

## PROSPECTION OF MEDICINAL CANNABIS IN THE BRAZILIAN MARKET: PRODUCTS, PRODUCTION METHODS, USE & INDUSTRIAL PROPERTY (IP)

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**Abstract:** The trajectory of medicinal Cannabis in Brazil began in academia in the 1970s, when Dr. Carlini published the first non-clinical study on rodents showing the bioprospecting of cannabidiol (CBD) as an anticonvulsant agent. Decades later, in 2014, medicinal Cannabis gained visibility with the case of girl Anny Fischer, who suffered from a rare and serious illness, allowing the family to gain authorization to import extracts containing high CBD and low delta-9-tetrahydrocannabinol. (THC) (> 0.2 mg). In the United States, the modern Cannabis industry is almost three decades old, beginning its rise in 1996 with the approval of medicinal use in California. Certainly, the prohibition of the *Cannabis sativa* L. plant favors difficult access to information about the therapeutic benefits linked to the legal Cannabis market. This review aims to introduce the basis of the production of legal cannabis products and present data from global and national markets. A bibliographical review was carried out based on NBR 10520 and 6023 (2002), on data released by the Canadian government, BDSA, ANVISA, Patient Associations and national and international patent banks. The results showed more than 250 imported products authorized by RDC335/2020, more than 60 products from associations and 18 products from national companies authorized by RDC 327/2019. In the area of Industrial Property, only 20 patent applications versus almost 70 thousand in the international market. We conclude that Brazil has a potentially promising market, at the beginning of its rise, and developing considerably, despite the prohibitions currently in force.

**Keywords:** *Cannabis sativa* L. Medicinal cannabis. Prospection. Industrial Property (IP).

## INTRODUCTION

The trajectory of medicinal *Cannabis* in Brazil began in academia in the 1970s, when Dr. Carlini published the first non-clinical study on rodents showing the bioprospecting of cannabidiol (CBD) as an anticonvulsant and antiepileptic agent (CUNHA et. al., 1980; CARLINI and CUNHA, 1981)

In the United States, the modern *Cannabis industry* is almost three decades old, beginning its rise in 1996 with the approval of medicinal use in California. Decades later, in 2014, medicinal *Cannabis* gained visibility with the case of girl Anny Fischer, who suffered from a rare and serious disease, early childhood epileptic encephalopathy type 2 (EIEE2)1, allowing the family to gain authorization to import extracts containing high CBD content and low delta-9-tetrahydrocannabinol (THC) content (> 0.2 mg) through RDC No. 17/2015 (BUGARTI, 2016; ANVISA, 2015).

Certainly, the prohibition of the *Cannabis sativa* L. plant and the lack of legislation that clearly regulates all sectors of Cannabis favors difficult access to information on the therapeutic benefits linked to the legal Cannabis market in the country, making *qualified* training of professionals difficult. healthcare and others, who can act safely in prescriptions, in the development of Cannabis products, in academic research and in the industrial sector.

## OBJECTIVES

This review aims to introduce the basis of the production of legal cannabis products and present data from global and national markets.

## METHODOLOGY

Bibliographic review method proposed by NBR 10520 and 6023 (2002), with references to the articles Pharmacology of Medical Cannabis (AMIN & ALLI, 2019) and Cannabis Sativa Bioactive Compounds and Their Extraction, Separation, Purification and Identification Technologies: An Updated Review (LIU et. al, 2022).

Product data provided by the Canadian government, BDSA, ANVISA and the associations: ABRACE Esperança, AMA+ME, AMME Medicinal, APEPI, Flor da Vida, Santa Planta and TerraCannabis.

Consultation in national Industrial Property (Invention Patents) banks, the INPI ( <https://busca.inpi.gov.br/pePI/jsp/patentes/PatenteSearchAvancado.jsp> ) and international banks, the American Google Patents ( <https://www.google.com/?tbn=pts> ) and the European Espacenet ( <https://worldwide.espacenet.com/> ). Using a single descriptor: “Cannabis”.

## RESULTS AND DISCUSSION

Cannabis *sativa* L. produces secondary metabolites containing approximately 540 natural components, including more than 100 phytocannabinoids, the main ones being delta-9-tetrahydrocannabinol ( $\Delta^9$ -THC) and cannabidiol (CBD), alkaloids, flavonoids, terpenes, among others (AMIN & ALI, 2019).

## PRODUCTION METHODS

### EXTRACTION METHODS

Microwave extraction (in English: MAE); with ultrasound (from English: UAE); cold pressurized (from English: CPE); supercritical fluid (English: SFE); in pressurized liquid (from English: PLE); enzymatic (from English: EAE); in a pulsating electric field (from English: PEF); with deep eutectic solvents (from English: DESE); by solid-liquid metastable dynamics (from English: RSLDE); Microwave distillation (English: MD); Hydroalcoholic Extraction (English: HAE) (Liu et. al, 2022).

### SEPARATION AND PURIFICATION METHODS

Solid phase extraction (SPE); Centrifugal separation chromatography (from English: CPC); Preparatory high performance liquid chromatography (English: Prep -HPLC); Nano-liquid chromatography (English: Nano-LC); Liquid chromatography of hydrophilic interactions (HILIC) (Liu et. al, 2022)

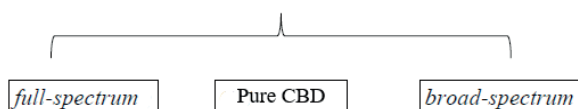
### COMPOUND IDENTIFICATION METHODS

Thin layer chromatography (TLC); Gas chromatography coupled to mass spectrometry (in English: GC-MS); High-performance liquid chromatography coupled to mass spectrometry (in English: HPLC-MS); Supercritical fluid chromatography coupled to mass spectrometry (SFC-MS); Nuclear Magnetic Resonance (NMR) (Liu et. al, 2022).

## CANNABIS MARKET AND PRODUCTS

According to the BDSA, it is estimated that legal Cannabis sales generated more than US\$29 billion worldwide in 2021, with more than US\$23 billion linked to the United States

### Medical Cannabis Products



**Figure 1.** Class of cannabis products sold according to composition: *Full-spectrum* (whole plant extract containing  $\Delta^9$ -THC); pure CBD; and *Broad-spectrum* (whole plant extract without  $\Delta^9$ -THC). Source: Author, 2022.

market, approximately US\$3.8 billion to the Canadian market and US\$1.5 billion in other markets.

In Brazil, cannabis products are limited to the Medicinal Cannabis market, which are distributed among associations (NGOs), Cannabis importing companies and pharmaceutical companies. The greatest variety of products is imported, but there is national production, led by the production of associations, but also with the participation of private sectors. More than 250 imported products authorized by RDC 335/2020 are sold, more than 60 products from associations and 18 products from national companies authorized by RDC 327/2019. It is estimated that approximately 60% of legally sold products are *full-spectrum*, 30% are *broad-spectrum* and 10% are isolated CBD.

## INDUSTRIAL PROPERTY AND INVENTION PATENTS

In the area of Industrial Property, only 20 patent applications were deposited in the INPI patent database. In contrast, more than 60 thousand invention patent deposits were found in international banks, with Google Patents being the record holder for deposits (figure 3). The search was carried out on August 26, 2022.

This discrepancy in the results reflects some points related to patentability that must be considered: the first is related to the country's Industrial Property Law (LPI 9,279/1996), which does not allow patentability only of the "idea of the invention", and the application for patent present in the document the proof (applicability) of the inventive activity. The second important point is that by LPI 9,279/1996 it is prohibited to patent natural products of animal, vegetable or microbiological origin, whether in whole or isolated form, as well as part of living beings, biological materials and natural biological

processes.

Regarding the findings of deposits in the national patent bank of the National Institute of Industrial Property - INPI, some claims were identified such as treatment method, pharmaceutical composition, among others, as well as some therapeutic applications for the treatment of cancer, autoimmune diseases, insomnia and others (table 1).

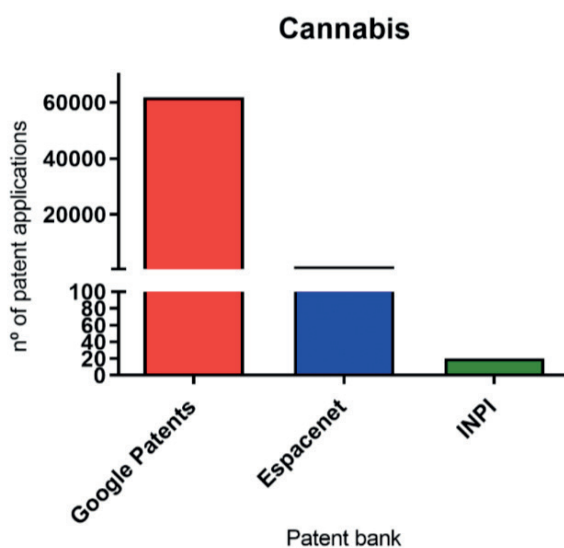
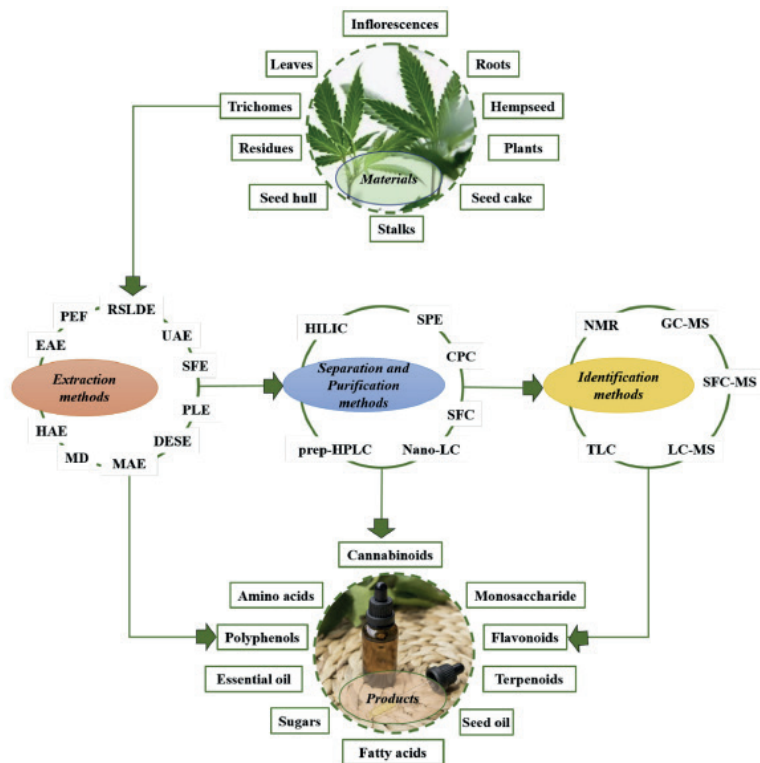


Figure 3. **Survey of Invention Patents using the descriptor term "Cannabis"**. The search was carried out on August 26, 2022 in the international patent databases Google Patents - USA (61,800 finds) and Espacenet - Europe (1,472), and national - INPI (20). Authorial Source, 2022.

PI CLAIMS - INPI	THERAPEUTIC APPLICATIONS
treatment methods	cancer
pharmaceutical composition	insomnia
use	pain
pharmaceutical associations	epilepsy
routes of administration	respiratory disease
extraction methods	autoimmune disease

Table 1. **Main findings in the Brazilian patent database INPI.**

Source: Author, 2022.



**Figure 2.** Schematic of a generic production line from *Cannabis sativa* L. The parts of the plant subjected to different extraction methods are listed; types of separation and purification; identification methods; components present in Cannabis products. Source: Liu et. al., 2022.

Patent Application Number	IP title	Year of Deposit/ Publication Grant
BR 112022003532-2 A2	PROTEIN-BASED CANNABIS COMPOSITIONS	2020 / 2022
BR 102020008857-2 A2	PHARMACEUTICAL PREPARATION BASED ON SUNFLOWER OIL WITH THE ADDITION OF CANNABIS OIL SATIVA	2020 / 2022
BR 102018076973-1 A2	PHARMACEUTICAL COMPOSITION COMPRISING CANNABIS EXTRACT, PHARMACEUTICAL PRODUCT, PREPARATION PROCESS OF SAID COMPOSITION	2018 / 2020
BR 112019001794-1 A2	COMPOSITION OF CANNABIS	2017 / 2018
BR 112019001852-2 A2	COMPOSITION OF CANNABIS	2017 / 2018
BR 112017008301-9 B1	CANNABIS EXTRACTS AND METHODS OF THEIR PREPARATION AND USE	2015 / 2021
BR 112020017023-2 A2	CANNABIS-BASED THERAPY AND METHOD OF USE	2019 / 2021
BR 102020001994-5 A2	PHYTOTHERAPEUTIC PRODUCT BASED ON FREEZE DRIED POWDER OBTAINED FROM THE ROOTS OF CANNABIS SATIVA FOR THERAPEUTIC PURPOSES	2020 / 2021

Table 1. Patent applications filed at INPI, Brazil.

The search was carried out on August 26, 2022 in the INPI national patent database. Source: Author, 2023.

Complementing the results of the search for patent applications for inventions carried out, it is possible to mention some of the main titles of applications filed and/or granted by INPI (table 1). The majority of patent applications were filed after 2017, with registration of a grant in 2021 of application BR 112017008301-9 B1, entitled "CANNABIS EXTRACTS AND METHODS OF THEIR PREPARATION AND USE", characterized by containing the extraction of active components of plant materials, and more particularly the preparation of a botanical medicinal substance for incorporation into a medicine, and use in pharmaceutical formulations. In particular, assets that comprise cannabinoids obtained through the extraction of Cannabis. A United States patent application (US2015056635, dated 10/21/2015).

## CONCLUSIONS

Brazil has a potentially promising market, which is beginning to rise, and has been developing considerably in recent years,

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especially since 2020. The billion-dollar turnover of the world market highlights how promising investment in the Brazilian Cannabis market is, with the emergence of several companies importing Cannabis products; several non-governmental associations spread across all regions of Brazil; in addition to some products available on pharmacy shelves.

Despite the prohibitions currently in force, the national market continues to grow, following international trends and hoping for better regulation in the country.

## THANKS

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