IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
WACO DIVISION

Canopy Growth Corporation, Plaintiff, v. GW Pharmaceuticals PLC, Defendant.	)	Civil Action No. 6:20-cv-1180 **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Canopy Growth Corporation ("Canopy") files this complaint for patent infringement against Defendant GW Pharmaceuticals PLC ("GW") and in support thereof alleges and avers as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, specifically including 35 U.S.C. § 271.

THE PARTIES

2. Canopy is a publicly traded corporation, incorporated in Canada, with its head office located at 1 Hershey Drive, Smiths Falls, Ontario, Canada, K7A 0A8.

3. On information and belief, GW is a public limited company organized under the laws of the United Kingdom, with a principal place of business at Sovereign House, Vision Park, Chivers Way, Histon, Cambridge, CB24 9BZ United Kingdom.

JURISDICTION AND VENUE

4. Canopy asserts claims for patent infringement against GW arising under the patent laws of the United States, Title 35 of the United States Code. Accordingly, this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

5. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(c). GW is a foreign entity and may be sued in any judicial district pursuant to 28 U.S.C. § 1391(c)(3).

6. This Court has personal jurisdiction over GW consistent with the requirements of the Due Process Clause of the United States Constitution and the Texas Long Arm Statute, due at least to its substantial business in Texas and this judicial district, including: (1) regularly doing or soliciting business, engaging in other persistent conduct, and/or deriving substantial revenue from goods sold and/or services provided to Texas residents; and (2) at least part of its infringing activities alleged herein. On information and belief, GW's flagship product, Epidiolex, which is produced using Canopy's patented extraction process, has been prescribed to patients in this district and across the state of Texas. Additionally, on information and belief, GW enlisted residents of Austin, TX, which is within this district, to participate in a study conducted as part of obtaining Food and Drug Administration (FDA) approval of Epidiolex. *See* Exhibit F.

7. This Court has personal jurisdiction over GW, directly or through intermediaries, including GW's U.S.-based sales team, because it has committed acts within Texas giving rise to this action and/or has established minimum contacts with Texas such that personal jurisdiction over GW would not offend traditional notions of fair play and substantial justice. On information and belief, GW, without authority, imports Epidiolex, which is made by Canopy's patented extraction process, into the United States (including the state of Texas and within this district) and/or offers to sell, sells, and/or uses Epidiolex within the United States (including the

state of Texas and within this district). On information and belief, GW markets Epidiolex throughout the United States, including in the state of Texas, through a commercial organization consisting of sales, medical affairs, marketing, and market access/payer teams.

8. On information and belief, Defendant has placed and continues to place products produced using Canopy's patented process, including at least Epidiolex, into the stream of commerce via an established distribution channel with the knowledge and/or intent that Epidiolex was sold and continues to be sold in the United States, including in the state of Texas and this district.

9. Accordingly, this Court may properly exercise personal jurisdiction over GW.

THE PATENT-IN-SUIT

10. U.S. Patent No. 10,870,632 (the "'632 Patent"), titled "Process For Producing An Extract Containing Tetrahydrocannabinol And Cannabidiol From Cannabis Plant Material, And Cannabis Extracts," was duly and legally issued by the United States Patent and Trademark Office (USPTO) on December 22, 2020. Canopy is the owner by assignment of the entire right, title, and interest in and to the '632 Patent, including the sole and undivided right to sue for infringement. A true and correct copy of the '632 Patent is attached hereto as Exhibit A.

BACKGROUND OF THE DISPUTE

11. This dispute relates to GW's continued, unauthorized use of Canopy's patented processes for extracting cannabidiol from cannabis plant material. Cannabidiol, or CBD, is one ingredient found in plants of the cannabis family that includes what are commonly known as hemp and marijuana. Unlike Δ^9-tetrahydrocannabinol, or THC—another of the active ingredients in cannabis—CBD does not cause noticeable intoxicating, euphoric effects. Current

research is ongoing, but indicates that CBD offers significant therapeutic benefits, including anti-inflammatory, analgesic, antiemetic, and anti-seizure effects.

12. Canopy is a Canadian corporation that focuses on legal development of hemp and marijuana-based compounds and resulting products, with operations in countries across the world. Canopy produces, distributes, and sells a diverse range of cannabis and hemp-based products and other consumer products for both recreational and medical purposes under a portfolio of distinct brands in Canada pursuant to the *Cannabis Act*, and globally pursuant to applicable international and Canadian legislation, regulations, and permits. Subsequent to the passage of the U.S. Agricultural Improvement Act of 2018 in December 2018, Canopy began building its hemp supply chain in the United States through its investment in hemp growing capability and in processing, extraction and finished goods manufacturing facilities. Canopy sells a line of hemp-derived CBD isolate products under the First & Free Brand, including oils, softgels and topical creams, and in September 2020, Canopy launched Martha Stewart CBD, a new line of premium quality, hemp-derived wellness gummies, oils and softgels.

13. Canopy acquired all right, title, and interest in the '632 Patent in connection with its acquisition of Germany's C3 Cannabinoid Compound Company, founded by top global herbal medicine manufacturer Bionorica SE. The '632 Patent is part of a patent family dating back more than twenty years to October 17, 2000, with the filing by named inventor Adam Mueller of German Patent Application No. 100 51 427, to which the '632 Patent claims priority. The '632 Patent family relates to pioneering processes for producing an extract from cannabis plant matter containing CBD using carbon dioxide (CO_2). *See* Ex. A at Abstract. The potential therapeutic applications of CBD and other cannabis active principles were a motivating factor in developing the processes described and claimed in the '632 Patent. Indeed, the '632 Patent identifies a variety

of anticipated medical applications, notably including the use of CBD as an anti-epileptic. *See, e.g.*, *id.* at 3:53-4:3.

14. GW is a biopharmaceutical company involved in the development and commercialization of cannabinoid therapeutics. On information and belief, GW's leading cannabinoid product is Epidiolex, an anti-epileptic medication consisting of a pharmaceutical formulation of highly purified CBD. As detailed below, on information and belief, GW manufactures the active pharmaceutical ingredient in Epidiolex—CBD—using the CO_2-based extraction process described and claimed in the '632 Patent. On information and belief, Epidiolex was approved by the FDA on June 25, 2018 for the treatment of seizures associated with certain diseases. On information and belief, Epidiolex became commercially available in the United States on November 1, 2018. On information and belief, GW has set a list price for Epidiolex of $1,235 per 100mL bottle, with a weighted average gross price of approximately $32,500 per patient per annum. GW reported approximately $366 million in net product sales of Epidiolex in the United States in the first nine months of 2020. On information and belief, the success of GW's Epidiolex is based, at least in part, on GW's use, without authority, of the CO_2 extraction process described and claimed in the '632 Patent, which enables the production of a CBD-rich extract from cannabis material.

15. On information and belief, GW is aware, or should be aware, that the extraction process it uses to manufacture Epidiolex infringes the claims of the '632 Patent. Although the '632 Patent recently issued, on information and belief, GW has been monitoring the '632 Patent family for over fourteen years. In May 2006, for instance, GW proactively challenged the issuance of a European counterpart application (European Patent No. EP 1 326 598) by filing an opposition before the European Patent Office. By the time GW filed its opposition, the parent

application of the ’632 Patent—U.S. Patent Application No. 10/399,362, which issued as U.S. Patent No. 8,895,078 (the “’078 Patent”)—had already been filed. In light of its monitoring and proactive steps to invalidate a European counterpart, GW knew, or should have known, of the existence of the U.S. counterpart applications in the ’632 Patent family.

16. Notably, on information and belief, GW in 2016 considered using Canopy’s predecessor in interest, Bionorica—an early pioneer of CO_2 extraction techniques—as its processor for extracting CBD. By this time, the ’078 Patent had already issued and the application that ultimately issued as the ’632 Patent had been filed. Although that deal did not materialize, these negotiations further evidence that GW has been aware of the patented processes described and claimed in the ’078 and ’632 Patents for many years. Indeed, in 2017, GW declined a license to the ’078 Patent. This case is not about restricting patient access to Epidiolex. Rather, Canopy brings this action to put a stop to GW’s knowing and unauthorized use of Canopy’s intellectual property.

PATENT INFRINGEMENT CLAIMS

Count I: Infringement of U.S. Patent No. 10,870,632

17. Canopy re-alleges and incorporates herein by reference the allegations contained in Paragraphs 1-16 above.

18. The ’632 Patent generally relates to a process for producing an extract containing tetrahydrocannabinol (THC), CBD, and optionally the carboxylic acids thereof from cannabis plant material. *See* Ex. A at 1:23-26. The patent describes that one “object of the present invention [is] to provide Δ^9-tetrahydrocannabinol, Δ^8-tetrahydro-cannabinol and cannabidiol in pure form and as an extract in the form of preparations for medical applications,” and to obtain these active principles from hemp varieties having low cannabinoid contents (e.g., fiber-type

hemp) because of their better availability. *Id.* at 4:59-67. When hemp of the fiber-type is used as a starting material, cannabidiol (and/or the carboxylic acids thereof) are found as the main constituents in the primary extract. *Id.* at 6:45-48. The patent explains that "[a]s cannabidiol taken for itself has interesting pharmacological properties while further lacking the psychotropic hallucinogenic effect of Δ^9-THC, cannabidiol itself is also of interest for practical application because it may be used, e.g., as an anti-epileptic." *Id.* at 9:29-33.

19. The processes described in the '632 Patent significantly improved upon other approaches to enriching, isolating, and/or synthesizing cannabinoids, and in particular those that relied on hexane and ethanol extracts. The extract produced from the patented processes can be used as an active principle for the production of a medication (e.g., for the indications described above, including as an anti-epileptic). *Id.* at 3:53-4:3, 14:22-27.

20. On information and belief, GW infringes one or more claims of the '632 Patent, either literally or under the doctrine of equivalents. Non-limiting examples of such infringement are provided below, based on the limited information currently available to Canopy.

Claim 1 of the '632 Patent recites as follows:

> A process for producing an extract containing Tetrahydrocannabinol (THC) and/or cannabidiol (CBD), and optionally the carboxylic acids thereof, from a *cannabis* plant material or a primary extract thereof, said process comprising:
>
> (1) subjecting the *cannabis* plant material or primary extract thereof to CO_2 in liquefied form under subcritical pressure and temperature conditions to extract cannabinoid components; and
>
> (2) reducing the pressure and/or temperature to separate tetrahydrocannabinol and/or cannabidiol, and optionally the carboxylic acids thereof, from the CO_2.

Claim 14 of the '632 Patent recites as follows:

> A process for producing an extract containing Tetrahydrocannabinol (THC) and/or cannabidiol (CBD) from a *cannabis* plant material or a primary extract thereof, said process comprising:

(1) decarboxylating cannabinoid carboxylic acids in the *cannabis* plant material or primary extract thereof;

(2) subjecting the decarboxylated *cannabis* plant material or primary extract thereof to CO_2 in liquefied form under subcritical pressure and temperature conditions to extract cannabinoid components; and

(3) reducing the pressure and/or temperature to separate tetrahydrocannabinol and/or cannabidiol from the CO_2.

21. On information and belief, GW performs each and every limitation of Claims 1 and 14, as well as many of the dependent claims of the '632 Patent. On information and belief, GW performs a process for producing an extract containing Tetrahydrocannabinol (THC) and/or cannabidiol (CBD). *See generally* Ex. B ("Our Cannabidiol Manufacturing Process"). The extract is produced from a cannabis plant material or a primary extract thereof. For example:

Ex. B at 1.

- The finished product is lightly compressed into bales and labelled with an individual batch item code and batch number for traceability, and prepared for dispatch to the processing center.
- On arrival at the processing plant, the dried plant material is pelleted, allowing the batch to be stored in a stable form for an extended period prior to further processing.

Id. Additionally, on information and belief, GW uses "plants of *Cannabis sativa* L, with defined chemical profiles and containing consistent levels of CBD as the major cannabinoid and a low level of delta-9-tetrahydrocannabinol (THC)." Ex. C at 12; *see also* Ex. D at 15:15-19 ("High CBD chemovars were grown, harvested and dried and stored in a dry room until required. The botanical raw material (BRM) was finely chopped using an Apex mill fitted with a 1 mm screen. The milled BRM was stored in a freezer for up to 3 months prior to extraction.").

22. On information and belief, GW's process includes decarboxylating cannabinoid carboxylic acids in the cannabis plant material or primary extract thereof. For example, GW achieves "active CBD via decarboxylation":

ACHIEVING ACTIVE CBD VIA DECARBOXYLATION

Since cannabinoids are naturally produced in the plant in their acid form, a chemical reaction called decarboxylation is used to convert the inactive acid into the active molecule CBD.

- Pelleted material is milled to create a uniform particle suitable for extraction.
- Naturally occurring cannabidiolic acid is heated to convert it to CBD that is biologically active.

Ex. B at 1. *See also* Ex. E at 5:33-40 ("In a first aspect the invention provides a method of extracting cannabinoids from plant material comprising a decarboxylation step[.]").

23. On information and belief, GW's process includes subjecting the decarboxylated cannabis plant material or primary extract thereof to CO_2 in liquefied form under subcritical pressure and temperature conditions to extract cannabinoid components. For example, "[a]fter decarboxylation is complete, the raw material is loaded into an extraction column and CO_2 is passed through at a pre-specified temperature until the extraction process is complete":

YIELDING A CBD-RICH EXTRACT

After decarboxylation is complete, the raw material is loaded into an extraction column and CO_2 is passed through at a pre-specified temperature until the extraction process is complete.

CO_2 extraction process destroys any bacteria present in the plant material and yields a CBD-rich extract containing cannabinoids and other natural plant-based components, including waxes and terpenes (aromatic compounds).

Ex. B at 1. *See also* Ex. D at 15:29-30 ("Extraction No 1 was performed using liquid CO_2 at 60 bar/10° C. to produce botanical drug substance (BDS)."); Ex. E at 5:33-40 ("In a first aspect the invention provides a method of extracting cannabinoids from plant material comprising a decarboxylation step, an extraction with liquid carbon dioxide (CO_2), and a step to reduce the proportion of non-target materials in the extract, characterised in that the extraction with liquid CO_2 is conducted under sub-critical conditions at a temperature of between 5-15° C and a pressure of between 50-70 bar.").

24. On information and belief, GW's process includes reducing the pressure and/or temperature to separate tetrahydrocannabinol and/or cannabidiol from the CO_2. For example:

> In a preferred embodiment liquid CO_2 is removed by depressurisation and the recovered extract held at a temperature in the range from -15°C to -20°C.

Id. at 7:21-23.

25. In view of the foregoing, GW infringes at least Claims 1 and 14 of the '632 Patent in violation of 35 U.S.C. § 271. Canopy's investigation of GW's operations and manufacturing process is ongoing. To the extent it is determined that GW uses Canopy's patented processes to produce CBD (the active pharmaceutical ingredient in Epidiolex) in the United States, GW directly infringes the '632 Patent in violation of 35 U.S.C. § 271(a).

26. To the extent that GW, and/or third-party contractors under the direction of GW, use the patented processes to produce the CBD in Epidiolex outside the United States, GW infringes the '632 Patent in violation of 35 U.S.C. § 271(g). On information and belief, GW, without authority, imports or has Epidiolex imported into the United States and/or offers to sell, sells, and/or uses Epidiolex within the United States. On information and belief, the active pharmaceutical ingredient in Epidiolex is CBD extracted using the process(es) claimed in the '632 Patent, and the extracted CBD is not materially changed by subsequent processes and does not become a trivial and nonessential component of another product.

27. Additionally, on information and belief, GW is liable for actively inducing infringement of the '632 Patent under 35 U.S.C. § 271(b) by having knowledge of the '632 Patent and knowingly causing or intending to cause, and continuing to knowingly cause or intend to

cause, infringement of the ’632 Patent, with specific intent, by others. For example, on information and belief, GW, with knowledge that the active pharmaceutical ingredient in Epidiolex, CBD, is made outside the United States by a process patented by the ’632 Patent, has actively induced and continues to induce third parties (e.g., physicians and/or pharmacies) and end users (e.g., patients) to offer for sale, sell, and/or use Epidiolex in the United States in violation of 35 U.S.C. § 271(g). On information and belief, GW, acting alone and/or through intermediaries, markets Epidiolex throughout the United States through a commercial organization consisting of sales, medical affairs, marketing, and market access/payer teams. On information and belief, GW’s marketing plan includes a combination of community neurology/epilepsy meetings, patient advocacy events, an extensive program for U.S. clinicians to share their Epidiolex experiences and a media-based awareness program.

28. On information and belief, GW’s infringement of the ’632 Patent has been and continues to be willful and deliberate. As detailed above, on information and belief, GW has had actual and constructive notice of the ’632 Patent family since at least as early as May 2006, and knowledge of the ’632 Patent as early as its U.S. filing date and no later than the date of service of this complaint. Despite having knowledge of the ’632 Patent and its infringement, on information and belief, GW has and continues to: (1) use Canopy’s patented processes to extract CBD in the United States and/or outside the United States; (2) import and/or have Epidiolex imported into the United States, with knowledge that the active pharmaceutical ingredient of Epidiolex is CBD produced by Canopy’s patented processes; and/or (3) offer to sell, sell, and/or use Epidiolex within the United States in violation of one or more of 35 U.S.C. §§ 271(a) and (g). On information and belief, GW also has and continues to actively induce others to offer to sell,

sell, and/or use Epidiolex, the active pharmaceutical ingredient of which is CBD produced by Canopy's patented processes, within the United States in violation of 35 U.S.C. § 271(b).

29. As a direct and proximate result of GW's acts of infringement, Canopy has suffered and continues to suffer damages and irreparable harm.

JURY DEMAND

Pursuant to Fed. R. Civ. P. 38(b), Canopy hereby demands a trial by jury of all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Canopy prays for judgment in its favor granting the following relief:

A. A finding that GW has infringed the '632 Patent in violation of one of more subsections of 35 U.S.C. § 271, including but not limited to subsections (a), (b), and/or (g);

B. An award of damages pursuant to 35 U.S.C. § 284 adequate to compensate Canopy for GW's infringement of the '632 Patent, including both pre- and post-judgment interest and costs as fixed by the Court;

C. A finding that GW's infringement of the '632 Patent has been willful and an appropriate enhancement of damages pursuant to 35 U.S.C. § 284;

D. A declaration that this is an exceptional case within the meaning of 35 U.S.C. § 285, and a corresponding award of Canopy's reasonable attorneys' fees incurred in connection with the litigation; and

E. Any additional and further relief the Court may deem just and proper under the circumstances.

December 22, 2020

BAKER BOTTS L.L.P.

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US010870632B2

(12) **United States Patent**
Mueller

(10) **Patent No.: US 10,870,632 B2**
(45) **Date of Patent: *Dec. 22, 2020**

(54) **PROCESS FOR PRODUCING AN EXTRACT CONTAINING TETRAHYDROCANNABINOL AND CANNABIDIOL FROM CANNABIS PLANT MATERIAL, AND CANNABIS EXTRACTS**

(71) Applicant: **Bionorica Ethics GmbH**, Neumarket (DE)

(72) Inventor: **Adam Mueller**, Coburg (DE)

(73) Assignee: **BIONORICA ETHICS GMBH**

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 150 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **14/276,165**

(22) Filed: **May 13, 2014**

(65) **Prior Publication Data**

US 2014/0248379 A1 Sep. 4, 2014

Related U.S. Application Data

(63) Continuation of application No. 10/399,362, filed as application No. PCT/EP01/11967 on Oct. 16, 2001, now Pat. No. 8,895,078.

(30) **Foreign Application Priority Data**

Oct. 17, 2000 (DE) 100 51 427

(51) **Int. Cl.**

A61K 36/00	(2006.01)
C07D 311/80	(2006.01)
A61K 31/35	(2006.01)
A61K 36/185	(2006.01)

(52) **U.S. Cl.**

CPC ***C07D 311/80*** (2013.01); ***A61K 31/35*** (2013.01); ***A61K 36/185*** (2013.01); *Y02P 20/54* (2015.11)

(58) **Field of Classification Search**

None

See application file for complete search history.

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Primary Examiner — Michael Barker
Assistant Examiner — Randall O Winston
(74) *Attorney, Agent, or Firm* — Sheridan Ross P.C.

(57) **ABSTRACT**

The invention relates to a method for producing an extract from *cannabis* plant matter, containing tetrahydrocannabinol, cannabidiol and optionally the carboxylic acids thereof. According to said method, the dried pint matter is ground and subjected to a CO_2 extraction and the primary extract obtained is separated. The invention method permits Δ^8 or Δ^9 tetrahydrocannabinol to be selectively obtained both from industrial hemp and from drug-producing hemp, optionally after dissolving the primary extract in ethanol, separating undesirable waxes and removing the solvent under reduced pressure.

25 Claims, 3 Drawing Sheets

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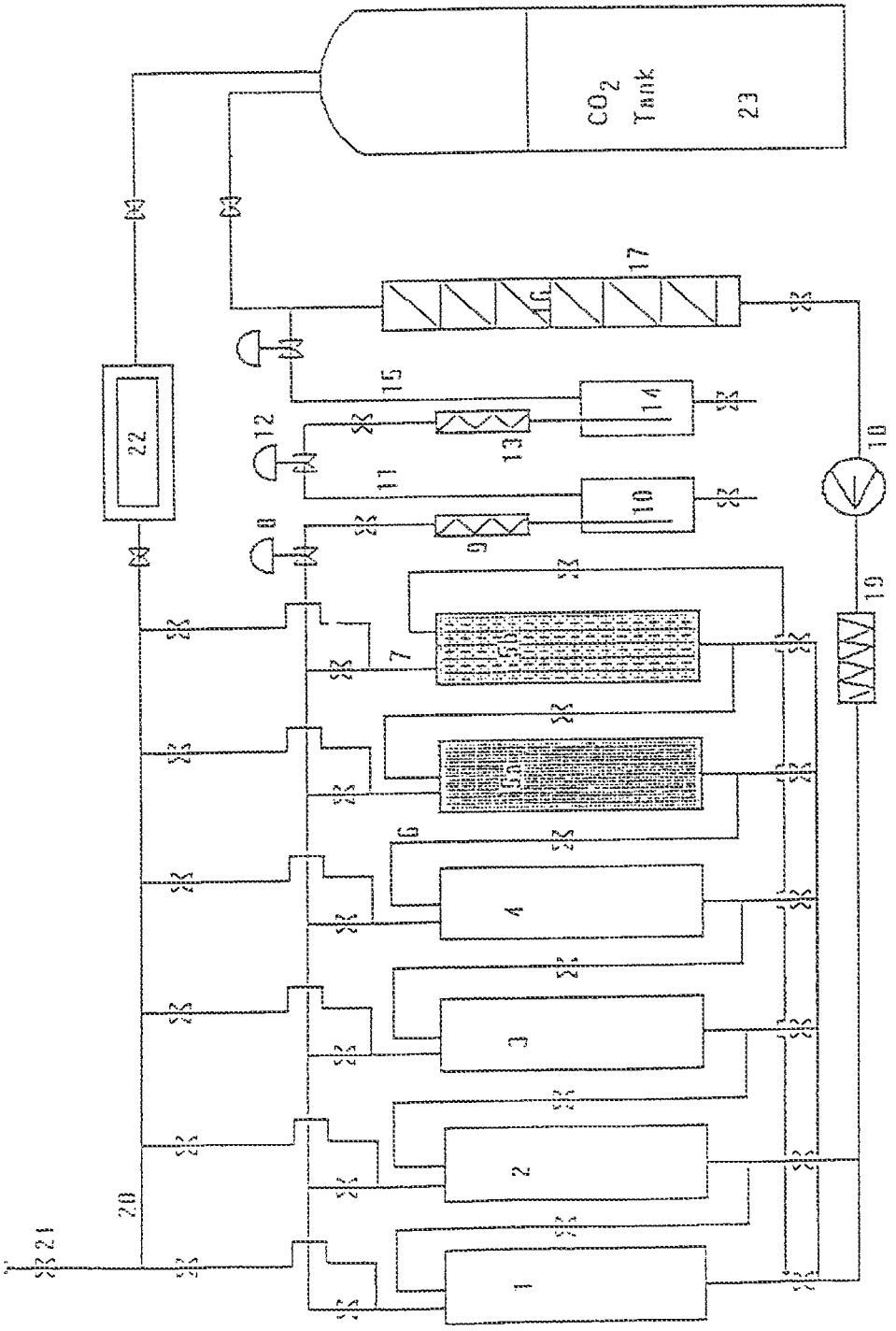

Fig. 1

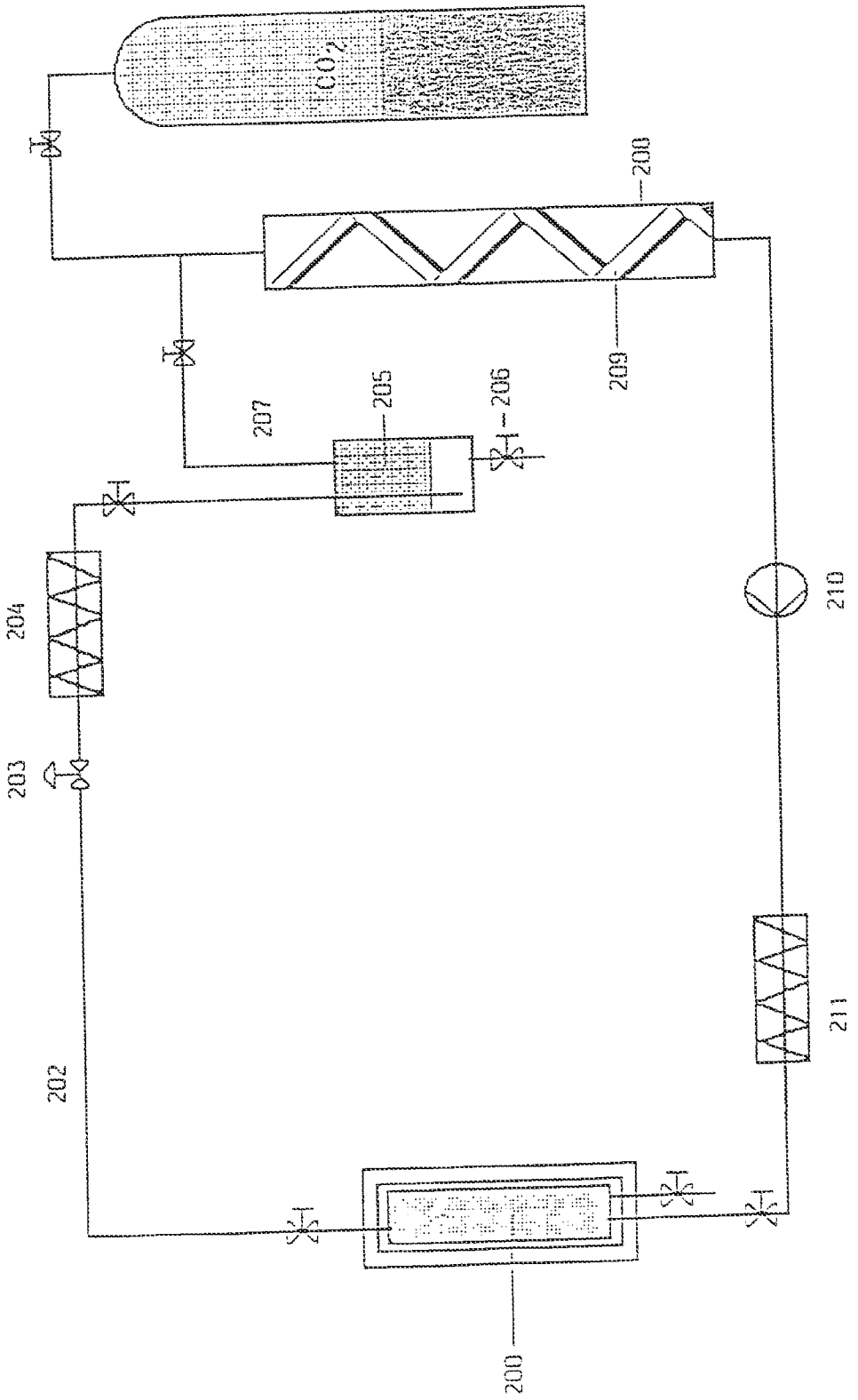

Fig. 2

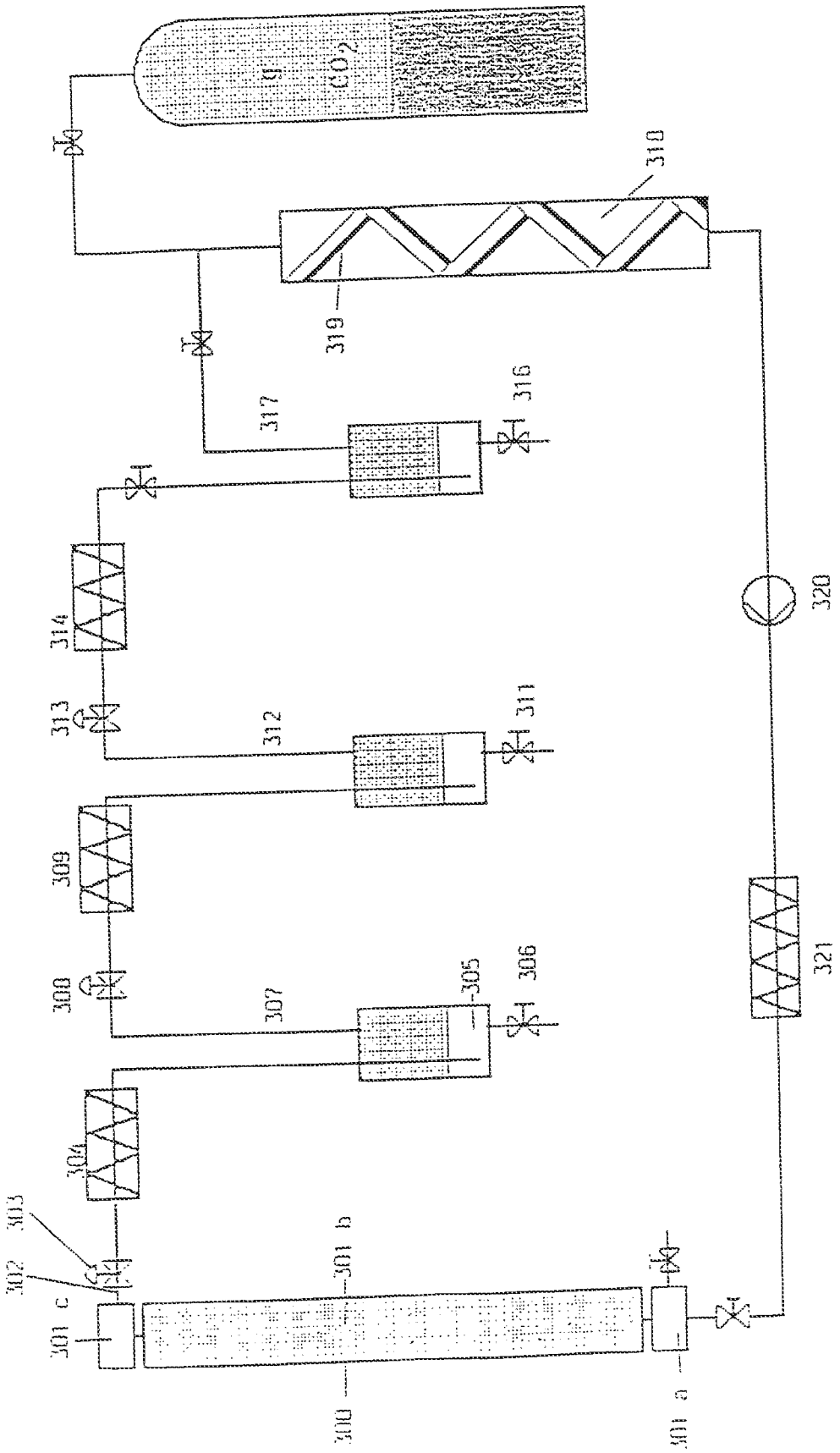
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Fig. 3

PROCESS FOR PRODUCING AN EXTRACT CONTAINING TETRAHYDROCANNABINOL AND CANNABIDIOL FROM CANNABIS PLANT MATERIAL, AND CANNABIS EXTRACTS

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a Continuation of co-pending application Ser. No. 10/399,362, filed on Oct. 16, 2013, and for which priority is claimed under 35 U.S.C. § 120; and this application is the National Phase of PCT/EP01/11967 filed on Oct. 16, 2001, which claims priority of application Ser. No. 10/051,427.8 filed in Germany on Oct. 17, 2000 under 35 U.S.C. § 119. The entire contents of these applications are hereby incorporated by reference.

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to a process for producing an extract containing tetra-hydrocannabinol, cannabidiol, and optionally the carboxylic acids thereof from *cannabis* plant material in accordance with the preamble of claim **1**, a primary extract from *cannabis* plant material in accordance with claim **8**, and a process for producing tetrahydrocannabinol in accordance with claim **13** and a process for producing cannabidiol in accordance with claim **14**.

Cannabis (hemp), together with the genus *Humulus* (hops), belongs to the family of Cannabinaceae, with hops, for instance, not containing any cannabinoids. For the botanical and chemotaxonomical differentiation of the genus *Cannabis* there are two different concepts. One differentiates between three species, *Cannabis sativa Linnaeus, Cannabis indica* LAM., and *Cannabis ruderalis*, while a different theory only sees the existence of the one collective species *Cannabis sativa* L. made up of the subspecies *Cannabis sativa* ssp. *sativa* and ssp. *indica*. Moreover the *cannabis* plant is differentiated into a drug type and a fiber type, with differentiation being performed on the basis of the quantity ratio of the main cannabinoids, cannabidiol (CBD) and Δ^9-tetrahydrocannabinol (Δ^9-THC). Fiber hemp, whose cultivation is permitted for fiber production, must not exceed a Δ^9-THC content of 0.3% relative to the dry plant mass, while the drug type may exhibit a Δ^9-THC content of approx. 5%-15% relative to the dry plant mass.

The ratio of Δ^9-THC to CBD in fiber hemp is mostly less than 1.5. The varieties rich in Δ^9-THC may reach a ratio of 2:1 to 7:1. *Cannabis sativa* L. occurs worldwide in all warm and moderate zones with the exception of the humid tropical rain forests. It is an annual to biennial, anemogamous herb which may attain a height of up to 8 m. The dioecous, rarely monecious inflorescences contain the active cannabinoids in the resin which is mainly secreted by the numerous glandular bracts in the leaf axils. As a general rule, all the plant parts of *Cannabis sativa* L. with the exception of the seeds may contain cannabinoids. The highest cannabinoid concentrations are found in the floral bracts and fruit stalks. The leaves have a low content of cannabinoids as a function of leaf age, while the stalk and particularly the root exhibit clearly lower cannabinoid contents.

In Germany, the known *cannabis* preparations having a hallucinogenic effect, marijuana and hashish, are subject to the regulations of the Narcotics Act as non-traffickable narcotics like opium, morphine, heroin, cocain and LSD.

Cannabis sativa L. contains more than 420 different components, with 61 compounds of these belonging to the class of cannabinoids. These are lipophilic, nitrogen-free, mostly phenolic compounds. The neutral cannabinoids are biogenetically derived from a monoterpene and a phenol, the acidic cannabinoids from a monoterpene and a phenolic acid, and present a C_{21} parent substance. In literature, two different numbering systems for cannabinoids are found. The older numbering system is based on the monoterpene skeleton, whereas the more recent IUPAC designation which is exclusively employed in the present application, relates to the dibenzopyrane skeleton.

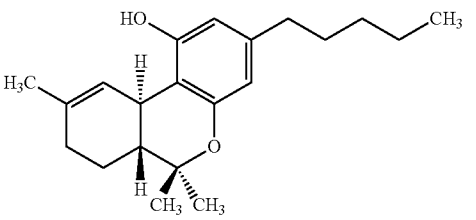
Among the most important cannabinoids there are:

Δ^9-tetrahydrocannabinol	Δ^9-THC
Δ^8-tetrahydrocannabinol	Δ^8-THC
cannabichromene	CBC
cannabidiol	CBD
cannabigerol	CBG
cannabinidiol	CBND
cannabinol	CBN

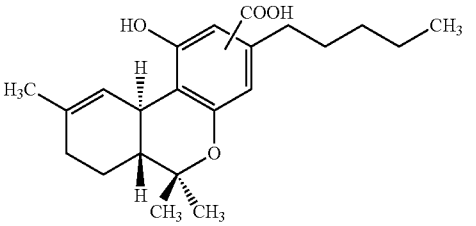
Besides the above mentioned cannabinoids, the associated carboxylic acids thereof are moreover found in the raw drug as well as in the plant products. As a general rule, the carboxylic acids have the function of a biosynthetic precursor. Thus, for instance, the tetrahydrocannabinols and Δ^5-THC and CBD are generated in vivo from the THC carboxylic acids by decarboxylation from the associated cannabidiol carboxylic acids.

Δ^8-THC may, for instance, also form upon cyclization of CBD. Another possibility is that Δ^8-THC may be generated under certain conditions, for instance acidity, by double bond isomerism from Δ^9-THC or its carboxylic acid, respectively.

In the following, the chemical structures of some cannabinoid active principles and the nomenclature of the two active principles at tetrahydrocannabinol are specified, which beer the IUPAC names (6aR-trans)-6a,7,8,10-tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo[b,d]pyran-1-ol or Δ^9-THC and (6aR-trans)-6a,7,10,10a-tetrayhydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo[b,d]pyran-1-ol or Δ^8-THC, Δ^9-THC is also known under the designation of Dronabinol.



Δ^9-Tetrahydrocannabinol



Δ^9-Tetrahydrocannabinol carboxylic acid

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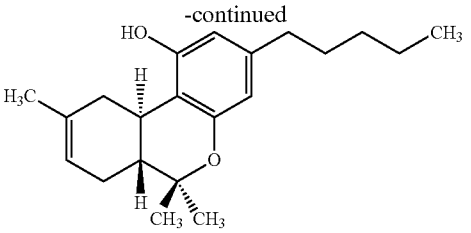
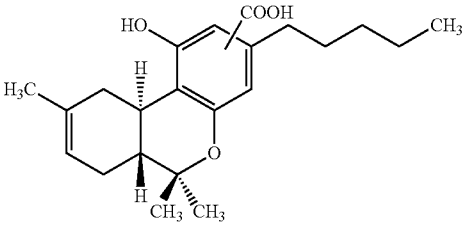
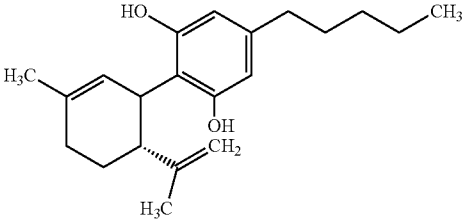


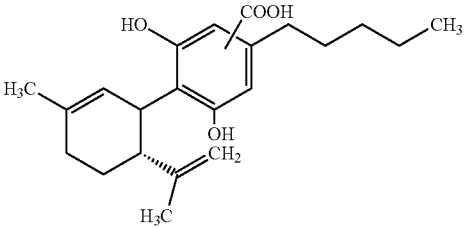
Δ^8-Tetrahydrocannabinol



Δ^8-Tetrahydrocannabinol carboxylic acid



Cannabidiol



Cannabidiol carboxylic acid

In the framework of the present invention, the expression "tetrahydrocannabinol" or "THC"—where not otherwise specified—is to encompass any isomers, in particular double bond isomers.

In any cultures and for a long time, cacannabis has been a traditional drug and a remedy. Up into the 20th century, *cannabis* was employed for the most variegated ailments—from asthma to migraine. Restrictive legislation against *cannabis* on the part of the USA, however, brought about its complete disappearance from the pharmacopoeiae and from physicians' repertories of treatment.

In the meantime, many of the therapeutical effects handed down are corning to be confirmed in clinical research. At present, the pharmacological use of *cannabis* active principles is of importance essentially in the following indications:

- the appetite stimulating effect, in particular in the case of AIDS-related afflictions accompanied by cachexia and wasting syndrome,
- the antiemetic action for inhibiting nausea and vomiting, particularly in connection with chemotherapy under administration of cytostatic agents,
- the reduction of muscle cramps and spasms in multiple sclerosis and tray lesions of the cord with paraplegia,
- pain and migraine treatment—in chronic pain therapy also complementarily with opioid treatment,
- lowering intra-ocular pressure glaucoma.
- mood improvement,

and in particular cannabidiol as an anti-epileptic.

Owing to the inter sting therapeutic range of the cannabinoids, a number of experiments were carried out to enrich, isolate and/or synthesize the cannabinoids exclusively from drug hemp.

Thus, e.g., DE 41 00 441 A1 discloses a process for producing 6,12-dihydro-6-hydroxy-cannabidiol and its use for producing trans-Δ^9-tetrahydrocannabinol. In particular DE 41 00 441 A1 describes the manufacture of 6,12-dihydro-6-hydroxy-cannabidol, which is obtained by reacting olivetol and cis-p-menth-2-ene-1,8-diol and its further reaction to trans-2-tetrahydrocannabinol by using suitable catalysts.

A drawback of this prior-art process, however, is the relatively high expenditure and the ultimately costly product obtained.

Apart from this, solvent extraction, e.g. with the aid of ethanol, and steam distillation of *cannabis* constituents is known; in particular a hashish oil (*cannabis* resin extract) also referred to as Oil, Red Oil or Indian. Oil is known, which is produced with the aid of solvent extraction or distillation from *cannabis* herb or *cannabis* resin and which is a dark brown, viscous and sticky oil. The oil thus obtained is subsequently mostly diluted w edible oil for improved handling and contains up to 65% of the hallucinogenic agent Δ^9-THC (Kielber/Kovan *Auswirkungen des Cannabiskonsums: Eine apertise zu pharmakelogischen and psychosozialen Konsequenzens*, Stuttgart: Wiss. Verl.-Ges. 1998).

Dronabinol, Δ^4-THC, has meanwhile been approved in the USA in accordance with USP [United States Pharmacopeia]24, pp. 613, 14 as a medicament—also in capsule form—. In accordance with this monography, dronabinol contains no less than 95% of Δ^9-THC and no more than 2% of Δ^8-THC.

As of Feb. 1, 1998, dronabincl may be prescribed as an anaesth in Germany.

WO 00/25127 A1 moreover relates to the extraction of hemp for the isolation of tetrahydrocannabinol from the natural *cannabis* plant. What is described in particular is an extraction process with an apolar organic solvent, followed by fractional distillation under reduced pressure in order to produce distillates having high tetrahydrocannabinol contents. As suitable apolar solvents, lower alkanes such as, e.g., hexane, heptane or isooctane are named in WO 00/25127 A1.

In accordance with Examples 1, 2, 3, 4 and 7 of reference WO 00/25127 A1 exclusively drug hemp having tetrahydrocannabinol dry concentrations of 2.20%-7.82% is extracted with hexane.

Such primary hexane extracts in accordance with WO 002517 A1 contain 28.76% (Example up to a maximum of 41.2% (Example 3) of tetrahydrmannabinol.

Apart from tetrahydrocannabinol, WO 00/25127 A1 does not disclose any further constituents of the hexane primary extract.

Starting out from the above explained prior art and from the new legal situation in the Federal Republic of Germany, it accordingly was the object of the present invention to provide Δ^9-tetrahydrocannabinol, Δ^8-tetrahydro-cannabinol and cannabidiol in pure form and as an extract in the form of preparations for medical applications, wherein the active principles should preferably be obtained from hemp varieties having low cannabinoid contents for the reason of better availability.

In terms of process technology, this object is accomplished through the characterizing features of claims **1**, **13** and **14**. With regard to an extract having the main constituents Δ^9-THC, Δ^8-THC and CBD, the above object is accomplished through the characterizing features of claim **8**.

In accordance with the invention, a primary extract containing tetrahydrocannabinol, cannabidiol, and optionally the carboxylic acids thereof, is obtained from *cannabis* plant material in that the dried plant material is comminuted, the plant material is extracted with the aid of CO_2 under supercritical pressure and temperature conditions at a temperature in the range of approx, 31° C. to 80° C. and at a pressure in the range of approx. 75 bar to 500 bar, or in the subcricital range at a temperature of approx. 20° C. to 30° C. and a supercritical pressure of approx. 100 bar to 350 bar; or extracted under subcricital pressure and temperature conditions; and the obtained primary extract is separated under subcricital conditions, or under conditions that are subcricital in terms of pressure and supercritical in terms of temperature.

In terms of cannabinoids, the primary extract of the invention contains high proportions of cannabidiol carboxylic acid (CBDS), cannabidiol (CBD), and Δ^9-tetra-hydrocannabinol carboxylic acid (Δ^9-THCS), and Δ^9-THC (when drug hemp is used).

The production of CO_2 extracts is known in principle. Thus, e.g., DE 198 00 330 A1 discloses the production of a pharmaceutically active extract from Tanacetum parthenium through CO_2 extraction with the aid of an extraction plant as used in the present invention.

As a particularly preferred *cannabis* plant material, for reasons of procurement on an industrial scale, one from*Cannabis sativa* in particular hemp of the fiber type, i.e. so-called industrial hemp, is used.

Owing to currently valid legislation, industrial hemp species of the fiber type may contain 0.3% of Δ^9-THC at maximum in the Federal Republic of Germany; for Switzerland an upperlimit of 0.5% Δ^9-THC applies, based on the dry plant mass in either case.

The like industrial hemp varieties may be cultivat d both in the Federal Republic of Germany and in Switzerland, for example, while requiring neither any complicated cultivating permission nor any complicated safety installations during storage.

It is thus advantageous if *cannabis* plant material of the fiber type r may be used for the production of primary extracts containing Δ^9-THC and CBD, for it is possible to employ such starting material having a low Δ^9-THC content for the inventive process without any further operating and handling permissions as are required in the case of drug hemp types.

Varieties entering into consideration here are in particular the French varieties Fedora 19, Felina 45 and Future 77, the Hungarianvarieties Kompolti and Uniko- and the Finnish variety Rhola 314, for the average for all varieties lies clearly below the specified limits (Mediavilla, V. nd Brenneisen, R. 1996: Mitt Gess Pflanzenbauwiss, 9; 243-244).

When it is possible to employ drug hemp types, however, the Δ^9-THC content in the primary extract is higher than in one produced of fiber hemp.

The addition to the CO_2 of an entraining agent selected from the group consisting of: propane, butane, ethanol and water, has the advantage that hereby the yields for Δ^9-THC and CBD may be increased without involving the drawbacks as with an extract produced, with ethanol or ethanol/water or methanol/chloroform or with other chlorinated hydrocarbons.

Typically the entraining agent concentrations are the range of 1-10% based on the employed quantity of CO_2.

The extraction process of the invention preferably operates in the supercritical range at a temperature of approx. 31° C. to 80° C. and a pressure of approx. 75 bar to 500 bar, in particular at a temperature of approx. 45° C. to 65° C. and a pressure of approx. 100 bar to 350 bar, preferably at a temperature of approx. 60° C. and a pressure of approx, 250 bar.

In the subcricital range, in contrast, a temperature of approx. 20° C. to 30° C. and a supercritical pressure of approx, 100 bar to 350 bar are used.

The measure of arranging a layer of adsorbent on the material to be extracted downstream relative to the CO_2 flow has the advantage that monoterpenes and sesquiterpenes as well as alkaloids, flavonoids and chlorophylls may be separated out, so that the inventive primary extracts are even the more superior to the ethanol extracts known in the prior art and to the extracts prepared with the aid of chlorinated hydrocarbons, for the latter in any case are fairly high in mono- and sesquiterpenes as well as chlorophylls, flavonoids and alkaloids.

As an alternative the CO_2 laden with THC and CBD as well as with proportions of reduced mono- and sesquiterpenes, flavonoids, chlorophylls and alkaloids may also be passed over adsorbers charged adsorbents or separators (FIG. **1**).

Preferred adsorbents are those selected from the group comprised of: silica gel, diatomaceous earth, bentonites, bleaching earth, activated carbons, in particular magnesium oxide and alumina, as well as mixtures thereof.

In order to increase the extraction yield, it is preferred to repeat extraction at least once, with extraction preferably being repeated with diatomaceous earth and/or some other adsorbent.

The inventive primary extracts from *Cannabis* plant material containing Δ^9-THC and cannabidiol are substantially free from monoterpenes and sesguiterpenes and moreover free from alkaloids and flavonoids, and contain practically no chlorophylls.

Where a hemp of the drug type is used as a starting material, Δ^9-THC is the mainconstituent of the primacy extract, and CBD the second highest proportion.

Where, however, a hemp of the fiber type is used as a starting material, which is being preferred, CBD and in a given case the carboxylic acids thereof are found as the main constituents of the primary extract.

The primary extract of the invention contains at least reduced proportions of menoterpene and sesquiterpene hydrocarbons, alkaloids, flavonoids and chlorophylls, and is preferably already free from these components, in particular from alkaloids, flavonoids and chlorophylls.

Where undesirable waxes are present in certain industrial and drug hemp varieties, these are purified after completed primary extraction and decarboxylation by subsequent dissolution of the primary extract, e.g., in cold (20° C.) ethanol or ethanol solution, and separated from the non-dissolved wax by filtration. The filtration residue amounts to approximately 3-5%. In order to obtain the purified extract, the solvent, e.g. ethanol, is again removed under reduced pressure.

In order to obtain Δ^9-THC and CBD from the primary extract thus purified, the cannabidiol carboxylic acids und Δ^9-tetrahydrocannabinol carboxylic acids contained in the primary extract are decarboxylated into cannabidiol and Δ^9-tetrahydrocanabinol through increase in temperature.

Where Δ^9-THC s to be obtained as the main constituent or in pure fry the CBD may be reacted into Δ^9-THC through catalyzed cyclization.

Here a Δ^8-THC may form depending on process conditions, which in itself also possesses interesting pharmacological properties. Thus Δ^8-THC may, for example, be employed as an antiemetic in pediatric oncology.

Where the primary extract was obtained from fiber hemp and the entire CBD is to be transformed to Δ^8-THC and Δ^9-THC, cyclization into Δ^8-THC and Δ^9-THC takes place during preparation of the secondary extract. Cyclization takes place under the following conditions:

The decarboxylated primary extract is mixed with a water-binding agent and a catalyst defined more closely hereinbelow. The mixture is treated in a high-pressure extraction plant (FIG. **2**) with supercritical CO_2, preferably at 300 bar and 70° C. By this treatment, the CBD present in the primary extract is substantially reacted to Δ^8-THC and Δ^9-THC.

The obtained extract is separated out under pressure and temperature conditions subcricital for CO_2, preferably at approx. 55 bar and approx, 25° C.

As a water-binding agent zeolitic molecular sieves having a pore size of 3-10 Å. preferably 5 Å may be used, and useful catalysts are metal-containing halogen salts containing the metals tin zinc, iron or titanium, preferably zinc chloride.

The secondary extract thus obtained only contains very little CSD and is highly enriched in Δ^8-THC and Δ^9-THC.

Suitably for obtaining pure or nearly pure Δ^9-THC or Δ^8-THC, respective y, a treatment in a high-pressure apparatus with supercritical CO_2 is performed as described in the following (FIG. **3**).

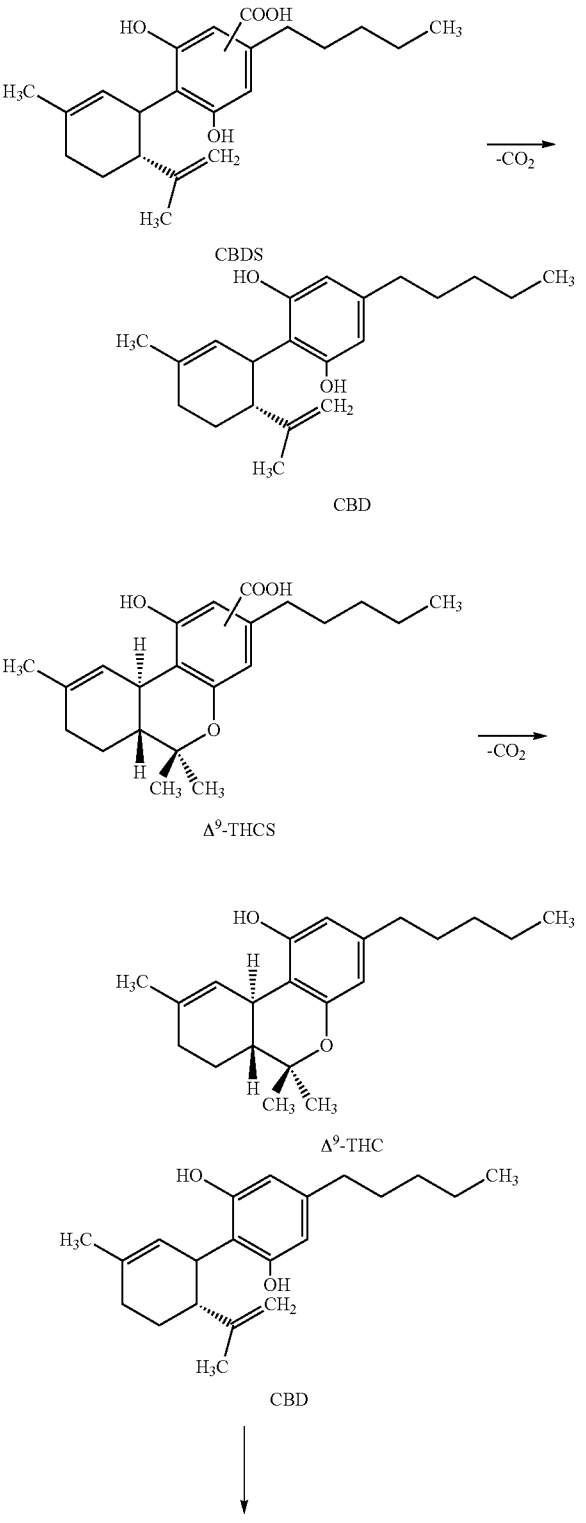
To this end, preferably a high-pressure column (FIG. **3**) subdivided into segments, comprising a bottom segment for dissolving the primary extract in supercritical CO_2, a purification segment filled, e.g., with silica gel (mean particle size of 0.02 mm to 0.2 mm, preferably 0.1 mm), a head segment for discharging the mixture dissolved in supercritical CO_2 of CBD, Δ^8-THC and Δ^9-THC into three separating vessels for separate separation of the purified CBD and the purified Δ^8-THC and THC.

The extraction conditions prevailing for purification in the column are supercritical for CO_2, preferably 180 bar and 55° C., in the first separating vessel where CBD is separated out for CO_2 suboricital conditions in terms of pressure and supercritical conditions in terms of temperature, preferably 70 bar and 50° C., in the second and third separating vessels, where Δ^8-THC and Δ^9-THC are separated out, conditions subcricital for CO_2 in terms of pressure and temperature are to prevail, in the second separating vessel preferably 60 bar and 30° C., in the third separating vessel preferably 55 bar and 25° C.

If fiber hemp is used, it may possibly be necessary to further purify the tetrahydrocannabinol products Δ^8-THC and Δ^9-THC thus obtained with the aid of additional processes such as preparative chromatography or HPLC.

Where the primary extract was obtained from drug hemp and purified CBD is furthermore desired as an end product besides purified Δ^9-THC, the cyclization of CBD into Δ^8-THC and Δ^9-THC, or the production of a secondary extract is omitted. Δ^8-THC is an isomer of Δ^9-THC and forms substantially during the cyclization of CBD to Δ^9-THC as well as in the presence of acids. Under certain circumstances it is necessary for the Δ^8-THC, Δ^9-THC and CBD thus obtained to be purified by further processes such as preparative chromatography or HPLC.

The reaction scheme of these reactions is given below:



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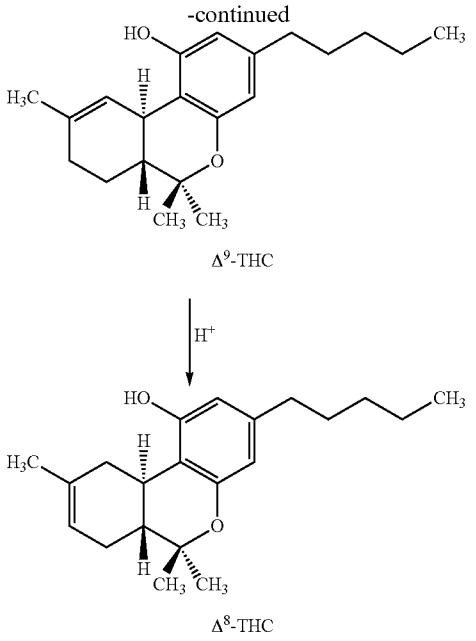

As may be seen from the scheme of formulae, Δ^9-THC may under the action of acids isomerize to Δ^8-THC.

As cannabidiol taken for itself has interesting pharmacological prorperties while further lacking the psychotropic hallucinogenic effect of Δ^9-THC, cannabidiol itself is also of interest for practical application because it may be used, e.g., as an anti-epileptic.

Cannabidiol may be obtained in accordance with the inventive process of claim **15**.

Δ^8-THC by itself also has substantially lower psychotropic hallucinogenic effects than Δ^9-THC and may be obtained in accordance with claim **14**.

BRIEF DESCRIPTION OF THE DRAWINGS

Further advantages and features of the present invention result from the description of practical examples and from the drawings, wherein:

FIG. **1** is a schematic representation of a CO_2 extraction plant for producing the primary extract of the invention;

FIG. **2** is a schematic representation of a CO_2 extraction plant for producing a secondary extract highly enriched in Δ^8-THC and Δ^9-THC; and

FIG. **3** is a schematic representation of a CO_2 extraction plant for separation of a primary and/or secondary extract in CBD optionally Δ^8-THC and Δ^9-THC in a high-pressure column.

DETAILED DESCRIPTION OF THE INVENTION

Ground *Cannabis* plant material comprised substantially of inflorescences and leaves is charged into extracting vessels **1-4**, CO_2 having been brought to a temperature of approx. 60° C. and to a pressure of approx, 250 bar, enters into contact with the material to be extracted in the extracting vessels **1-4** and extracts the desired cannabinoid components, in particular comprising Δ^9-tetrahydrocanhabinol and car nabdiolas well as the carboxylic acids thereof. Suitably for extraction a flow rate of 50-150 kg of CO_2/kg of starting material is used.

At the upper end of extracting vessel **4**, an extract enriched in the cannabinoids leaves the vessel via conduit **6***a* and arrives at the bottom of separating vessel **5***a*. The separating vessels **5***a* and **5***b* are in the exemplary case filled with various zeolitic molecular sieves and with diatomaceous earth as an adsorbent. In separating vessels **5***a* and **5***b*, the same pressure and temperature conditions prevail as in extracting vessels **1-4**. The zeolitic molecular sieves placed in container **6***a* have an internal surface of approx. 800 m^2/g, the zeolitic molecular sieves placed in container **5***b* have an internal surface of approx. 1200 m^2/g.

By charging containers **6***a* and **5***b* with molecular sieves—preferred, however not indispensable—alkaloids, flavonoids and chlorophylls are further separated from the CO_2 loaded with extract. This CO_2 extraction mixture thus purified exits from the head of vessel **5***b* via conduit **7**, pressure regulation valve **8**, with extraction pressure being reduced to less than 75 bar, in the exemplary case to approx. 60 bar. The CO_2 extract mixture then arrives at heat exchanger **9** where it is heated to a temperature supercritical for CO_2, preferably to 45° C.

Under these pressure and temperature conditions, extraction of that extract portion takes place in the separating vessel **10** which essentially still contains undesirable monoterpenes and sesquiterpenes. The extract mixture consisting of CO_2 and essentially of Δ^9-THC and cannabidiol as well as the carboxylic acids thereof, exits from separating vessel **10** via conduit **11**, pressure regulation valve **12**, heat exchanger **13**, and finally is conveyed into separating vessel **14**.

With the aid of pressure regulation valve **12**, the separation pressure in container **14** is set to pressure conditions subcricital for CO_2, in the exemplary case 50 bar. The separation temperature in vessel **14** is controlled by heat exchanger **13** to a temperature subcricital for CO_2, in the exemplary case about 20° C. Under these conditions the pure CO_2 is separated from the primary extract enriched in Δ^9-THC and cannabidiol and the carboxylic acids thereof in separating vessel **14**.

The pure CO_2 is conveyed via conduit **15** to liquefier **17** that is equipped with a condenser coil **16**. From here the liquid CO_2 is supplied via pressurizing pump **18** to heat exchanger **19**, to be available for the following extraction cycle.

For opening the extracting vessel, i.e., for charging and emptying the vessels with, or of, the starting material, the CO_2 is either vented directly via conduit **21**, or supplied via conduit **20** to recycling plant **22** which then pumps the liquid CO_2 into the CO_2 storage vessel **23**.

FIG. **2** shows a schematic representation of a CO_2 extractionplant for producing a secondary extract highly enriched in Δ^8-THC and Δ^9-THC.

For the reaction, in particular the decarboxylation, of the cannabinoid carboxylic acids contained in the primary extract into Δ^9-THC and CBD, the primary extract in the exemplary case is treated during about 2 hours at 80° C.

A mixture of decarboxylated primary extract, water-binding agent and catalyst is introduced into the extracting vessel **200**. CO_2 at a temperature of 70° C. and a pressure of 300 bar enters into contact with the material to be extracted and extracts the desired components.

Following cyclization, the secondary extract highly enriched in Δ^8-THC and Δ^9-THC exits from vessel **200** at the top end of extracting vessel **200** via conduit **202** and arrives in separating vessel **205** via regulating valve **203**—wherein pressure is reduced to 60 bar or 55 bar, respectively—and heat exchanger **204**, the temperature being 30°

C. or 25° C., respectively. Through valve **206** the secondary extract thus obtained, which contains small, amounts of CBD and is highly enriched in Δ^8-THC and Δ^9-THC, may be withdrawn from separating vessel **205**.

The pure CO_2 is conveyed via conduit **207** to liquefier **208** which is equipped with a condenser coil **209**. From there the liquid C_2 is supplied via pressurizing pump **210** to heat exchanger **211**, to be available for the following extraction cycle.

FIG. **3** shows a schematic representation of a CO_2 extraction plant for separation of a primary and/or secondary extract CBD, optionally Δ^8-THC and Δ^9-THC, in a high-pressure column.

Via action column **300** wherein an extraction pressure of 180 bar and a temperature of 55° C. prevail, consisting of bottom segment **301***a*, purification segment **301***b* (charged with silica gel) and had segment **301***c*, the extract mixture dissolved in CO_2 arrives via duct **302**, regulating valve **303** and heat exchanger **304** in separating vessel **305**, where preferably a pressure of 70 bar and a temperature of 50° C. are to prevail. It is here that the CBD is obtained.

Via duct **307**, regulating valve **308** and heat exchanger **309** the extraction mixture arrives in the second separating vessel **310**, preferably with a pressure of 60 bar and a temperature of 30° C. prevailing. It is here that the separation of Δ^8-THC takes place. Via valve **311** the obtained Δ^8-THC may be withdrawn.

The Δ^9-THC still dissolved in CO_2 is transferred into separating vessel **315** via duct **312**, regulating valve **313** and heat exchanger **314**. There it is separated out under a pressure of preferably 55 bar and a temperature of preferably 2.5° C. Via valve **316** the obtained Δ^9-THC may be withdrawn.

The pure CO_2 is conveyed via conduit **317** to liquefier **318** which is equipped with a condenser coil **319**. From here the liquid CO_2 is supplied via pressurizing pump **320** to heat exchanger **321**, to be available for the following extraction cycle.

Modifications in the described plant system possible without the scope of the invention being restricted thereby.

As industrial hemp of the fiber type, in the present exemplary case the French *Cannabis sativa* variety Fedora 19 is employed. The raw drug has an average content of approx. 0.25% of Δ^9-THC and 1.54% of CED.

As a result a primaryextract having the properties indicated in Table 1 is obtained.

TABLE 1

Primary extracts from industrial hemp with different solvents

Measured substance	EtOH primary extract	Hexane primary extract* in accordance with WO00/25127	Inventive primary CO_2 extract
Chlorophyll	3.00%	2.85%	0.010%
CBD	14.50%	12.40%	58.000%
Δ^9-THC	2.30%	2.30%	9.500%
Δ^8-THC	0.00%	0.00%	0.000%
CBN	0.50%	0.50%	0.100%
Flavonoid glycosides	12.50%	8.50%	0.150%
Alkaloids: cannabisativin	0.20%	0.35%	0.001%
Monoterpenes:			
α-Pinene	0.02%	0.03%	0.001%
ß-Pinene	0.01%	0.02%	0.001%
Myrcene	0.02%	0.02%	0.001%

TABLE 1-continued

Primary extracts from industrial hemp with different solvents

Measured substance	EtOH primary extract	Hexane primary extract* in accordance with WO00/25127	Inventive primary CO_2 extract
Sesquiterpenes:			
Caryophyllene	0.53%	0.45%	0.020%
ß-Humulene	0.18%	0.22%	0.008%
Δ-Selinene	0.10%	0.15%	0.004%

*This column relates to a test comparing the CO_2 extracts in accordance with the present invention with the prior-art hexane extracts of WO00/25127 as discussed at the outset. An industrial hemp having the following raw drug data: water content; 11.2% (wt); Δ^9-THC 0.25% (wt.); and CBD: 1.54% were extracted with hexane in accordance with WO00/25127. To this end, 100 g of air-dried, pulverized industrial hemp was extracted for 24 hours in 4 l of hexane in accordance with the Soxhlet method. The solvent was removed under reduced pressure, and the obtained extract was analyzed with a view to the parameters indicated in Table 1.

When one compares the data of the CO_2 primary extract in accordance with the present invention as shown in Table 1 with the hexane extract in accordance with WO00/25127 and the ethanol extract, initial y the relatively good coincidence primary extracts obtained by means of the organic solvents is conspicuous.

Moreover in comparison with the CO_2 primary extract of the present invention, there results a disadvantageously high chlorophyll content of 3.00% for the hexane extract and of 2.85% for the ethanol extract. For the extract of the invention, the chlorophyll content thus is lower by a factor of almost 300 than in the prior-art extracts.

A low chlorophyll content is particularly advantageous because under certain circumstances, such as when a soft gelatin is used for encapsulation of the extract in the framework of galenic formulation, chlorophyll may involve cross-reticulations which may prevent the active principles contained in the extract from being released.

The desired CBD content is in the inventive CO_2 extract higher by a factor 4 to 5, and the Δ^9-THC content also by a factor >4, in comparison with the prior-art solvent extracts.

If one regards the overall cannabinoid content, essentially or composed of CBD, Δ^9-THC and CM, it may be seen that even the inventive primary CO_2 extract already is made up at more than two thirds of these constituents, whereas the prior-art extracts only contain an overall cannabinoid content of approx. 15 to 17%.

Moroeover what is conspicuous in comparison with the extract of the invention are the highly elevated (more than 80-fold) flavonoid glycoside contents of the ethanol and hexane extracts.

The detected terpene and alkaloid quantaties r also strongly elevated in comparison with the extracts according to the invention:

The contents of undesirable monoterpenes listed in Table 1 are higher by a factor of 10-30 than in the two primary extracts obtained with ethanol and hexane than in the CO_2 primary extract, and while the sesquiterpene content is higher by a factor 20 to 40 than in the inventive CO_2 extracts.

It is moreover noted that the primary extracts obtained with the aid of lipophilic solvents contain the alkaloids that are readily soluble in these solvents, such as, cannabisativin which is highly cytotoxic. This alkaloid contamination may very well also still occur in an extract prepared in accordance with WO00/25127 from the primary extract described there, following additional purification and enrichment steps in accordance with WO00/25127 which extract is said to have a 98% content of Δ^9-THC.

In contrast, already the primary extracts of the invention without any further purification steps—as shown in Table 1—practically do not contain any more cannabisativin.

Thus the ethanol extract contains about 200 times more toxic alkaloids, in particular the highly oytotoxic cannabissativin, and the hexane extract in accordance with WO00/25127 even about 350 times more than the CO_2 primary extract of the invention.

Thus the CO_2 extracts of the present invention are superior both to the hexane extracts in accordance with WO00/25127 and to the customary ethanol extracts, because of their high cannabinoid contents and the fact that they are largely free from alkaloids, fiavonold glycosides, mono- and sesolterpenes.

What is particularly advantageous is the circumstance that the present invention starts out from a hemp having a THC proportion near Zero, which is not even the case in WO00/25127 as this reference starts out from higher THC concentrations in the raw drug inasmuch as drug hemp, not industrial hemp is extracted there.

In view of this very fact it thus is already surprising that THC and cannabinoids may at all be enriched in technically useful amounts from readily available industrial hemp by means of CO_2 extraction.

Table 2 shows the components of a secondary extract after completed aneilation.

TABLE 2

Secondary extract following cyclization (FIG. 2)

Measured substance	CO_2 secondary extract P_1 = 300 bar T_1 = 70° C. P_2 = 55 bar T_2 = 25° C.
Chlorophyll	0.01%
CBD	1.5%
Δ^9-THC	41.2%
Δ^8-THC	24.3%
CBN	0.1%

Table 3 shows the components of a primary otract purified by high-pressure column in accordance with FIG. **3**.

TABLE 3

Purified primary extract after chemical purification in a high-pressure column (FIG. 3)

Measured substance	Purified primary extract P_1 = 180 bar T_1 = 55° C. P_2 = 70 bar (separating vessel No. 5) T_2 = 50° P_3 = 60 bar (separating vessel No. 10) T_3 = 30° C. P_4 = 55 bar (separating vessel No. 15) T_4 = 25° C.		
	Separator No. 5	Separator No. 10	Separator No. 15
Chlorophyll	0.01%	0.01%	0.01%
CBD	85.0%	0.0%	1.5%
Δ^9-THC	2.0%	0.0%	87.0%
Δ^8-THC	0.0%	0.0%	0.0%
CBN	0.1%	0.1%	0.1%

Table 4 shows the components of a secondary extract which was purified in a high-pressure column.

TABLE 4

Purified secondary extract following purification in a high-pressure column (FIG. 3)

Measured substance	Purified secondary extract P_1 = 180 bar T_1 = 55 ° C. P_2 = 70 bar (separating vessel No. 5) T_2 = 50° C. P_3 = 60 bar (separating vessel No. 10) T_3 = 30° C. P_4 = 55 bar (separating vessel No. 15) T_4 = 25° C.		
	Separator No. 5	Separator No. 10	Separator. No. 15
Chlorophyll	0.01%	0.01%	0.01%
CBD	90.0%	0.1%	0.3%
Δ^9-THC	0.5%	1.0%	96.0%
Δ^8-THC	0.2%	85.0%	1.5%
CBN	0.1%	0.1%	0.1%

It is, of course, fundamentally also possible to use a drug hemp for carrying out the process of the invention.

The above mentioned primary extract is treated further in accordance with the description in FIG. **2** and FIG. **3** and is suited as an active principle for the production of a medicament for the indications described at the outset.

Suitable application types are inhalation, oral, parenteral, as well as enteral application.

What is claimed is:

1. A process for producing an extract containing Tetrahydrocannabinol (THC) and/or cannabidiol (CBD), and optionally the carboxylic acids thereof, from a *cannabis* plant material or a primary extract thereof, said process comprising:

(1) subjecting the *cannabis* plant material or primary extract thereof to CO_2 in liquefied form under subcritical pressure and temperature conditions to extract cannabinoid components; and

(2) reducing the pressure and/or temperature to separate tetrahydrocannabinol and/or cannabidiol, and optionally the carboxylic acids thereof, from the CO_2.

2. The process according to claim **1**, further comprising subjecting the CO_2 extracted from step (2) to increased pressure and temperature and recycling said CO_2 to step (1).

3. The process according to claim **1**, wherein in step (1) the CO_2 in liquefied form is at a pressure of 70 bar or less.

4. The process according to claim **3**, wherein in step (1) the CO_2 in liquefied form is at a temperature of between about 20° C. to about 30° C.

5. The process according to claim **1**, wherein in step (1) the CO_2 in liquefied form is at a pressure of about 60 bar.

6. The process according to claim **1**, wherein in step (2) the CO_2 in liquefied form is at a pressure of about 55 bar or less.

7. The process according to claim **3**, wherein in step (2) the CO_2 in liquefied form is at a pressure of about 55 bar or less and a temperature of about 20° C. or less.

8. The process according to claim **1**, which further comprises separating monoterpenes and sequiterpenes from the tetrahydrocannabinol and cannabidiol using a separator.

9. The process according to claim **1**, wherein the *cannabis* plant material contains 0.5% or less of Δ^9-THC based on the dry plant mass.

10. The process according to claim **1**, wherein an adsorbent for extracting components other than tetrahydrocannabinol, cannabidiol and optionally the carboxylic acids thereof is arranged downstream in terms of the CO_2 flow.

11. The process according to claim 10, wherein the adsorbent is selected from the group consisting of silica gel, diatomaceous earth, bentonites, bleaching earth, activated carbons, magnesium oxide and alumina, as well as mixtures thereof.

12. The process according to claim 11, wherein the absorbent is for extracting components selected from the group consisting of alkaloids, flavonoids, monoterpenes, sesquiterpenes, and chlorophylls.

13. The process according to claim 1, further comprising a step of decarboxylating cannabinoid carboxylic acids in the *cannabis* plant material or primary extract thereof.

14. A process for producing an extract containing Tetrahydrocannabinol (THC) and/or cannabidiol (CBD) from a *cannabis* plant material or a primary extract thereof, said process comprising:

(1) decarboxylating cannabinoid carboxylic acids in the *cannabis* plant material or primary extract thereof;

(2) subjecting the decarboxylated *cannabis* plant material or primary extract thereof to CO_2 in liquefied form under subcritical pressure and temperature conditions to extract cannabinoid components; and

(3) reducing the pressure and/or temperature to separate tetrahydrocannabinol and/or cannabidiol from the CO_2.

15. The process according to claim 14, further comprising subjecting the CO_2 extracted from step (3) to increased pressure and temperature and recycling said CO_2 to step (2).

16. The process according to claim 14, wherein in step (2) the CO_2 in liquefied form is at a pressure of 70 bar or less.

17. The process according to claim 16, wherein in step (2) the CO_2 in liquefied form is at a temperature of between about 20° C. to about 30° C.

18. The process according to claim 14, wherein in step (2) the CO_2 in liquefied form is at a pressure of about 60 bar.

19. The process according to claim 14, wherein in step (3) the CO_2 in liquefied form is at a pressure of about 55 bar or less.

20. The process according to claim 16, wherein in step (3) the CO_2 in liquefied form is at a pressure of about 55 bar or less and a temperature of about 20° C. or less.

21. The process according to claim 14, which further comprises separating monoterpenes and sequiterpenes from the tetrahydrocannabinol and cannabidiol using a separator.

22. The process according to claim 14, wherein the *cannabis* plant material contains 0.5% or less of Δ^9-THC based on the dry plant mass.

23. The process according to claim 14, wherein an adsorbent for extracting components other than tetrahydrocannabinol, cannabidiol and optionally the carboxylic acids thereof is arranged downstream in terms of the CO_2 flow.

24. The process according to claim 23, wherein the adsorbent is selected from the group consisting of silica gel, diatomaceous earth, bentonites, bleaching earth, activated carbons, magnesium oxide and alumina, as well as mixtures thereof.

25. The process according to claim 24, wherein the absorbent is for extracting components selected from the group consisting of alkaloids, flavonoids, monoterpenes, sesquiterpenes, and chlorophylls.

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