Basic Conditions, The Journal of Organic Chemistry, vol. 70, (24) 10057-10061, (2005)

Pandey, U.C. et al., Stereochemistry of Strictic Acid and Related Furano-Diterpenes from Conyza Japonica and Grangea Maderaspatana, Phytochemistry, vol. 23 (2), 391-397, (1984).

Simpson, B.S., Chemical and Pharmacological Investigation of Dodonaea Polyandra, Ph.D. Thesis, Division of Health Science, School of Pharmacy and Medical Sciences, University of South Australia (2011).

Wilson, S.R. et al., The Chemistry of the Euphorbiaceae. A New Diterpene from Croton Californicus, Journal of the American Chemical Society, vol. 98 (12), 3669-3674, (1976).

Zdero, C. et al., Clerodane Derivatives From Diplostephium, Phytochemistry, vol. 31 (1), 213-216, (1992).

* cited by examiner

Primary Examiner — Golam M M Shameem
Assistant Examiner — Laura Daniel
(74) Attorney, Agent, or Firm — Olson & Cepuritis, Ltd.

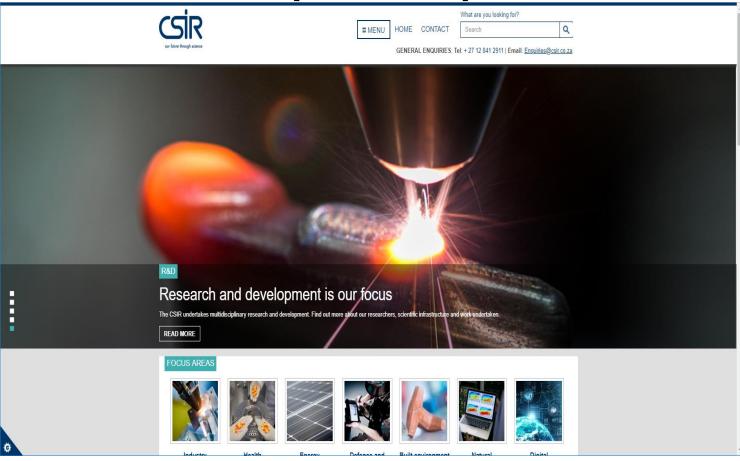
(57) ABSTRACT

New clerodane compounds isolated from plant material from Dodonaea polyandra are disclosed. The compounds have anti-inflammatory activity. Pharmaceutical and cosmetic compositions containing the compounds, as well as methods of treating inflammation using the compounds, are also disclosed.

17 Claims, 16 Drawing Sheets

COUNCIL FOR SCIENTIFIC AND INDUSTRIAL RESEARCH (CSIR)

- Parastatal, organized by Act of Parliament in 1945
- works with educational and research institutions, private sector companies, and local communities, on projects across a range of scientific fields including biosciences, health, energy, defense,
- the largest research organization on the African continent
- employs approximately 2000 science engineering and technical staff
- Various groups within CSIR informally act as a "small business facilitator" for IPLCs



COLLABORATIONS WITH ACADEMIC, GOVERNMENT, OR NGOS TO VALORIZE TK AND TCE INNOVATIONS

- CSIR has provided assistance to TK holders with:
- Scientific validation
- IP protection (patent filing)
- license agreement negotiation
- Commercial partner identification
- And more

REPUBLIC OF SOUTH AFRICA PATENTS ACT, 1978

FORM P.8 (to be lodged in duplicate)

A&A Ref: 131100 EduP/ek

PUBLICATION PARTICULARS AND ABSTRACT (Section 32(3)(a) - Regulations 22(1)(g) and 31)

21	01 PATENT APPLICATION NO	22	LODGING DATE			ACCEPTANCE DATE		
	95 5853		13	July 1995		13 1 97		
51	INTERNATIONAL CLASSIFICATION			NOT FOR PUBLICATION	BLICATION			
	A61K; A01N; C07C			CLASSIFIED BY:	AD.	AMS & ADAMS		
71	FULL NAME(S) OF APPLICANT(S)							

72 FULL NAME(S) OF INVENTOR(S)

CSIR

ELSIE AMANDA DORFLING

EARLIEST PRIORITY CLAIMED	COUNTRY		D COUNTRY NUMBER		DATE			
	33	ZA	31	94/2540	32	13 APRIL 1994		

NOTE: The country must be indicated by its International Abbreviation - see schedule 4 of the Regulations

54 TITLE OF INVENTION

INSECT REPELLENTS

57 ABSTRACT (NOT MORE THAN 150 WORDS) NUMBER OF SHEETS

The sheet(s) containing the abstract is/are attached.

If no classification is furnished, Form P.9 should accompany this form. The figure of the drawing to which the abstract refers is attached.

A&A P208

ECONOMIC DEVELOPMENT FOR COMMUNITIES THROUGH COLLABORATIVE EXPLOITATION OF IPLC TK: SOUTH AFRICA'S FEVER TREE

- Traditional healers (THC) shared TK regarding the *Lippia javanica* plant (also known as "Lemon Bush" or "Fever Tree") which contains compounds with antiseptic, anti-inflammatory, and insect repellent activity, with CSIR
- CSIR researchers confirmed the insect-repellent effects of *Lippia javanica*, obtained a patent, established a community enterprise based on the commercial cultivation of the plant, helped the community find an industry partner to develop and commercialize an insect repellent candle from the discovery. Project has created at least 35 jobs, providing employment and tech transfer for members of the Maswanganyi and Mabunda communities
- Benefit sharing agreement between THC and CSIR specifies that six percent of the royalty CSIR receives from its separate license to the manufacturer, relating to sales of the mosquito repellent candles sold under the "Fever Tree" brand, goes to the THC for distribution to the knowledge holder communities





ECONOMIC DEVELOPMENT FOR COMMUNITY THROUGH COLLABORATIVE EXPLOITATION OF IPLC TK: MONATIN

- TK regarding sweetening power of Molomo Monate, a plant containing Monatin, a non-caloric natural sweetener purported to have between 1400 and 3000 times the sweetening power of cane sugar
- CSIR researchers entered ABS agreement with TK holders, investigated the properties of the plant, obtained patent protection, and negotiated a license agreement with U.S.-based multinational food additive giant Cargill (for use in soft drinks).
- In 2012, CSIR also procured one of the first bioprospecting permits granted by the DEA and identified the relevant indigenous knowledge holding communities for benefit sharing
- Seleka and Shongoane indigenous communities of Lephalale in Limpopo Province receive ten percent of CSIR's milestone and royalty licensing income (five percent per community) to be paid into the national Bioprospecting Trust Fund for distribution to the communities.
- In 2015 CSIR deposited 2.6 million ZAR from milestone payments into the fund and the monies were distributed to the communities in 2016.



- (19) United States
- (12) Patent Application Publication (10) Pub. No.: US 2006/0252135 A1 Brazeau et al.
 - Nov. 9, 2006 (43) **Pub. Date:**
- POLYPEPTIDES AND BIOSYNTHETIC PATHWAYS FOR THE PRODUCTION OF STEREOISOMERS OF MONATIN AND THEIR PRECURSORS
- (75) Inventors: **Brian J. Brazeau**, Oskaloosa, IA (US): Ellen Burke, San Diego, CA (US); Mervyn DeSouza, Plymouth, MN (US); Steven J. Gort, Brooklyn Center, MN (US); Paula M. Hicks, Eden Prairie, MN (US); Sherry R. Kollmann, Maple Grove, MN (US); Peter Luginbuhl, San Diego, CA (US); Sara C. McFarlan, St. Paul, MN (US); Toby Richardson, San Diego, CA (US); Fernando A. Sanchez-Riera, Eden Prairie, MN (US): Christopher Solheid, Minneapolis, MN (US); David Weiner, Del Mar, CA (US); Lishan

Correspondence Address: STERNE, KESSLER, GOLDSTEIN & FOX 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005 (US)

Zhao, Carlsbad, CA (US)

(73) Assignee: Cargill, Incorporated, Wayzata, MN

(21) Appl. No.: 11/411,229 (22) Filed: Apr. 26, 2006

Related U.S. Application Data

(60) Provisional application No. 60/674,932, filed on Apr. 26, 2005.

Publication Classification

(51) Int. Cl. C12N 9/10 (2006.01)C12P 13/22 (2006.01)C12N 1/21 (2006.01)(52) U.S. Cl. 435/108; 435/193; 435/252.3

ABSTRACT

Monatin and certain stereoisomers of monatin, such as R,R monatin and S,R monatin, as well as salts thereof, are produced using polypeptides and biosynthetic pathways. These polypeptides and biosynthetic pathways are also useful in the production of R-2-hydroxy-2-(indoly-3-ylmethyl)-4-keto glutaric acid, an intermediate that is formed in certain monatin synthesis pathways, including some biosynthetic pathways.

HOW CAN PATENTS ON TK/TCES BE CHALLENGED?

Patents may be improperly obtained by third parties on IPLC TK

- Opposition/reexamination (in patent office)
- Litigation (more expensive)

 In both cases pand evidence
 - In both cases need evidence or prior
 - public knowledge/use of the TK/TCE

TKDL Reference from U.S. Patent Application No. 13/582,133 File Wrapper

 Claims to Sandalwood oil compositions for cancer treatment

Certain claims rejected based on entries from Indian Traditional Knowledge Digital Library (TKDL)

TKDL references (containing additional information) were provided to the applicant and made available to the public as part of the file history for the application

If no positive legal protection against use of such TK, third parties could use it freely, even if they could not patent it directly.



TKRC CODE

IPC Code

Key Attributes of TKDL

Title of Traditional Knowledge Resource

Knowledge Known Since

A01A-1/1483, A01A-1/1720, A01A-1/251, A01A-1/473, A01A-1/754, A01B-1/23, A01C-1/14, B01B-5/196, B01C-1/160, B01C-1/172, B01C

L/273, B01D-20/21, B01F-1/26, B01G-1/195

A61K 33/06, A61K 33/28, A61K 35/20, A61K 36/185, A61K 36/481, A61K

36/54, A61K 36/67, A61K 36/906, A61P 35/00, C01B 33/22

DETAILS OF PROCESS / FORMULATION

1. Tila is a therapeutic single / compound formulation consisting of useful parts of following ingredient(s): dog, Calomel/Subchloride of mercury, Soap stone/talc/ steatites/Hydrated magnesium silicate, *, Elettaria cardamomum (Linn.) Maton (cardamom, Lesser Cardamom), Astragalus sarcocola, Cinnamomum camphora (Linn.) J. Presl (camphor faurel, camphor tree, camphortree, Camphor), Cinnabar, Santalum album Linn. (sandalwood), Piper nigrum Linn. (Black Pepper), Clarified butter

2. Therapeutic composition / formulation is mentioned below

i dog	Tongue	ash/cosi	garan 1	numbers
2 Calomet/Subchloride of mercury			2	gm
3 Soap stone/talc/ steatites/Hydrated magnesium silicate	*			gm
••				gm
 Elettaria cardamomum (Linn.) Maton (cardamom, Lesser Cardamom) 	Seed			gm
Astragalus sarcocola			2	gm
Cinnamornum camphora (Linn.) J. Presi (camphor laurel, camphor tree, camphoriree Camphor)	٠.,			gm
Cinnabar			3	gm
Santalum album Linn. (sandalwood)	100		3	gm
to Piper nigrum Linn. (Black Pepper)			2	1 numbers
11 Clarified butter				2 gm

- 3. The apeutic composition mentioned above is prepared acTLA:Tila is a solution used locally for massage. It can be a solution of the powdered drugs or water extract or oil of the drugs mentioned in the formulation.
- 4. A composition as described above is formulated as Thin medicated ofly preparation for local use
- Mode of administration : Liniment
- 6. It is useful in the treatment of Cancer

LIST OF DOCUMENTS WITH DATE OF PUBLICATION (PRIOR ART) :

Mohammad Azam Khan Ikseer Azam, Vol. IV (19th century AD), Matba Nizami, Kanpur,

Page 309

THE DANGERS OF RELYING ON "DEFENSIVE" PROTECTION FOR TK

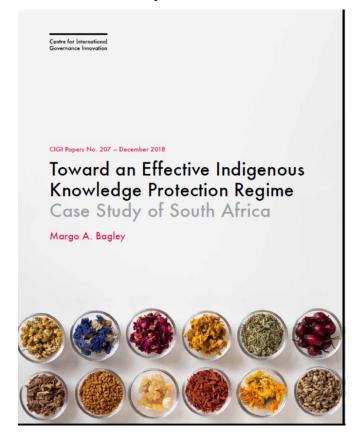
- - TK (in database) may not be patented, but can still be freely used by third parties if no positive protection granting holders of the knowledge the right to control its uses.
- Third parties may not be able to directly access the databases, however, the records in the database that are used in rejections will be made available to the public at large through access to file histories in the patent office
- Examiner will not always find most relevant TK in database (e.g. Avon case) so some patents will still issue covering TK
 - •- Such patents still could be challenged and revoked based on that same traditional knowledge, in a database or not

TKDL ENTRIES CITED AGAINT AVON APPLICATION; APPLICATION AMENDED, REJECTIONS OVERCOME

- 2014 EPO Avon patent application covering wrinkle-reduction products and methods of use
- Plumbago indica, Canaga odorata, Sapindus rarak, Curcuma xanthorrhiza
- Claims rejected based on TKDL entries
- Applicant was able to overcome rejection and obtain allowance of the patent

A BETTER APPROACH: POSITIVE PROTECTION AND DEFENSIVE PROTECTION EXAMPLE, SOUTH AFRICA'S TK PROTECTION REGIME (NOT ALL OPERATIONAL YET)

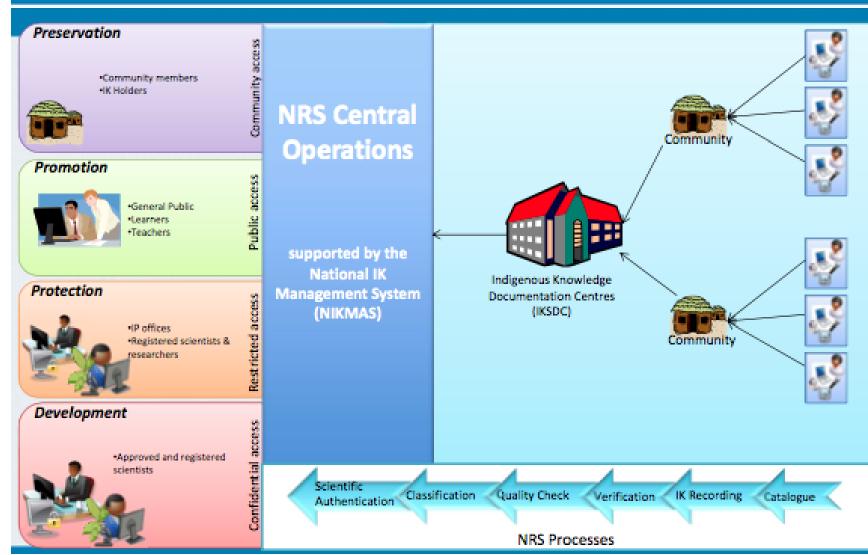
- bioprospecting laws and regulations;
- a new traditional knowledge collection, documentation, and publication system (NIKMAS/NRS) and a national office focused on protecting and promoting TK (NIKSO (informally CSIR)),
- intellectual property protection for Indigenous knowledge (including the introduction of substantive patent examination and a patent application disclosure of origin requirement); and
- sui generis Indigenous knowledge legal protection through the Protection, Promotion, Development, and Management of Indigenous Knowledge bill ("the IK Protection bill").



The National Recordal System (NRS), supported by the National Indigenous Knowledge Management System (NIKMAS), a digital repository for the collected knowledge; preserves and protects the information in a catalogued, searchable format, while allowing controlled dissemination according to strict criteria.

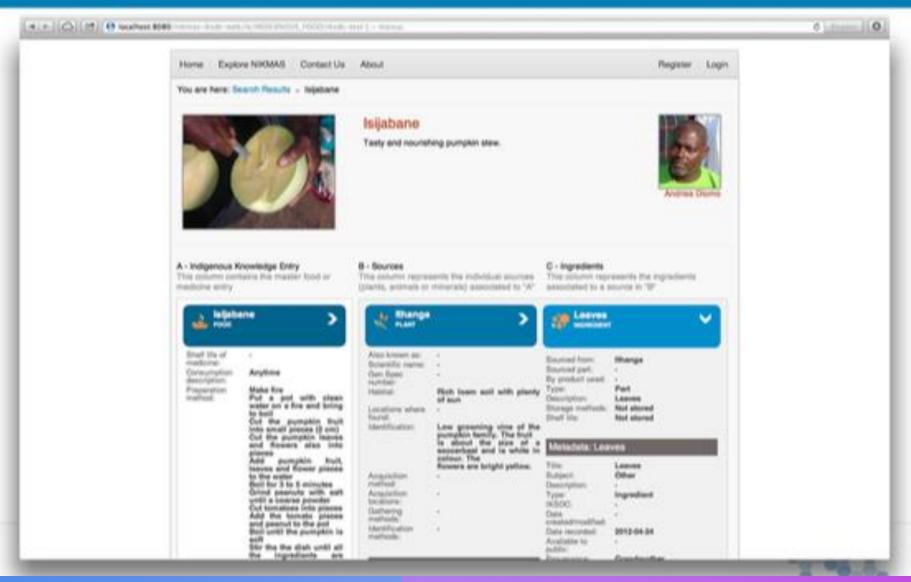


NRS OVERVIEW





NIKMAS SEARCH ON IK ENTRIES



NEW IK PROTECTION LAW FEATURES

- The South African Protection, Promotion, Development and Management of Indigenous Knowledge law will provide "positive" not merely "defensive" protection for South African indigenous knowledge.
- establishes a TK registration office, defines the kinds of indigenous knowledge that can be protected, and provides that the duration of protection is <u>perpetual</u> as long as the statutory requirements are met.
- gives communities in which ownership of protected indigenous knowledge is vested the <u>exclusive right to</u> <u>commercially benefit from the property, be acknowledged as its source, restrain unauthorized uses, and license uses</u>.
- excludes certain uses of indigenous knowledge from its provisions, such as for criticism or academic review, news reporting, non-commercial research, or in case of a national emergency.
- License provisions: for functional indigenous knowledge, the licensee is only required to pay a royalty for 20 years from the date of the agreement and for indigenous cultural expressions, royalty payments end 50 years after the agreement.
- provides protection for <u>indigenous knowledge originating outside of South Africa</u> if reciprocal protection is available under the laws of the foreign jurisdiction.

PRIMARY ALTERNATIVES TO UTILITY PATENT PROTECTION?

- Utility Models (petty patents) for simple inventions, generally not processes, shorter term (6-10 years), much less expensive to obtain
- Industrial Designs –protects ornamental appearance (15-25 year term) also less expensive
- Trade Secrets –Law may provide protection
 against misappropriation of information that
 provides an economic advantage to its owner from
 not being generally known or readily ascertainable
 by proper means (perpetual protection possible, but
 not if secret is made public in any way)



Figure 1. Countries with Utility Model Protection in 2020³⁵

D. Cahoy, "Why Harmonize?"

CONCLUSIONS

- The global patent system can benefit IPLCs by allowing them to more effectively protect and exploit their innovations
- But patents are expensive to obtain and maintain and the process entails risk (patents may not issue, may be invalidated, may be too expensive to enforce)
- Pro bono and Inventor Assistance Programs may be helpful, collaborations with academic, government or NGO institutions to validate, protect, and exploit TK may be as well
- TK can also be used to invalidate erroneously granted patents, but need not be in a database to do so. TK in databases should also be protected by positive law against misappropriation.