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**How do you patent
medicinal uses of cannabis –
a substance known for
thousands of years?**





In one word?





You can't!

(ok, it's two words)



You name it- Cannabis was mentioned...

Autism

Cuts &
burns

Constipation
and diarrhea

Tinnitus

Heartburn
Acid reflux

Biofilm
anti fouling

Acne

Cavities in teeth

treating male
infertility

Menstrual pain
(as tampons)

Osteoporosis

anti
Aging

Topical
for
wrinkles

Asthma

- **A written reference, even a post on the web, can destroy a later patent if:**
 - It said cannabis works -even without proof.
 - It gave motivation to try using Cannabis for an indication as a suggestion
 - The ref, together with other references make the invention obvious (combination of references) such as :
 - Cannabis found to be active in one inflammatory disease and now active in another inflammatory disease.



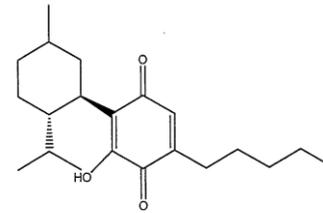
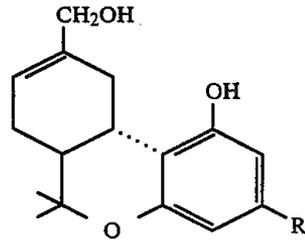
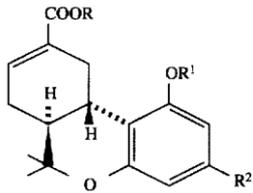
- Better chance than cannabis
- Last few years a flood of such patents- only in the last two years **1412** patents on CBD and/or THC in the claims.
- Time window is closing fast- in a few years all indications for CBD or THC will be either published or patented
- Need to be restricted to purified compounds- to overcome prior art of cannabis.
- Arguments that it was not obvious to try using CBD or THC for disease X in view of the same use by cannabis extract - difficult .



- A better chance of getting a patent
- Will be restricted to the specific combination specific terpene maybe even ratio.
- Need to show comparative data that is better than the extract (having both) and better than each of the components used alone



- Easiest patent to get
- Mostly need to show novelty, non-obviousness, if different, will not be difficult to show





- ***New per se***

- New delivery system – possible to patent possible if sufficiently different from prior delivery systems (can be only by the ratios of the components)
- Usually suitable not only to cannabinoids but to molecules having similar properties (size, hydrophobicity etc.)

- **Previously known for other compounds but not for cannabis/cannabinoids**

- Difficult – may be considered obvious, to use a previously known carrier (transdermal for example) also for cannabis or purified cannabinoids
- Can protect “ a patent of selection”- showing that out of many transdermal formulations tested only one (or few) had significantly better results for CBD or cannabis



- Patentable for disease X (if both the drug and the cannabis and cannabinoid are known for disease X) only if synergism is shown
- Synergism for at least one disease parameter (may be reduction of side effect)
- Typically synergism if features only for a range of concentrations- patent may need to be restricted to this

US granted patent 9,095,554 (group of California breeders) – first issued patent in US for a plant

- A hybrid cannabis plant, or an asexual clone of said hybrid cannabis plant, or a plant part, tissue, or cell thereof, which produces a female inflorescence, said inflorescence comprising:
 - a) a **Bt/B_D** genotype;
 - b) a **terpene profile** in which myrcene is not the dominant terpene;
 - c) a **terpene oil content greater than about 1.0%** by weight; and
 - d) a **CBD content greater than 3%**;
- wherein the **terpene profile** is defined as terpinolene, alpha phelladrene, beta ocimene, careen, limonene, gamma terpinene, alpha pinene, alpha terpinene, beta pinene, fenchol, camphene, alpha terpineol, alpha humulene, beta caryophyllene, linalool, cary oxide, and myrcene, and wherein the terpene oil content is determined by the additive content of the terpenes in the terpene profile; and wherein the terpene contents and CBD content are measured by gas chromatography-flame ionization detection (GC-FID) and calculated based on dry weight of the inflorescence; wherein a representative **sample of seed producing said plants has been deposited under NCIMB Nos. 42246, 42247, 42248, 42249, 42250, and 42254**

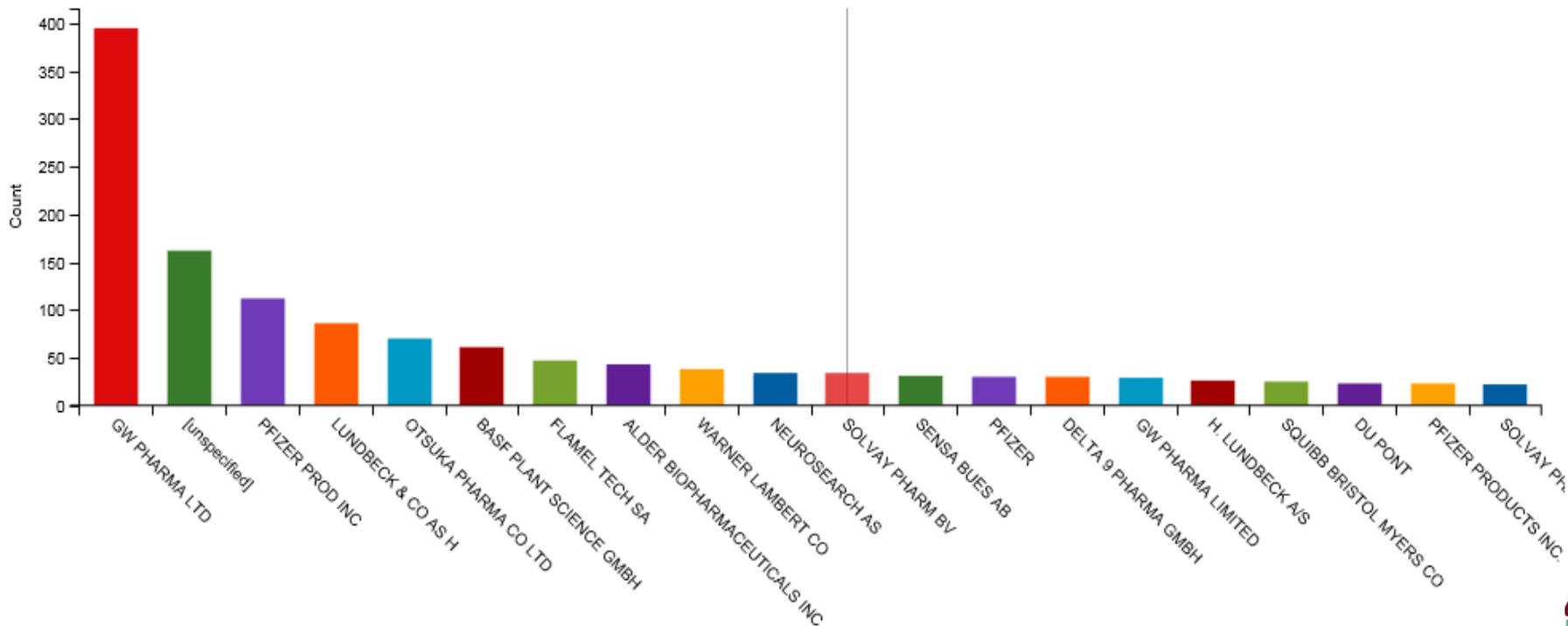




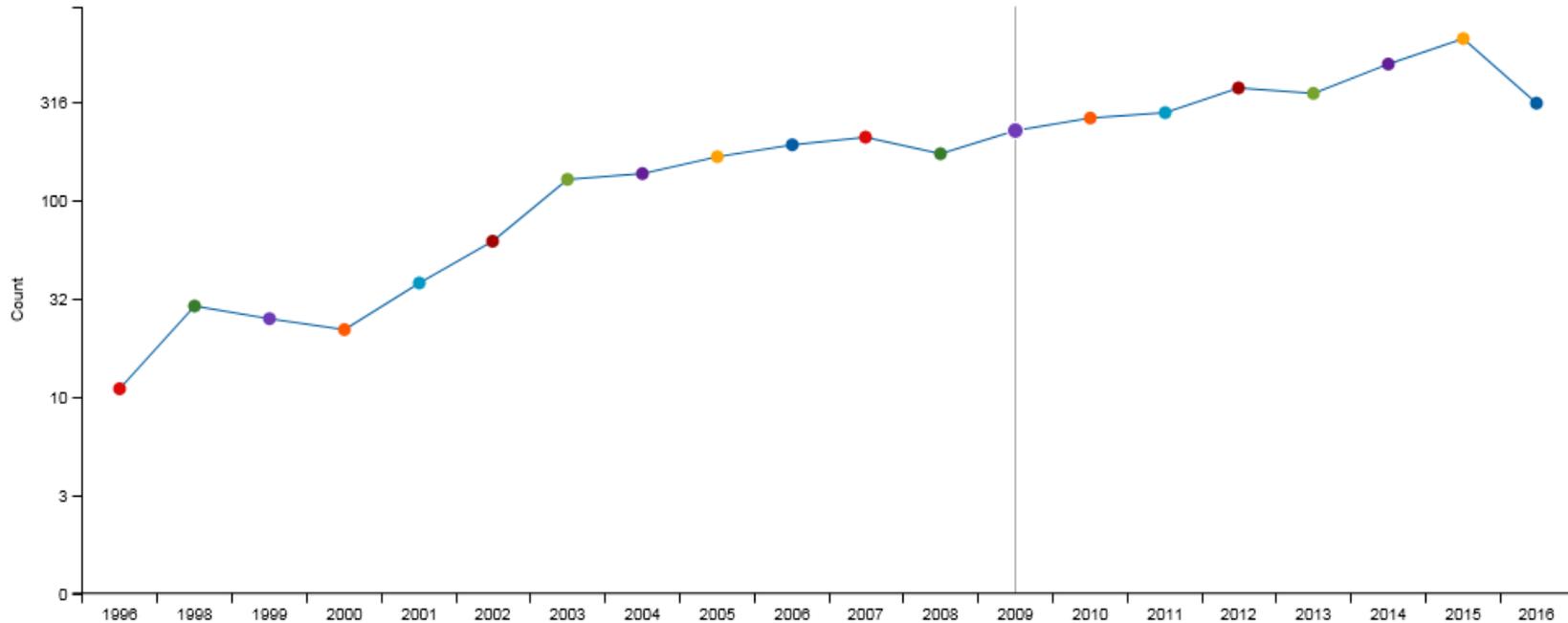
- **Regular patent**- used to protect the method of creating a new variety, or the DNA sequences used to create a variety. Must be new and non-obvious over previous patent. More recently, regular **patents** have been extended to theoretically cover varieties created through traditional breeding,.
- **Plant patent** (in the US)- only apply to asexually propagated crops, the plant must be new, distinct, uniform and stable.
- **Plant breeders rights**- applies to seed (and tuber) propagated crops, which includes most vegetable and field crops. In US the plant must be new, distinct, uniform and stable. In Europe must show **improvement** over the currently available varieties

- Method of extractions. How can we enforce? Police them?.
- Method of synthesis of new compounds- can be enforceable if needed to be submitted to the FDA.
- Method of analysis. Should be enforced by trying to describe a new system, device or kit
- Smoking apparatus

Who is filing Cannabis-related patents?



Number of patents having the word "cannabis" in the claims





Fail early fail cheap- look at FTO at the beginning



- **Easy – Direct proof in court by chemical analysis**

- New Chemical compound; new mixture (New combination or new ratio), new carrier

Medium- Indirect proof in court by documents, impurities, genetic markers

New synthesis, new method of isolation – proof in court starting materials, impurities ,or by submitted protocols to FDA

Plant- genetic markers s? Traits?

New Use, new disease - by advertisements, or documents submitted to regulatory agencies

Difficult- No physical evidence to submit to courts

Screening for drugs- how to you prove he drug was found by your screen? What if physical screening is done in a “non-patent country”? New target

Nutraceuticals for disease X- How to protect their “use” when they are sold without disease indication





THANK YOU

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