

## The "CANs" and CANNot's of CANNabis [and Psychedelics] IP rights



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## Introduction

Donna Tobin Royer Cooper Cohen Braunfeld, USA



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## **Donna Tobin** USA

## Carmela De Luca Canada

Claire Gregg Australia



# Patenting in Australia and neighbouring regions

Claire Gregg DCC, Australia



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## The "CANs" and "CANNots" of CANNabis [and psychedelics] IP rights:

Australia and neighbouring regions

## **Claire Gregg, PhD**

Principal Davies Collison Cave, Australia

PREPARED

Claire Gregg

#### AGENDA

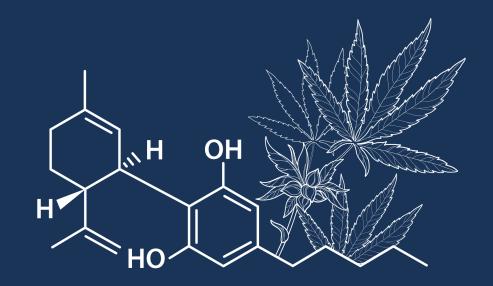
- Part 1: Setting the scene
- Part 2: Legal status of medicinal cannabis
- Part 3: Legal status of medicinal psychedelics
- Part 4: Patenting medicinal cannabis and psychedelics invention
- Part 5: Trade marks and advertising (Australia)
- Part 6: Key takeaways







## Part 1. Setting the scene





## **Brief history**



## <u>Medicinal</u> cannabis

- Used for thousands of years to reduce pain and other somatic and psychological symptoms
- International Opium Convention (1925) and UN Single Convention on Narcotic Drugs (1961)
- Recent explosion in patent activity as laws evolve to permit medicinal use

## Medicinal psychedelics

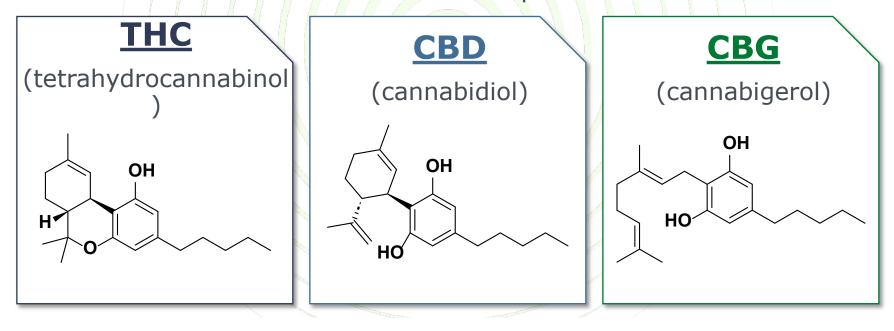
- Used for hundreds of years, with medical research dating back to late 1800s
- LSD and MDMA explored in psychiatry from 1940s until being banned in late 1960s and mid 1980s, respectively
- Increased patent activity as research emerges to support medical use



## **Medicinal cannabis**

## Use of CANNABINOIDS to treat a medical condition

Functional class: compounds that activate cannabinoid receptors

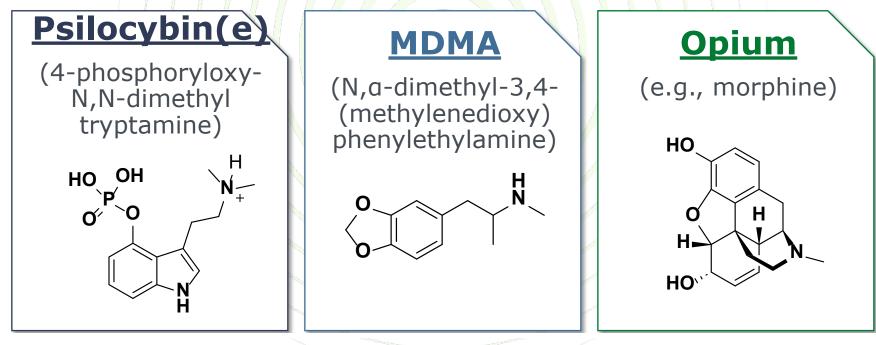




## **Medicinal cannabis**

## Use of PSYCHOTROPIC SUBSTANCES to treat a medical condition

Functional class: compounds that produce changes in perception, mood and cognitive processes



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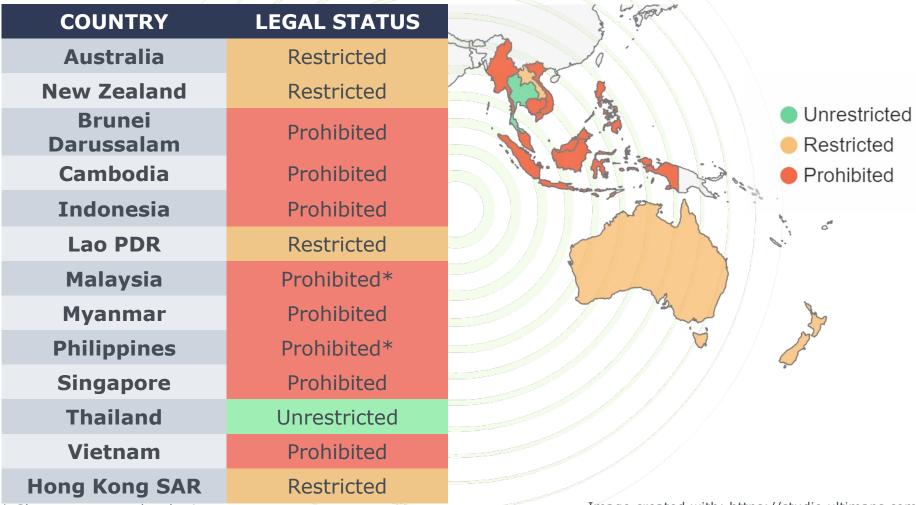
## Part 2. Legal status of medicinal cannabis

Australia New Zealand ASEAN Hong Kong





## Legal status – medicinal cannabis

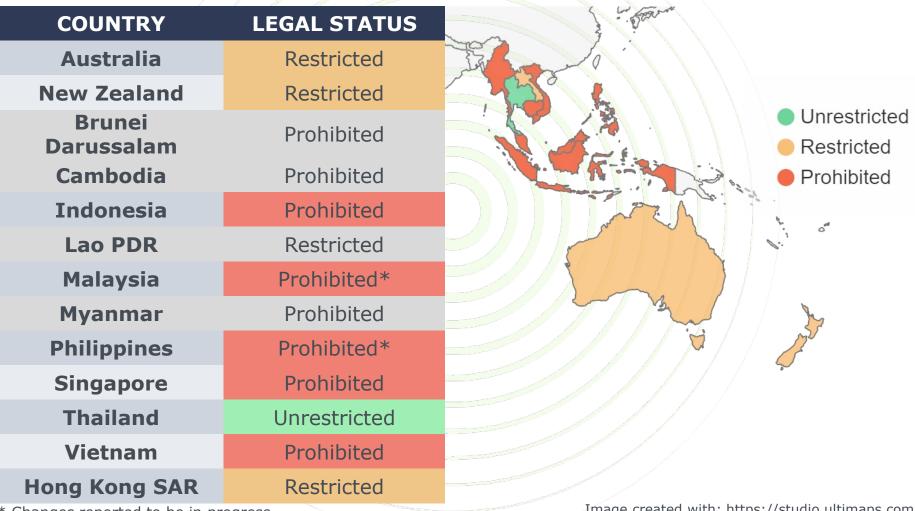


\* Changes reported to be in progress

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## Legal status – medicinal cannabis



\* Changes reported to be in progress

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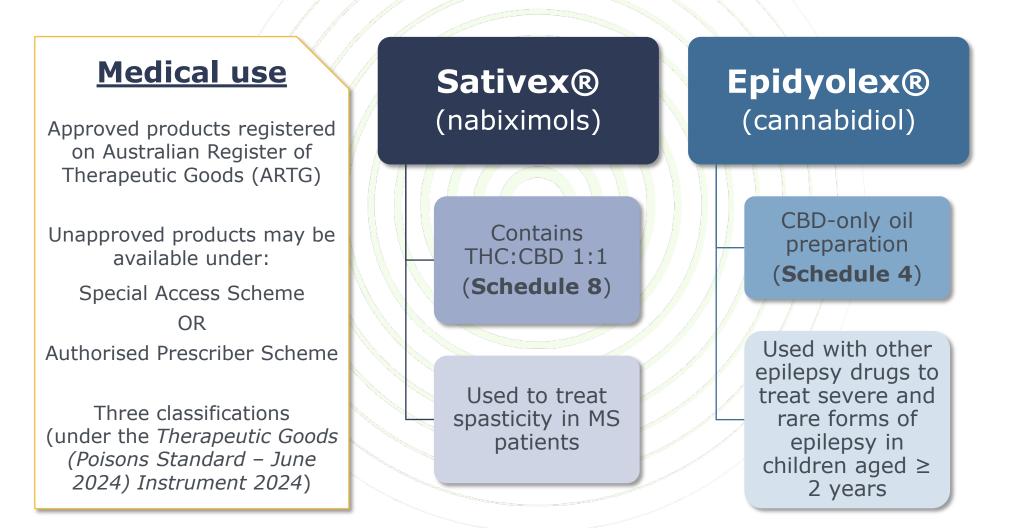
## Medicinal cannabis – Australia

Medical use Approved products registered on Australian Register of Therapeutic Goods (ARTG)	Schedule 8 (controlled drug – prescription only)	<ul> <li>CBD dominant (CBD ≥ 60% and &lt; 98%)</li> <li>Balanced (CBD &lt;60% and ≥ 40%)</li> <li>THC dominant (THC 60% - 98%)</li> <li>THC product (THC &gt;98%)</li> </ul>
Unapproved products may be available under: Special Access Scheme	Schedule 4 (prescription only)	• CBD product (CBD $\geq$ 98%)
OR Authorised Prescriber Scheme		• "Low dose" oral, oromucosal or sublingual CBD preparations
Three classifications ( <i>Therapeutic Goods (Poisons</i> <i>Standard – June 2024)</i> <i>Instrument 2024</i> )	Schedule 3 (pharmacist only)	<ul> <li>CBD = plant derived or synthetic (-)- CBD</li> <li>CBD ≥ 98% of total cannabinoids</li> <li>THC ≤ 1% of total cannabinoids</li> <li>Daily dose CBD ≤ 150 mg</li> </ul>

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## Medicinal cannabis – Australia





## Medicinal cannabis – Australia

**Key legislation:** Therapeutic Goods Act 1989; Narcotic Drugs Act 1967; Customs (Prohibited Imports) Regulations 1956

### **Manufacture**

Licenses from TGA and/or Office of Drug Control (ODC) to manufacture, cultivate, produce (separate), or obtain for the purpose of cultivating

Compliance with:

- Australian Code of Good Manufacturing Practice
  - Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017

#### **Importation**

Permits from ODC for importation of any medicinal cannabis products

Permit required for each shipment and each substance and/or preparation type

(valid for 12 months)

Overseas manufacturers must also establish compliance with Australian Good Manufacturing Practice

#### **Research**

License from TGA and/or ODC for research use

Approval from TGA required to conduct clinical trials

"Permitted supply" for manufacturers incudes:

- clinical trials that are likely to be approved;
- other scientific research; or
- for use as a reference std.



## Medicinal cannabis – New Zealand

Medical use Approved products registered by Medsafe (Sativex® and Epidyolex® approved)	<b>Class B</b> (controlled drug – prescription only)	<ul> <li>Cannabis preparations containing THC or non-psychoactive analogues produced by processing of a cannabis plant material</li> <li>Synthetic THC and non-psychoactive THC analogues (e.g., CBD)</li> </ul>
Approval from Ministry of Health require to prescribe, supply or administer unapproved products	Class C (controlled drug – prescription only)	• Cannabis fruit, plant or seed from genus <i>Cannabis</i>
(under the <i>Misuse of Drugs</i> <i>Regulations 1977</i> ) Three classifications (under the <i>Misuse of Drugs</i>	<b>"CBD</b> <b>Products"</b> (pharmacist only)	<ul> <li>Contains CBD ≤ 4.5 g</li> <li>THC ≤ 2% total cannabinoids</li> <li>No other controlled drugs / psychoactive substances</li> <li>Daily dose CBD ≤ 150 mg</li> </ul>
		psychoactive substances



## Medicinal cannabis – New Zealand

Key legislation: Misuse of Drugs Act 1975; Medicines Act 1981

### **Manufacture**

License from Medicinal Cannabis Agency (Ministry of Health) for cultivation, manufacture or supply

License from Ministry of Health to manufacture medicine

Compliance with:

New Zealand Code of Good Manufacturing Practice

#### **Importation**

Importation of a cannabis seed, starting material, cannabis-based ingredient or medicinal cannabis product (except "CBD Products") requires a license from Medicines Control

A "plant import health standard" must be published by the Ministry for Primary Industries before cannabis plants can be imported

#### <u>Research</u>

License with a research activity from Medicinal Cannabis Agency

Approval from Ministry of Health also required to conduct clinical trials

Additional licenses as needed for cultivation, importation, production, etc., for research use



## Medicinal cannabis – Indonesia

- Class I narcotic (Law Number 35 of 2009 on Narcotics)
  - Medical and recreational use illegal
  - Includes THC, all Cannabis plant-derived cannabinoids and several synthetic cannabinoids
- Several court decisions have confirmed medicinal and recreational cannabis are both illegal
  - Prohibition includes compassionate use
  - Constitutional Court confirmed Class I narcotics can only be used for developing science, but not for therapy (Case No. 13/PUU-XXII/2024)
- Permits required from the Health Ministry for acquisition, cultivation, storage and use for the **benefit of science and technology**



## Medicinal cannabis – Malaysia

- Schedule I controlled drug (Dangerous Drugs Act 1952)
  - > Medicinal and recreational use generally considered to be illegal
  - Includes cannabis, cannabis resin, THC, CBD and other analogues (natural or synthetic)
- 2021 media reports suggested upcoming changes to legalize importation and use of medicinal cannabis products
  - In 2023, former Health Minister suggested that certain uses of medicinal cannabis may already be permitted under law
- Licenses, permits and exemptions available for **research or clinical trials** (*Dangerous Drugs Act 1952*; *Poisons Act 1952*; *Sale of Drugs Act 1952*)
  - Licenses and permits available from Ministry of Health
  - Research exemption for planting or cultivating plants from which raw cannabis may be obtained for research, educational, experimental or medical purposes



## **Medicinal cannabis – Philippines**

- Prohibited drug (Comprehensive Dangerous Drugs Act 2002)
  - Medicinal and recreational use illegal
  - Includes cannabis, cannabis resin, and extracts and tinctures thereof, THC and isomers thereof
- House Bill No. 10439 passed in July 2024 (*Access to Medical Cannabis Act*)
  - > To establish right of patient access to medical cannabis on compassionate grounds
  - > To expand research into medicinal properties of cannabis
- Permits available for certain scientific research on cannabis and its medicinal properties from Philippine Drug Enforcement Agency
  - > Cultivation for research or medicinal purposes also permitted
  - Requires adherence to Dangerous Drugs Board guidelines



## Medicinal cannabis – Singapore

- Class A controlled drug (Misuse of Drugs Act 1973)
  - Medicinal and recreational use illegal
  - Includes cannabinol (CBN) and derivatives (e.g., THC, CBD, CBG), cannabis and cannabis resin
- Licenses to import or export, manufacture, supply, offer to supply or possess any controlled drug, including for research purposes
  - Available from Health Sciences Authority (HSA)
- Singapore's National Research Foundation is currently developing synthetic cannabinoids for medicinal use



## **Medicinal cannabis – Thailand**

- Declassified as narcotic drugs under the Narcotics Act 2021
  - > First Asian country to decriminalize medicinal cannabis
  - Led to explosion in recreational use
- Plans to re-criminalize recreational use have been shelved
  - Draft legislation by the Ministry of Public Health in June 2024 proposes cannabis buds be reclassified as narcotics starting in 2025
  - In July 2024, Narcotic Control Board supported reclassifying cannabis and hemp as Category 5 narcotics, excluding parts such as stems, roots, leaves, seeds, and extracts with THC not exceeding 0.2%
  - Permits contemplated for growing, exporting and possessing for medical and research use
  - Proposals forwarded to the Narcotics Control Committee for further consideration



## Medicinal cannabis – Vietnam

- Schedule I controlled drug (Law No. 73/2021/QH14 on Prevention and Control of Narcotic Substances)
  - Medical and recreational use prohibited
  - > Includes cannabis, cannabis resin, and extracts and tinctures thereof
  - <u>Exception</u> for CBD products sourced from industrial hemp and containing no more than 0.3% THC
- Permits available for research, examination, testing, inspection and production (but not cultivating) cannabis from "competent authorities" as stipulated by the Government
  - Drug Administration of Vietnam
  - > Ministry of Health



## Medicinal cannabis – Hong Kong

- Dangerous drug (Dangerous Drugs Ordinance (Cap. 134))
  - Prohibited dangerous drugs include "cannabinol and its tetrahydro derivatives (THC); and their 3-alkyl homologues"
  - CBD included in February 2023
  - > Other derivatives <u>not currently prohibited</u>
- Certain persons have statutory authority to possess, supply or manufacture dangerous drugs
  - Includes doctors, pharmacists and "a person in charge of a laboratory used for the purposes of research or instruction and attached to a university or to an approved hospital or institution"





Australia New Zealand ASEAN Hong Kong





## Legal status – medicinal psychedelics

COUNTRY	LEGAL STATUS	2 Low Dardenne
Australia	Restricted	Se di
New Zealand	Prohibited	The second se
Brunei Darussalam	Prohibited	
Cambodia	Prohibited	Restricted
Indonesia	Prohibited	• Prohibited
Lao PDR	Prohibited	market 1 ar
Malaysia	Prohibited	
Myanmar	Prohibited	
Philippines	Prohibited	
Singapore	Prohibited	
Thailand	Restricted	
Vietnam	Prohibited	
Hong Kong SAR	Prohibited	

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## Legal status – medicinal psychedelics

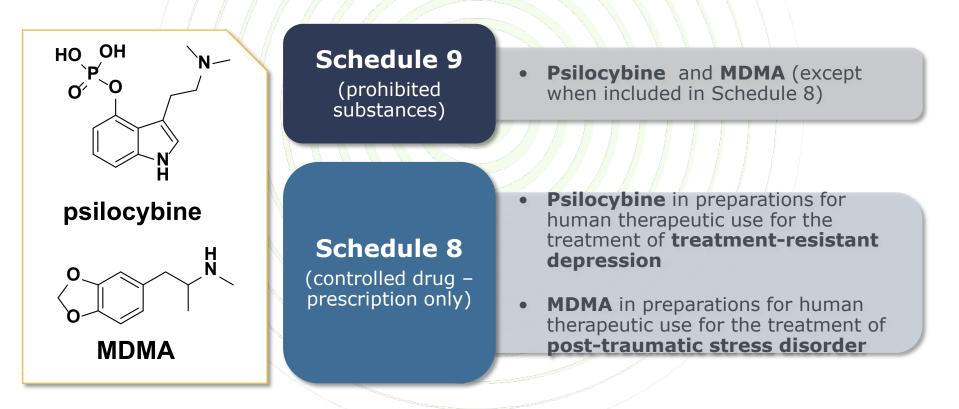
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Australia	Restricted	Se lo i
New Zealand	Prohibited	The second se
Brunei Darussalam	Prohibited	
Cambodia	Prohibited	Restric
Indonesia	Prohibited	Prohibi
Lao PDR	Prohibited	market the or
Malaysia	Prohibited	
Myanmar	Prohibited	
Philippines	Prohibited	
Singapore	Prohibited	
Thailand	Restricted	
Vietnam	Prohibited	
Hong Kong SAR	Prohibited	
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## Medicinal psychedelics – Australia

 Poisons Standard amended as of 1 July 2023 to down-schedule certain psychedelics from Schedule 9 to Schedule 8



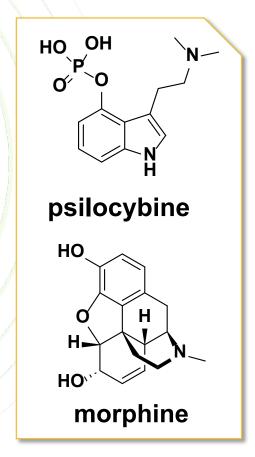


## Medicinal psychedelics – Thailand

With effect from 23 April 2024, the Health Minister issued:

Ministerial Notification Re: Category 5 Narcotics Which Are Not Cannabis or Hemp Extract and Whose Consumption is Permitted for Treatment of Disease or for Research Purposes (2024)

- Psilocybine and opium (incl. opium alkaloids) reclassified as Category 5 Narcotics
  - Can be used in medical treatment or for research purposes
  - Approval from Thailand FDA required for use and production
  - Importation of medicinal drug formulations containing psilocybine or opium is not allowed







## Part 3. Patenting medicinal cannabis and psychedelics inventions

Australia New Zealand ASEAN Hong Kong





## **Patent considerations**

Contrary to law, morality or public order

Patentability of isolated plant material

Patentability of second medical uses

Patent term extension



## **Contrary to law, morality or public order**

COUNTRY	LEGAL CLAS	SIFICATION	PATENTABLE (NOT CONTRARY TO LAW, ETC.)	
	Cannabis	Psychedelic s	Cannabis	Psychedelic s
Australia	Restricted	Restricted	Yes	Yes
New Zealand	Restricted	Prohibited	Yes	Yes
Indonesia	Prohibited	Prohibited	Unknown**	Unknown**
Malaysia	Prohibited	Prohibited	Yes*	Unknown**
Philippines	Prohibited	Prohibited	Yes*	Unknown**
Singapore	Prohibited	Prohibited	Yes*	Unknown**
Thailand	Unrestricted	Restricted	Yes	Yes
Vietnam	Prohibited	Prohibited	Unknown**	Unknown**
Hong Kong SAR	Restricted	Prohibited	Yes	Yes

\* Patents have been granted for medicinal cannabis inventions, but certain inventions may be considered contrary to public order or morality

\*\* May be considered contrary to public order or morality, particularly if there is no medical application disclosed



## **Isolated plant material**

COUNTRY	LEGAL CLASSIFICATION		PATENTABLE (NOT CONTRARY TO LAW, ETC.)		ISOLATED PLANT	
	Cannabis	Psychedelic s	Cannabis	Psychedelic s	MATERIAL	
Australia	Restricted	Restricted	Yes	Yes	Yes	
New Zealand	Restricted	Prohibited	Yes	Yes	Yes	
Indonesia	Prohibited	Prohibited	Unknown	Unknown	Yes*	
Malaysia	Prohibited	Prohibited	Yes	Unknown	Yes*	
Philippines	Prohibited	Prohibited	Yes	Unknown	Yes*	
Singapore	Prohibited	Prohibited	Yes	Unknown	No**	
Thailand	Unrestricted	Restricted	Yes	Yes	No	
Vietnam	Prohibited	Prohibited	Unknown	Unknown	Yes	
Hong Kong SAR	Restricted	Prohibited	Yes	Yes	Yes	

\* Generally permitted where corresponding EP or AU claims granted

\*\* According to current examination practice



## Second medical uses

COUNTRY	LEGAL CLASSIFICATION		PATENTABLE (NOT CONTRARY TO LAW, ETC.)		ISOLATED PLANT	SECOND MEDICAL
	Cannabis	Psychedelic s	Cannabis	Psychedelic s	MATERIAL	USES
Australia	Restricted	Restricted	Yes	Yes	Yes	Yes
New Zealand	Restricted	Prohibited	Yes	Yes	Yes	Yes
Indonesia	Prohibited	Prohibited	Unknown	Unknown	Yes	Limited
Malaysia	Prohibited	Prohibited	Yes	Unknown	Yes	Yes
Philippines	Prohibited	Prohibited	Yes	Unknown	Yes	Yes
Singapore	Prohibited	Prohibited	Yes	Unknown	No	Yes
Thailand	Unrestricted	Restricted	Yes	Yes	No	Yes
Vietnam	Prohibited	Prohibited	Unknown	Unknown	Yes	No
Hong Kong SAR	Restricted	Prohibited	Yes	Yes	Yes	Yes



## Allowable second medical use claims

COUNTRY	METHOD OF TREATMENT	SWISS- TYPE	GERMAN- TYPE	EPC2000
Australia	$\checkmark$	$\checkmark$	$\checkmark$	<b>×</b> *
New Zealand	×	$\checkmark$	×	<b>×</b> *
Indonesia	×	×	×	$\checkmark$
Malaysia	×	$\checkmark$	×	<b>×</b> *
Philippines	×	$\checkmark$	×	<b>×</b> *
Singapore	×	$\checkmark$	×	<b>×</b> ∗
Thailand	×	$\checkmark$	×	<b>×</b> *
Vietnam	×	×	×	×
Hong Kong SAR	×	$\checkmark$	×	$\checkmark$

\* Allowable for first medical uses only



### **Patenting medicinal cannabis inventions**

COUNTRY	LEGAL CLASSIFICATION		PATENTABLE (NOT CONTRARY TO LAW, ETC.)		ISOLATED PLANT	SECOND MEDICAL
	Cannabis	Psychedelic s	Cannabis	Psychedelic s	MATERIAL	USES
Australia	Restricted	Restricted	Yes	Yes	Yes	Yes
New Zealand	Restricted	Prohibited	Yes	Yes	Yes	Yes
Indonesia	Prohibited	Prohibited	Unknown	Unknown	Yes	No
Malaysia	Prohibited	Prohibited	Yes	Unknown	Yes	Yes
Philippines	Prohibited	Prohibited	Yes	Unknown	Yes	Yes
Singapore	Prohibited	Prohibited	Yes	Unknown	No	Yes
Thailand	Unrestricted	Restricted	Yes	Yes	No	Yes
Vietnam	Prohibited	Prohibited	Unknown	Unknown	Yes	No
Hong Kong SAR	Restricted	Prohibited	Yes	Yes	Yes	Yes



### Patenting medicinal psychedelics inventions

COUNTRY	LEGAL CLASSIFICATION		PATENTABLE (NOT CONTRARY TO LAW, ETC.)		ISOLATED PLANT	SECOND MEDICAL
	Cannabis	Psychedelic s	Cannabis	Psychedelic s	MATERIAL	USES
Australia	Restricted	Restricted	Yes	Yes	Yes	Yes
New Zealand	Restricted	Prohibited	Yes	Yes	Yes	Yes
Indonesia	Prohibited	Prohibited	Unknown	Unknown	Yes	No
Malaysia	Prohibited	Prohibited	Yes	Unknown	Yes	Yes
Philippines	Prohibited	Prohibited	Yes	Unknown	Yes	Yes
Singapore	Prohibited	Prohibited	Yes	Unknown	No	Yes
Thailand	Unrestricted	Restricted	Yes	Yes	No	Yes
Vietnam	Prohibited	Prohibited	Unknown	Unknown	Yes	No
Hong Kong SAR	Prohibited	Prohibited	Yes	Yes	Yes	Yes



### Patent term extension – Australia

#### **Eligibility**

- Patent claims and in substance discloses a pharmaceutical substance per se\*
- A product containing the pharmaceutical substance is included in the ARTG
- At least 5 years elapsed between the patent date and the first regulatory approval date

#### <u>Timing</u>

- Application must be filed **six months** from the later of
  - (i) the **date of grant** of the patent; or
  - (ii) the **date of first inclusion in the ARTG** of a product containing the pharmaceutical substance
- First inclusion may be a third party product

#### **Duration**

- Equal to time elapsed between the patent date and the earliest first regulatory approval date of any pharmaceutical substance within the scope of the claims, reduced by 5 years
- > Maximum **5 years**
- Avoid multiple products in single patent

\* Or a pharmaceutical substance when produced by a process that involves the use of recombinant DNA technology





### Part 5. Trade marks and advertising (Australia)





### Trade marks - Australia

- Australian trade mark law prevents registration of trade marks that "contain scandalous matter" or that would be "contrary to law"
- Trade Marks Office historically raised objections to the registration of trade marks associated with selling or promoting cannabis or marijuana on the basis that the use of those marks would be illegal
- Since Narcotic Drugs Act 1967 was amended 2016 to allow for medical and scientific use of cannabis, official practice has changed



### **Trade marks - Australia**





MEDICAL CANNABIS SERVICES



MEDICAL CANNABIS AUSTRALIA



Australian Institute of Medicinal Cannabis





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### **EMPOWER PSYCHEDELICS**



### Advertising - Australia

- Prescription and unapproved medicines prohibited from being advertised to the public
- Types of information likely to be considered advertising:
  - Any statement, pictorial representation or design that promotes use or supply of medicinal cannabis
  - Referring to medicinal cannabis in promotional materials or company, business or trading names (for businesses that promote *treatment services*)
  - > Advertising health services that supply or prescribe medicinal cannabis
  - Listing medical conditions that can be treated
  - Consumer testimonials or endorsements
- TGA has issued over 100 infringement notices for unlawful advertising
- Labelling requirements: Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93)





### Part 6. Key takeaways





### Key takeaways

#### Medicinal cannabis

- Complex legal compliance issues
- Law now well developed in some jurisdictions
  - AU, NZ, TH and HK worthwhile patent destinations
  - MY and PH poised for change and worth considering
  - ID, SG and VN unlikely to change soon

#### Medicinal psychedelics

- Law far less developed
- Limited scope for legal activity
  - AU and TH worthwhile patent destinations
  - NZ may be poised for change and worth considering
  - May be some time before other ASEAN countries and HK catch up

#### Patent strategy

- Several factors to consider
  - Contrary to law, morality or public order
  - > Isolated plant material
  - Second medical uses
  - > Patent term extension
- Important to have correct research permits
  - Patent publication can evidence illegal activity

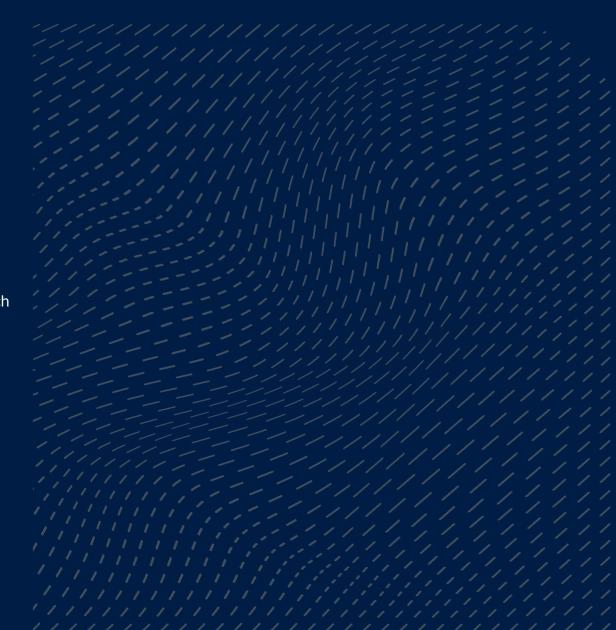




### Thank you



**Claire Gregg** BTech, BSc (Hons), PhD, MIPLaw, GradDipPsych Principal Davies Collison Cave, Australia cgregg@dcc.com https://www.linkedin.com/in/clairegregg1/





### INTELLECTUAL PROPERTY PROTECTION FOR CANNABIS AND PSYCHEDELICS IN THE UNITED STATES

Donna Tobin Royer Cooper Cohen Braunfeld, USA



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## The "CANs" and "CANNots" of CANNabis [and Psychedelics]

### INTELLECTUAL PROPERTY PROTECTION FOR CANNABIS AND PSYCHEDELICS IN THE UNITED STATES





## **Definitions- Cannabis**

### CANNABIS

A plant that contains many biologically active chemical compounds, including terpenes and cannabinoids like delta-9-tetrahydrocannabinol ("THC") and cannabidiol ("CBD"). The two primary legal classifications of cannabis are marijuana and hemp.

### MARIJUANA

Refers to strains of cannabis that contain more than 0.3% THC on a dry weight basis. Used primarily as a psychoactive drug. Usually Delta 9 CBD.

### HEMP

Cannabis that has a low THC concentration (no more than 0.3%) derived only from the cannabis sativa species typically non-psychoactive when consumed \*\*CBD may be extracted from marijuana or hemp

### **DELTA 8**

Hemp derived CBD. Produces a feeling of being high like Delta 9





## **Definitions- Psychedelics**

- Psilocybin -naturally occurring psychedelic drug compound produced by more than 200 species of fungi.
- Lysergic Acid (LSD) a synthetic chemical, made from a substance found in ergot, a fungus that infects rye
- 3,4-methylenedioxymethamphetamine (MDMA) aka Ecstasy (tablet) and Molly (crystal form) synthetic drug
- Ketamine –Lab synthesized, some plants have trace amounts
- Peyote (Mescaline) Small cactus used for over 5000 years







### **Cannabis and Psychedelics – Applications**

Investigated by large and small drug companies for pain, nervous system diseases, and mental and behavioral disorders .

US Clinical Trials:

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Cannabis and cannabinoids – for over 20 years
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**Psychedelics – Current** 

Regulatory Review – 1 MDMA for treatment resistant depression disorder Phase 3 clinical trials – 3 Psilocybin, Ketamine Phase 2 – 34

Phase 1 - 25





#### **US Federal Law**

The US Government has the authority to grant:

Patents and Copyrights under the Patent and Copyright clause of the US Constitution. U.S. Const. Art.1 § 8., cl 8.

Trademarks under the Commerce Clause of the U.S. Constitution. U.S. Const. Art.1 § 8., cl 3. A requirement of a registrable trademark is that it is used in US commerce.

As a result, trademarks cannot be granted on illegal substances which cannot legally be used in US commerce, such as cannabis.

Patents and copyrights which relate to cannabis and other illegal drugs can be granted.







#### Federal Law-

Drug Enforcement Administration

#### Controlled Substances Act ("CSA")

Schedule 1 - No currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse.

Includes - heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), 3,4-

methylenedioxymethamphetamine (ecstasy), methaqualone, and peyote

#### State Law

As of February 2024:

47 states, the District of Columbia, and 3 territories (Guam, Puerto Rico, U.S. Virgin Islands) allow for the use of cannabis for medical purposes.

24 states, the District of Columbia, and 2 territories (Guam and North Mariana Islands) allow for the use of cannabis for adult recreational purposes.

New York: legalized medical use of marijuana in 2014; legalized recreational use in 2021 Denver, Colorado – 1<sup>st</sup> city to decriminalize Psilocybin Oregon – Psilocybin use for over 21 in supervised facilities





#### Marijuana remains a Schedule 1 drug under the CSA

Therefore, it remains a <u>federal</u> crime to possess, use, sell, or distribute marijuana for *either* medicinal or recreational purposes in interstate commerce – commerce between 2 states or the US and another country. Ban includes CBD derived from marijuana

#### However, the 2018 Farm Bill removed hemp from the legal definition of marijuana

This means that cannabis plants and derivatives (like CBD derived from hemp) **that contain 0.3% or less of THC on a dry-weight basis** are not considered controlled substances and can be the subject of US trademarks.

For example, the USPTO has been approving trademarks for skin care preparations, topical medicinal products, and cosmetics that feature hemp ingredients, including CBD derived from hemp.

BUT the Food ad Drug Administration "FDA") still has authority to regulate certain products containing cannabis and cannabis-derived compounds.

 trademark applications covering certain CBD-infused foods, beverages, dietary supplements and pet foods are still refused, even if derived from hemp, because such goods may not be introduced lawfully into commerce without FDA approval.





### What About Delta 8?

Delta-8-THC is a tetrahydrocannabinol having similar chemical structures and pharmacological activities to those contained in the cannabis plant and may be synthetically produced from non-cannabis materials, which does not fall under the definition of hemp.

Is it legal?

Can Delta 8 products be the subject of a US trademark Registration?





- FDA Approval for Schedule 1 substances Schedule 1 Status removed if FDA approves drug
  - Licensing and compliance is expensive
  - Only well capitalized Private Companies
  - Start-ups research in other countries –
  - FDA approval and patents based on overseas research and clinical trials
    - Ketamine nasal spray to treat depression has made it through process
      - Trademark for SPRAVATO for "Human pharmaceutical preparations for the prevention and treatment of central nervous system diseases"
    - MDMA and psilocybin promising

Example: Preparation of psilocybin, different polymorphic forms, intermediates, formulations and their use U.S. Patent No. 10,947,257 (filed July 2, 2020) (claiming an oral formulation of psilocybin and methods of treating major depressive disorder);



## **Patent Protection**





### **Basics**

- Novel, nonobvious, useful, and within the scope of patent-eligible subject matter, which is the range of inventions for which patents can be granted.
- Must be "a process, machine, manufacture, or composition of matter."
- Does not include Laws of Nature, abstract idea and natural phenomena.
- Excludes naturally occurring psychedelics in plants and fungi





## **Patent Protection**

- USPTO does grant patents on Schedule I Substances
- Plant Patents Utility Patents and Design Patents are available
- Modified structures of psychedelic compounds, new methods of production and novel formulations can be patented
- Secondary patents that claim modified versions of a base compound
- Variations on crystalline structure of a natural compound
- Compositions
  - Medications
  - Pharmaceuticals
- Manufactured Products
  - $\circ$  Oils
  - Cosmetics
- Machines
  - Harvesting Machines
  - Drying machines
- Processes
  - Cultivation methods
  - Propagation methods







## **Plant Patents**

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Plant Patent Act 35 USC § 161 et seq.

About 1 – 2,000 cannabis plant patents granted per year

- Protection of new and non-obvious cultivated asexually produced plants such as rooting, cutting, grafting, budding, cloning.

- Applicant must show identifiable features that make plant new and non-obvious
- -Applicant must show the reproduction.
- -Protection applies only to plant
- -Infringement requires asexual reproduction and exact duplication
- -Does not protect seeds or pollen.
- -Term of 20 years from filing date

Example: "Cannabis Plant Named Divinia" US PP 33,483





## **Utility Patents**

THE REPORT OF CONTINUES

About 400 – 500k Cannabis related utility patents granted per year.

Cover new and useful process, machine, article of manufacture or composition of nature.

Can cover plant tissue, cells, seeds, parts of a plant, methods used to grow, cultivate or process the plant and extracts of the plant.

Examples:

-Method of Continuously Producing Cannabis from Cannabis Plant and Use Thereof (US Pat. No.

11,554,149)

-Oil Extract of Cannabis and Method of Obtaining (US Pat. No. 11,541,089);

-Cannabis Farming Methods (US Pat. No. 11,528,855);

-Systems and Methods for Cannabis CBD Extraction (US Pat. No. 11,406,914);

-Powderized Cannabis and Uses Therefore (US Pat. No. 11,364,505);

-Cannabis-Infused Milk (US Pat. No. 10,028,987), and

-Method of Juicing Cannabis Plant Matter (US Pat. No. 9,974,821).





## Patents- Plant Variety Protection Act

.- Enacted in 1970 to protect new, distinct, uniform and stable

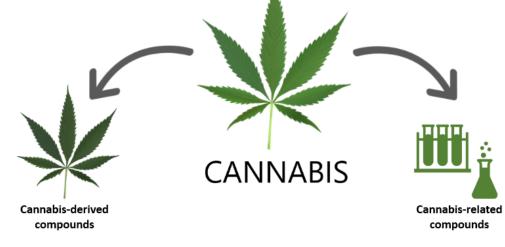
-Sexually produced and tuber propagated plants.

Only applies to seed bearing plants

Infringing acts – sexually multiplying variety and producing hybrids,

Provided by Department of Agriculture whose authority is under the commerce clause.

Term 20 years (25 for trees and vines).







### **Practical Concerns**

Risk of Federal Prosecution – detailed description and enablement

Issuance of "Bad" Patents

Prior Art

Enforcement

– Federal Courts

-State Courts



### **QUESTIONS?**



### CONTACT

## DONNA TOBIN dtobin@rccblaw.com 212.994.0454





## THE "CAN'S AND "CANNOTS" OF CANNABIS [AND PSYCHEDLICS] IP RIGHTS

Carmen de Luca Smart & Biggar, Canada



STRENGTHENING THE PRACTICE OF THE INDEPENDENT IP ATTORNEY www.ficpi.org

## THE "CAN'S AND "CANNOTS" OF CANNABIS [AND PSYCHEDLICS] IP RIGHTS.

FICPI 22<sup>nd</sup> Open Forum, Madrid September 27, 2024



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## Legal Status of Cannabis and Psilocybin

#### Cannabis

Cannabis Act legalized use and recreational possession as of October 17, 2018:

- Restrictions on promotion
- Restrictions on packaging/labelling
- Restrictions on displaying



#### **Psychedelics**

**Use, possession, sale** prohibited under Controlled Drugs and Substances Act (CDSA).

Exemptions Available Under s.56(1) CDSA:

- Scientific Purposes
- Clinical Studies
- Class Exemptions (Special Access Program)



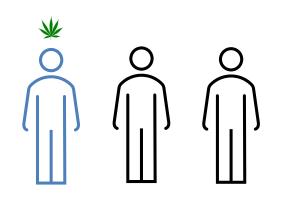


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## **Canadians Love Their Cannabis!**

## ~1 in 3 Canadian adults reported use in previous 12 months

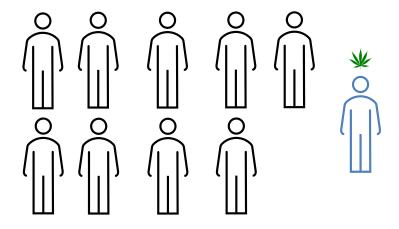
- 18-24 years (38.4%)
- 25-44 years (34.5%)
- 45 years and older (15.5%)



Statistics Canada 2023

## About 1 in 10 Canadians reported daily or about daily use in the previous 12 months

- 18-24 years (8.7 %)
- 25-44 years (10.3%)
- 45 years and older (4.6%)





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### **Canadians Love Their Cannabis!**

- In 2022/2023 fiscal year, sales of legal recreational cannabis increased 15.8% to 4.7 billion
- **Dried cannabis remained the top seller** in 2022/2023, accounting for almost two-thirds (64.9%) of sales
- Most of the increase was due to higher sales of inhaled extracts (+59.0%), which accounted for one-quarter of total cannabis sales
- Growers sold \$2.8 billion of cannabis seeds, vegetative plants and flowering tops (including leaves) in 2023, down 2.9% from a year earlier but 75.5% higher compared with 2019—the first full year of legalization.

Statistics Canada 2023

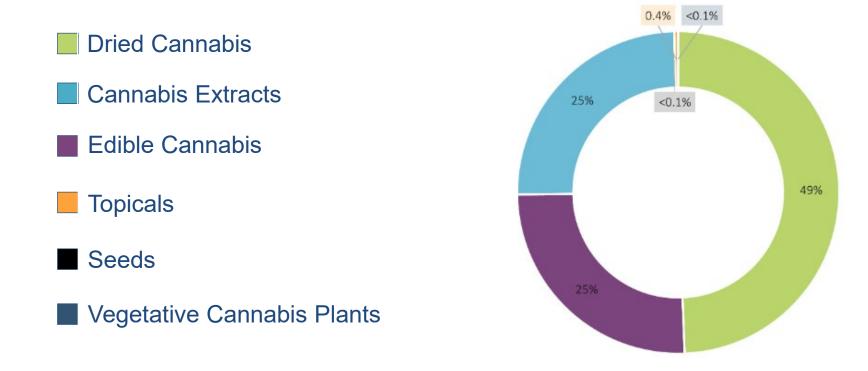


68

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# Canadians Love Their Dried, Edible and Topical Cannabis!

**Figure 1:** Total medical and non-medical sales in packaged units, by product type 21,295,337 units sold (Up 5% from last quarter)



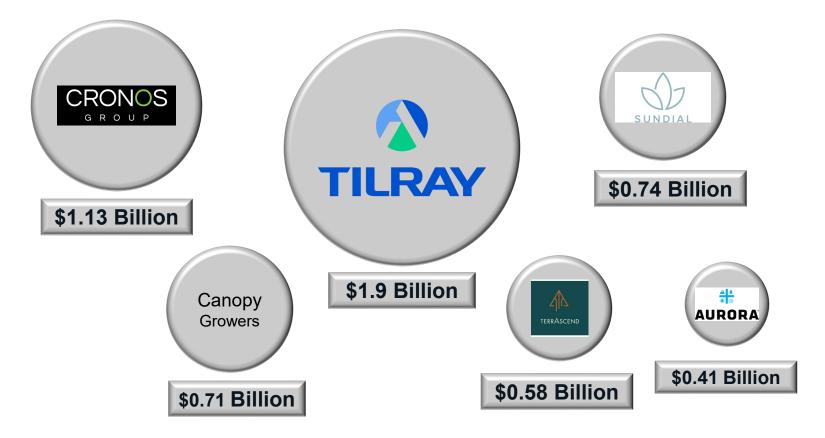
Data reported under the Cannabis Tracking System Ministerial Order in October 2023.



69

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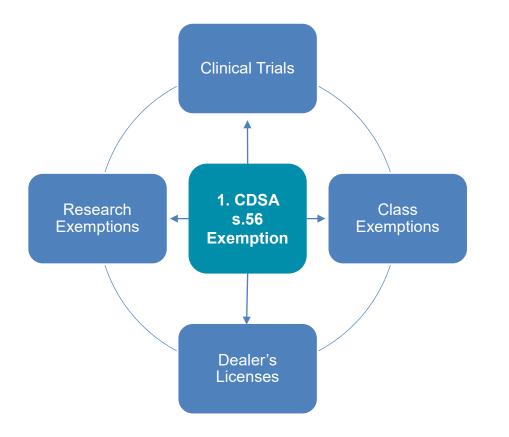
# Canadian Cannabis Companies by Market Cap (as of August 2024):





70

### Psychedelics Regulatory framework: Exemption regime and special access program

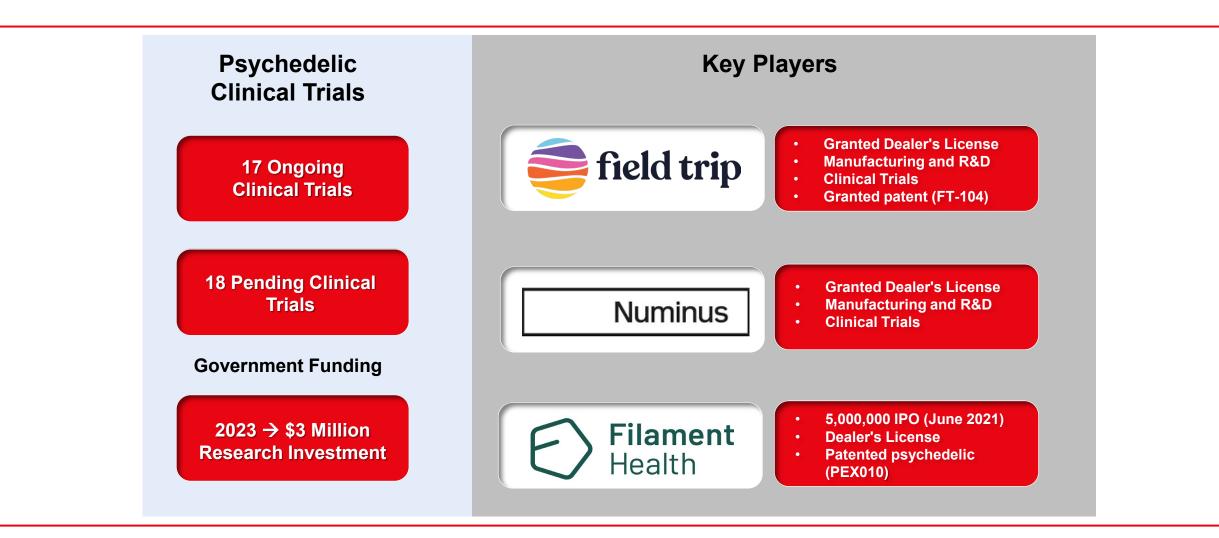




- Submitted by healthcare professional. (Food & Drug Regs.)
- Require s. 56(1) exemption unless class exemption applies.



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# Overview Cannabis Act (S.C. 2018, c.16) and Cannabis Regulations (SOR/2018-144)

Restrictions to Promotion:

s. 17 – 24 CA, Part 6.1 Cannabis Regulations (CR)



Restrictions to Display: s. 29 and s. 30 CA



Restrictions to Packaging, Labelling, and Branding: s. 25-28 *CA*, additional prohibitions in Part 7 *CR*.



Restrictions to Sale: s. 31 and s. 37 CA



# Prohibition on promotion by claiming health or cosmetic benefits(s. 104.12 CR)

### **Examples of health claims:**

- "pain reduction"
- "reducing anxiety"
- "reducing inflammation"
- "sleep aid"



### **Examples of cosmetic claims:**

- "improves skin elasticity"
- "soothes dry skin"
- "reduces signs of aging"
- "skin brightening"
- "smooths wrinkles"





74

### Promotion Alcoholic Beverages, Tobacco and Vaping Products (S. 104.15 And 104.16 Cr)

You cannot promote cannabis, a cannabis accessory or a service related to cannabis if there are reasonable grounds to believe that the promotion could associate it with :



an alcoholic beverage







75

# Packaging and Labelling – Brand Elements

#### Implications for "Cannabis" Trademarks

#### Brand name

The brand name of the cannabis product must be displayed but it <u>must not be in metallic or fluorescent</u> <u>colours.</u>

#### An additional brand element (optional)

Only one other brand element (in addition to the brand name) may be displayed on the label (ex. Slogan or logo)

• It <u>must not be in metallic or fluorescent colours</u>

### Scent or Sound

The interior surface and exterior surface of any container in which a cannabis product is packaged, and any covering of a container, <u>must not be capable of emitting a scent or sound[117, CR]</u>.



# Trademarks Saving Provision in Cannabis Act

**Special Exclusion:** the *Cannabis Act* has a "saving" provision (s. 132(1) and 132(2)), that states that the absence of use of a trademark as a result of compliance with the *Cannabis Act* constitutes special circumstances that excuse non-use for the purposes of the *Trademarks Act*.

- Can register Cannabis related trademark if meets general registrability rule.
- s.132(1) and s.132(2) preclude non-use as ground for invalidity.
- Not fool proof, entitlement to use trademark can be contested if use contravenes federal law.



# Intellectual Property and Cannabis and Psychedelics

#### **Trademarks**

- Goods and services related to recreational cannabis use, such as "cannabis", "dried cannabis", "live cannabis plants" or "medicinal marijuana for the relief of nerve pain" can be registered as trademarks.
- Currently 7578 Canadian and international marks searching the Canadian Trademarks Database for "cannabis" in any field (mark, owner, goods, services etc) and including only active marks (pending and registered marks)



# **Registration TMA1216376**

**Cannabis Link Express** 

2023-12-29

Cannabis Link Express Inc. 1669 Seymour Cres London ONTARIO N6G5N6

#### Goods

- 1) Baked goods being brownies, cakes.... all containing cannabis;... breakfast cereals containing cannabis; ... candy containing cannabis; ... chewing gum containing cannabis; chocolate containing cannabis; coffee-based beverages containing cannabis; ... corn-based snack foods containing cannabis; energy bars containing cannabis; grain-based snack foods containing cannabis; ... tea-based beverages containing cannabis; ...
- 2) Cannabis plant seeds; live cannabis plants;
- Carbonated beverages infused with cannabis; carbonated soft drinks containing derivatives of cannabis; energy drinks containing cannabis; fruit-based beverages containing cannabis; fruit-flavoured beverages infused with cannabis;
- 4) Bongs; cannabis grinders; cannabis-derived resins and oils for recreational use, for smoking;... dried cannabis; lighters for smokers; odour-proof travel cases and jars for storing cannabis; rolling papers for cannabis cigarettes; smokers' articles, namely, smoking pipes for use with marijuana and cannabis

#### Services.

Online and retail sale of cannabis products ....



# **Registered TMA1058792**

2019-10-11

Goods (Nice class & Statement)

3(3) Cannabis oils for cosmetic purposes; Cannabis skin lotions;



5(4) Cannabis oil containing tetrahydrocannabinol for pharmaceutical purposes; Cannabis oil containing cannabidiol for pharmaceutical purposes

16(1) Legal publications;

29(5) Cannabis oils for food;

30(6) Cannabis infused foods, namely chocolate bars infused with cannabis, candies infused with cannabis, gummies infused with cannabis, and brownie squares infused with cannabis; Cannabis infused drinks, namely teas infused with cannabis;

31(7) Fresh cannabis; Live cannabis plants; Cannabis seeds for sowing, unprocessed cannabis seeds for oils;

34(2) Cannabis related products namely dried cannabis; cannabis oils for oral vaporizers for smoking; Cannabis oils for electronic cigarettes; Accessories used for the ingestion of Cannabis, namely oral vaporizers for smoking purposes, bongs, cigarette rolling papers, and roach clips;

Services (Nice class & Statement)

35(1) Online advertising for others via a computer communications network;

41(2) Educational research services;

45(3) Legal research; legal services; providing legal information.



80

# **Plant Breeders' Rights**

### Protects new plant varieties, including new varieties of cannabis

- Cannabis breeders can protect cannabis strains under the Plant Breeders' Rights Act (SC 1990, c.20).
- Applications for protection are submitted to the Plant Breeders' Rights Office (PBRO), which is administered by the Canadian Food Inspection Agency (CFIA).

### **Current Registrations:**

- 45 registrations for cannabis
- 19 registrations for hemp

<u>Cannabis</u>		
Denomination:	'OC23T941'	
Botanical Name:	Cannabis sativa	
	Aurora Cannabis Enterprises <u>Inc.</u>	
	409 Granville Street	
Applicant/Holdow	Suite 1700	
Applicant/Holder:	Vancouver, British Columbia	
	V6C 1T2	
	Canada	
Breeder:	Andrew Hand, Aurora Cannabis Enterprises Inc., Comox, British Columbia	
Application Date:	2024-05-09	
Provisional Protection::2024-05-09		
Application Number:	lication Number: 24-11739	

Plant Varieties Journal Number 132 - July 2024



# Intellectual Property and Cannabis and Psychedelics

#### **Industrial Designs**

Industrial designs protect the esthetically pleasing, visual aspects of products, such as their packaging. Available for marijuana related accessories and packaging.

- protect the packaging of dry or edible cannabis products
- the shape of accessories designed to be used with cannabis, such as smoking pipes, containers, etc.





## National Application/Registration 185804

#### CANNABINOID ORAL PRODUCT

2020-09-24

#### **Registered Proprietor(s):**

SPIRULINEX, LLC 570 BRYANT STREET SAN FRANCISCO, 94107 CALIFORNIA, UNITED STATES OF AMERICA





83

## National Application/Registration: 199466

CANNABINOID ORAL PRODUCT

2022-06-06

#### **Registered Proprietor(s):**

CRONOS GROUP INC. 111 PETER ST, SUITE 300 TORONTO, M5V 2G9 ONTARIO, CANADA

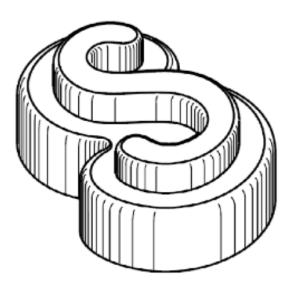


FIG. 1



84

# National Application/Registration 208988

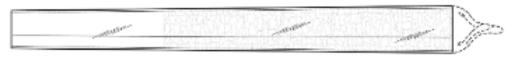
#### CANNABIS CONE

2024-01-05

#### **Registered Proprietor(s):**

PINNRZ INC. 30 COMMERCIAL RD EAST YORK, M4G 1Z4 ONTARIO, CANADA













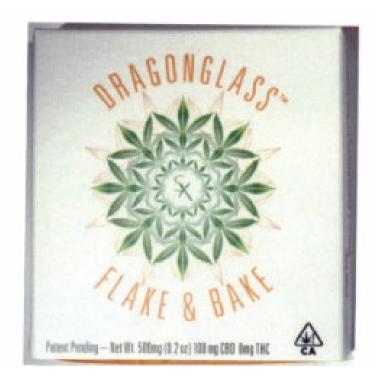
# National Application/Registration 185808

#### CANNABINOID PRODUCT PACKAGE

2020-09-29

#### **Registered Proprietor(s):**

SPIRULINEX, LLC 570 BRYANT STREET SAN FRANCISCO, 94107 CALIFORNIA, UNITED STATES OF AMERICA





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86

# **Patenting Cannabis and Psychedelics**

### **CANNOT** Patent:

- Higher Life Forms unpatentable in Canada
- Cannabis plants per se unavailable





### **CAN** Patent

- Modified Plant cells and cell lines
- Modified nucleic acids
- Non-viable e.g. dried, cannabis products
- Isolated cannabis active agents, and extracts
- Pharmaceutical compositions + uses
- Processes and methods
- Products and machines
- Production equipment, patches, controlled dose dispensers





### Issued Canadian Claims – Formulations/Compositions

Patent No. & Issue Date	Title	Claim
CA2965493C Dec 7, 2021	Oral Cannabinoid Formulations	What is claimed is: 1. A liquid cannabinoid formulation, wherein at least 95% of the total cannabinoids is tetrahydrocannabinol (THC), cannabinol (CBN), cannabidiol (CBD) and cannabichromene (CBC) which are in a cannabinoid mixture wherein: (1) THC is less than or equal to 9%; (2) CBD is greater than or equal to 40%; (3) CBN is greater than or equal to 40%; and (4) CBC is less than 1%; wherein the cannabinoid formulation is infused in a medium chain triglyceride (MCT).
CA3034004C Aug 3, 2021	Water soluble compositions comprising purified cannabinoids	1. A liquid composition, comprising: one or more purified cannabinoids selected from the group consisting of D9- THC, D8-THC, THCA, THCV, D8-THCV, D9-THCV, THCVA, CBD, CBDA, CBDV, CBDVA, CBC, CBCA, CBCV, CBCVA, CBG, CBGA, CBGV, CBGVA, CBN, CBNA, CBNV, CBNVA, CBND, CBN DA, CBN DV, CBNDVA, CBE, CBEA, CBEV, CBEVA, CBL, CBLA, CBLV, and CBLVA; Vitamin E TPGS; and water, wherein the liquid composition comprises a ratio of total purified cannabinoid content to Vitamin E TPGS of about 1:1 to about 1:10 based on mass percent.
CA3000862C March 14, 2023	Medical Chewing Gum Comprising Cannabinoid	1. A medical chewing gum comprising gum base polymers and one or more cannabinoids as an active pharmaceutical ingredient, the gum base polymers comprising polyvinyl acetate and vinyl laurate-vinyl acetate copolymer in an amount of more than 90% by weight of the gum base polymers, wherein the gum base polymers include 20 - 95% by weight of polyvinyl acetate and 5 - 80% by weight of vinyl laurate-vinyl acetate copolymer.

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88

### **Recently Issued Canada Claims – Uses**

Patent No. & Issue Date	Title	Claim
CA2952994C March 14, 2023	Use of Cannabinoids in the Treatment of Epilepsy	<ol> <li>Cannabidiol (CBD) for use in the treatment of febrile infection related epilepsy syndrome (FIRES).</li> <li>CBD for use according to claim 1, wherein the CBD is to be used in combination with two or more concomitant anti-epileptic drugs (AED).</li> <li>CBD for use according to claim 1 or claim 2, wherein the treatment is of a complex partial seizure (focal seizure with impairment).</li> <li>CBD for use according to any one of claims 1-3, wherein the CBD is present as a highly purified extract of cannabis which comprises at least 98% (w/w) CBD.</li> <li>CBD for use according to claim 2, wherein</li> </ol>
CA3076963C, March 29, 2022	Use of cannabidol in treatment of pulmonary hypertension	<ol> <li>Use of cannabidiol or a pharmaceutically acceptable salt or ester thereof to treat or prevent pulmonary arterial hypertension (PAH).</li> <li>Use of cannabidiol or a pharmaceutically acceptable salt or ester thereof in the manufacture of a medicament to treat or prevent PAH.</li> <li>Cannabidiol or a pharmaceutically acceptable salt or ester thereof for use to treat or prevent PAH.</li> </ol>



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89

### **Recently Issued Canadian Claims – Plant Related Patents**

Patent No. & Issue Date	Title	Claim					
	Utility Patents						
CA3085007C Dec 21, 2021	High cannabigerol cannabis plants, methods of producing and methods of using them	<ul> <li>I. A cannabinoid-producing diploid plant cell from a female inflorescence of a (i) cannabis plant, (ii) asexual clone of the plant, (iii) part of the plant, or (iv) tissue of the plant, wherein said cannabis plant produces a female inflorescence, said inflorescence comprising: <ul> <li>a) a functional Bi allele and/or a functional BD allele;</li> </ul> </li> <li>b) a cannabigerol (CBG max) content of at least 2.0% by weight; and</li> <li>c) a non-CBG max cannabinoid content of at least 5.0% by weight, wherein the contents of CBG max and non-CBG max cannabinoid(s) are measured by high performance liquid chromatography (HPLC) and calculated based on dry weight of the inflorescence; wherein samples of seed that produce plants comprising a), b), and c) have been deposited under NCIMB Nos. 43257, 43261, 43263, and 43264.</li> </ul>					



90

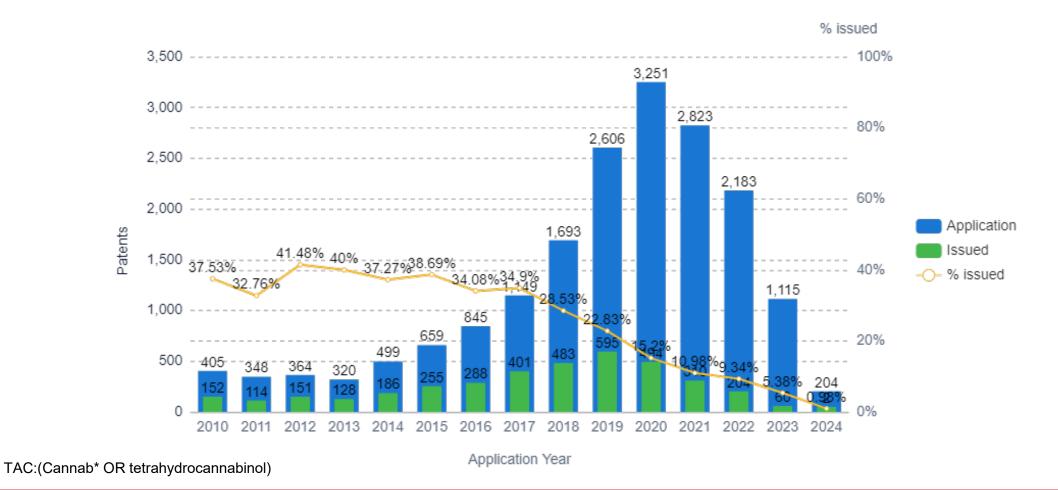
### Recently Issued Canadian Claims – Drinks/Beverages

Patent No. & Issue Date	Title	Claim
CA2893697C, Jan 18, 2018	Single serve beverage pod containing cannabis	<ol> <li>A method of preparing a single-serve container configured for receipt in a single-serve brewing machine, the method comprising:         processing cannabis by pulverizing the cannabis to a particle size that is less than a threshold and by heating the cannabis to decarboxylate the cannabis, the threshold being one millimeter or less than one millimeter;         adding the processed cannabis to the single-serve container;         adding, to the single-serve container, a lipid-rich food-based extraction agent, wherein the extraction agent is in the form of a powder, is solid at room temperature and provides at least 0.9 grams of fat in the container; and sealing the single-serve container.     </li> <li>A packaged beverage product comprising:         <ul> <li>a body portion defining a cavity; processed cannabis located within the cavity, the processed cannabis being processed by heating the cannabis to decarboxylate the cannabis; and a lipid-rich food-based extraction agent located within the cavity, the extraction agent being a powder and solid at room temperature.</li> </ul></li></ol>
CA3076963C March 29, 2022	Liquid Dosage forms comprising cannabis, methods of making and use	<ol> <li>An emulsion comprising at least one cannabinoid, a carrier oil, an emulsifier, and an aqueous solution, wherein the emulsifier is a lecithin present in about 0.01 to about 10 weight percent, and the emulsion is a nanoemulsion.</li> <li>A beverage comprising the emulsion of any one of claims 1 to 19.</li> </ol>



91

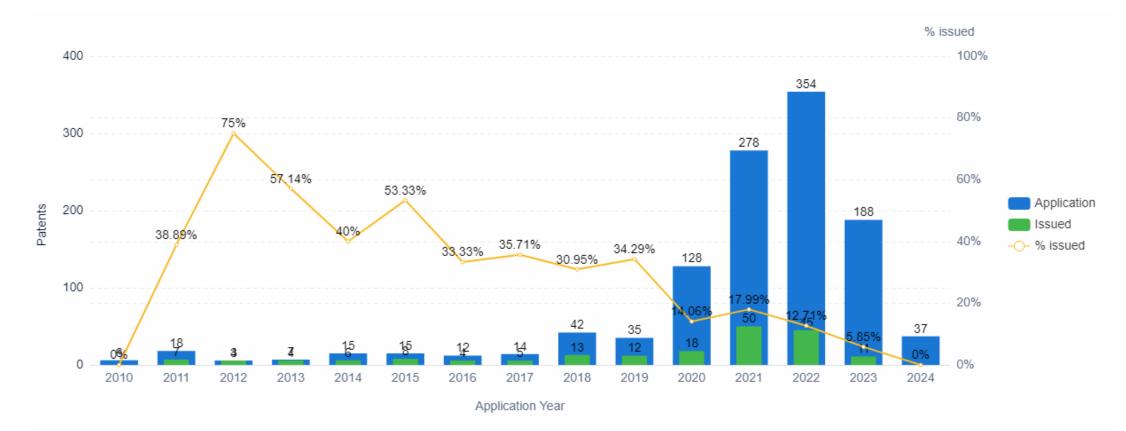
# Cannabis: Application and Issue Trend (US, CAN, AUS, WIPO)



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92

# Psilocybin: Application and Issued Trend (US, CANADA, AUS, WIPO)



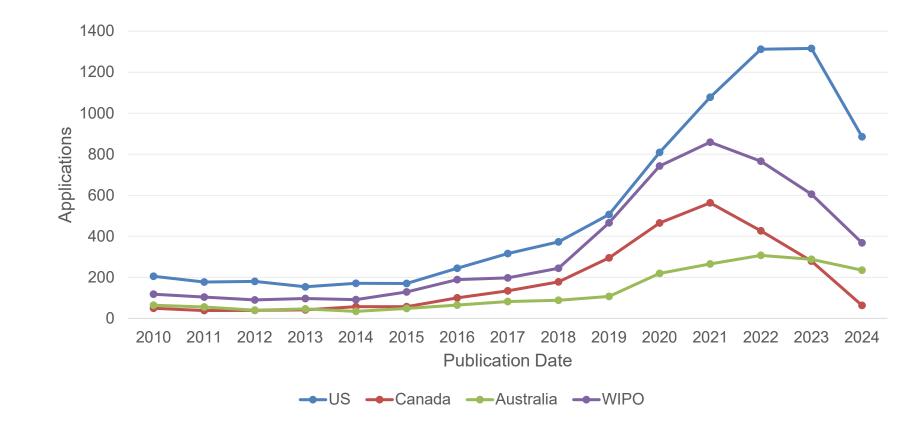
TAC: "psilocybin" OR "psilocin" OR "4-phosphoryloxy-N,N-dimethyltryptamine" OR "4-PO-DMT"

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### **Cannabis: Patent Application Trends**



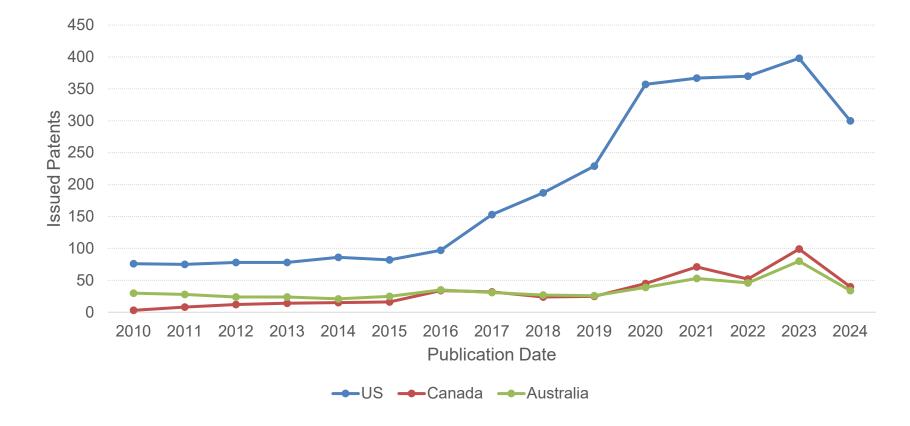
TAC:(Cannab\* OR tetrahydrocannabinol)



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### **Cannabis: Issued Patent Trends**

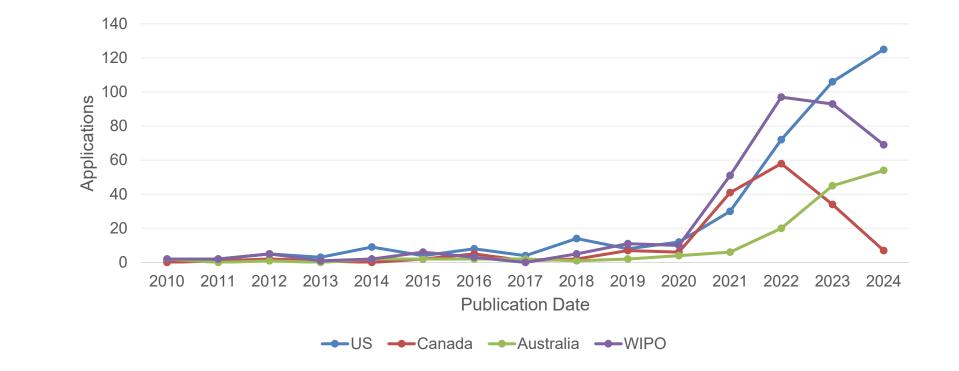


TAC:(Cannab\* OR tetrahydrocannabinol)



95

### **Psilocybin: Patent Application Trends**



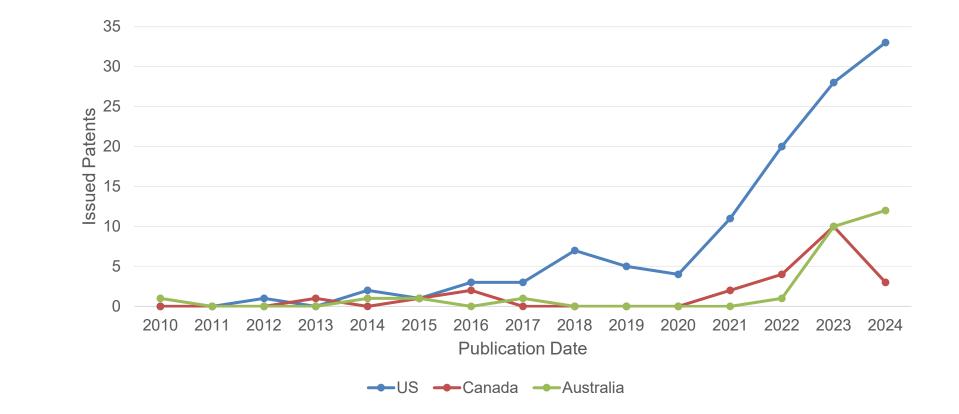
TAC: "psilocybin" OR "psilocin" OR "4-phosphoryloxy-N,N-dimethyltryptamine" OR "4-PO-DMT"



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### **Psilocybin: Issued Patent Trends**

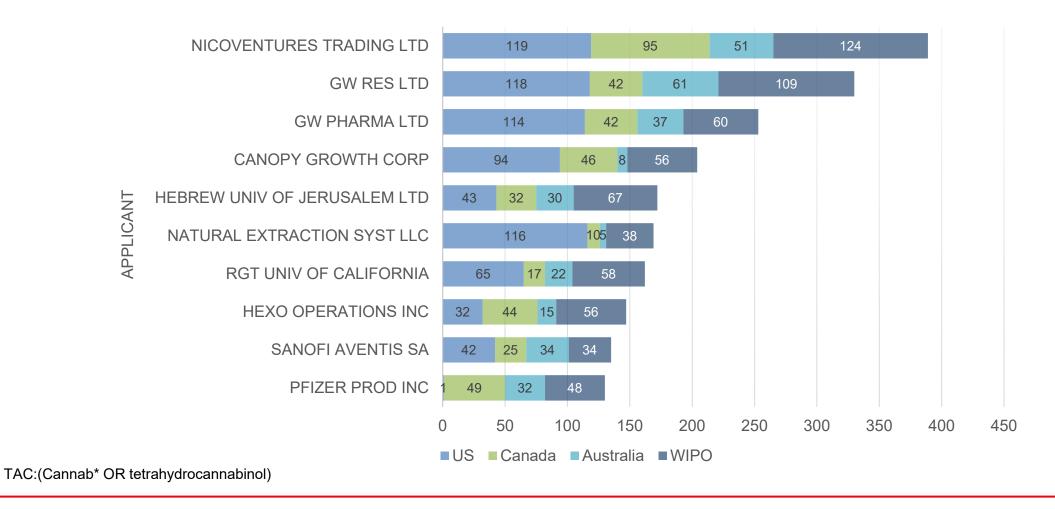


TAC: "psilocybin" OR "psilocin" OR "4-phosphoryloxy-N,N-dimethyltryptamine" OR "4-PO-DMT"



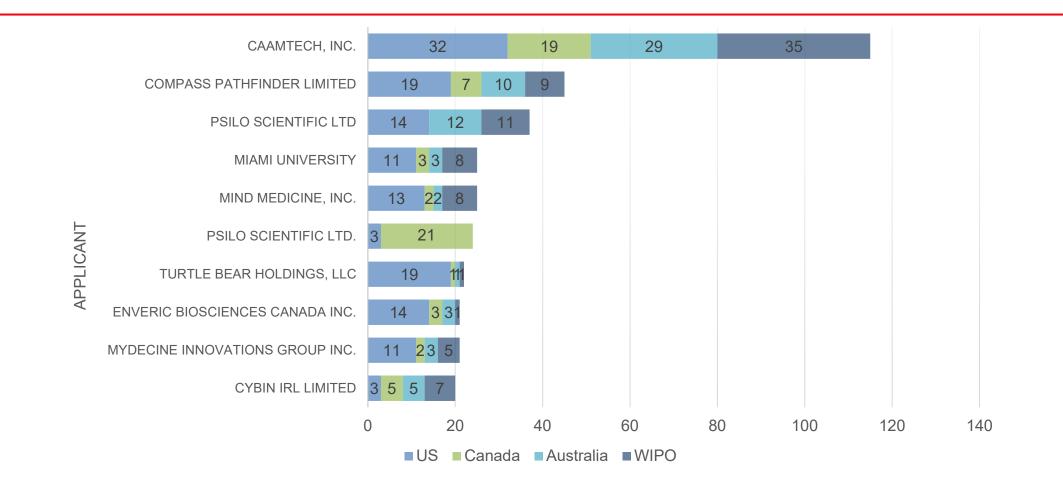
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### **Cannabis: Top Applicants per Jurisdiction**



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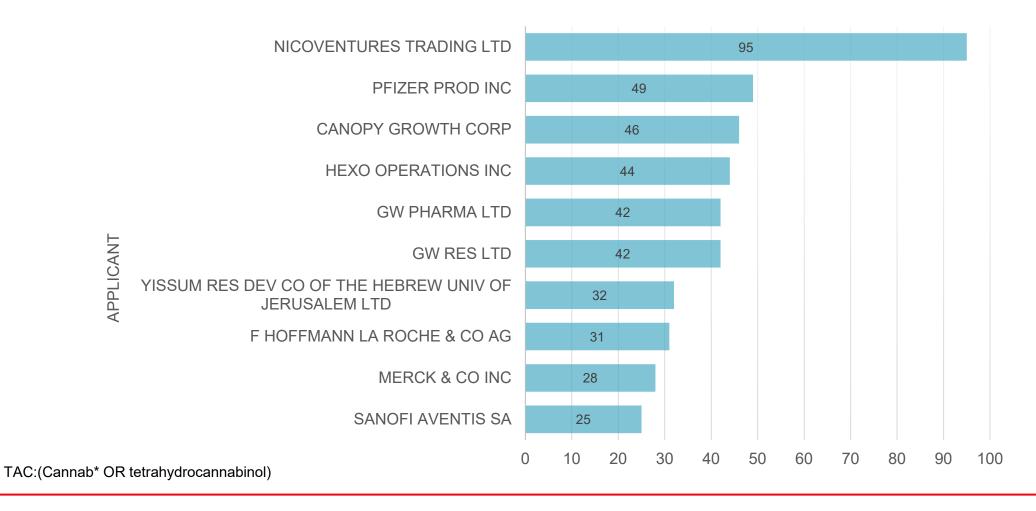
## **Psilocybin: Top Applicants Per Jurisdiction**



TAC: "psilocybin" OR "psilocin" OR "4-phosphoryloxy-N,N-dimethyltryptamine" OR "4-PO-DMT"



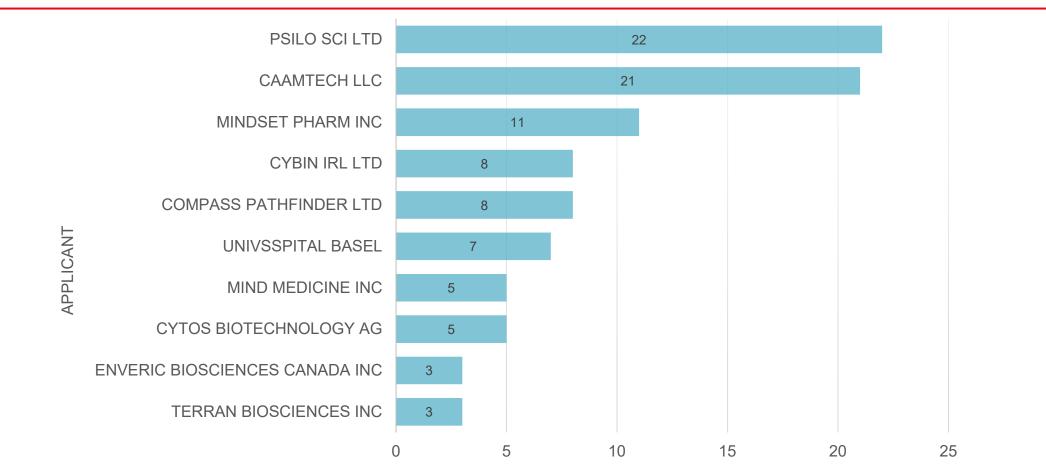
### **Cannabis: Top Applicants Canada**



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### **Psilocybin: Top Applicants Canada**

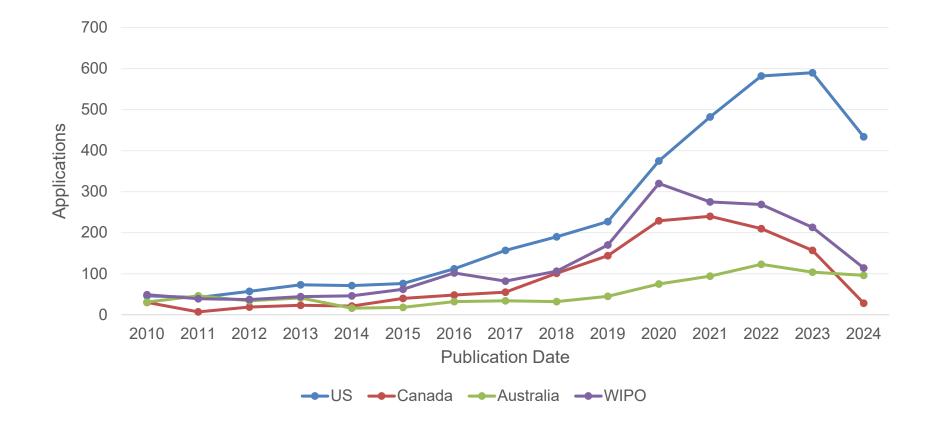


TAC: "psilocybin" OR "psilocin" OR "4-phosphoryloxy-N,N-dimethyltryptamine" OR "4-PO-DMT"



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## **Cannabis Edible Products – Application Trend**

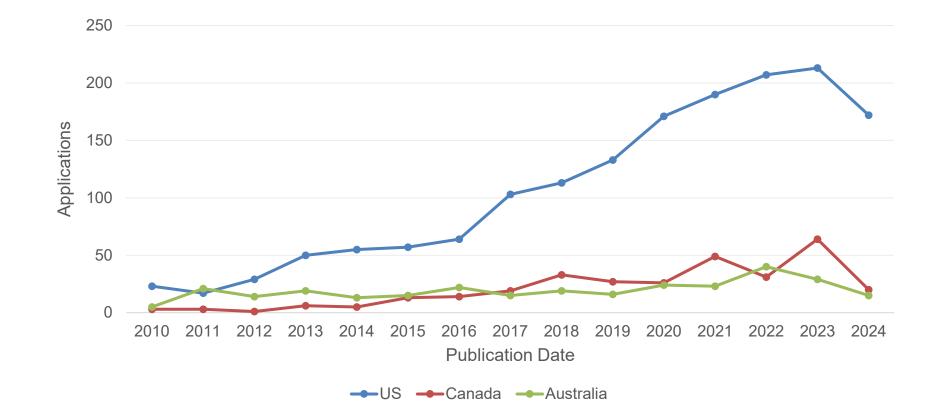


TAC: ((cannabis OR cannabinoid OR cannabidiol OR tetrahydrocannabinol OR THC OR CBD) NEAR3 (infused OR edible OR food OR drink OR meat OR meal OR alcohol OR liquor OR brew OR refreshment OR beverage OR liquid OR aqueous))



10 2

# Cannabis Edible Products – Issued Patent Trend



TAC: ((cannabis OR cannabinoid OR cannabidiol OR tetrahydrocannabinol OR THC OR CBD) NEAR3 (infused OR edible OR food OR drink OR meat OR meal OR alcohol OR liquor OR brew OR refreshment OR beverage OR liquid OR aqueous))



### The "Can's and "Cannots" -

#### Summary of CANS: Patents

 Patents available for a variety of Cannabis related subject matter

### PBRs

Available for Cannabis varieties

### Trademarks

Trademark Cannabis related Marks

### Copyrights

Available for Cannabis related material

### **Industrial Designs**

 Available for variety of cannabis related accessories and packaging

### Summary of CANNOTS: Patents

 Patent higher life forms such as Cannabis plants

### Advertising (Trademarks)

- Promotion, labelling, and branding heavily regulated with numerous prohibitions
- Display of Cannabis related branding and promotion heavily regulated/prohibited



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# Thank you. **QUESTIONS?**









FICPI World Congress & ExCo Meeting 12-18 October 2025 Naples, Italy

FICPI Korean Symposium 2-5 April 2025 Jeju Island, Republic of Korea



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