CESCON BARRIEU

The Cannabis Industry in Brazil

May 2025

Regulatory Landscape in Brazil

- Since 2019: Anvisa authorizes cannabis-based medicinal products
- X Domestic cultivation not yet allowed
- ? ANVISA's recent vote

Turning Point – Anvisa's Vote

Draft regulation allowing the cultivation of industrial hemp (Cannabis sativa L. with THC levels $\leq 0.3\%$).

The regulation will establish requirements for companies registered with Brazil's National Registry of Seeds and Seedlings, using cultivars approved.

Turning Point – Anvisa's Vote

- Approval would enable domestic cultivation, significantly reducing Brazil's dependence on imported cannabis-based products.

- This move follows a judicial decision from Brazil's Superior Court of Justice (STJ), mandating Anvisa and the Federal Government to regulate cannabis cultivation for medicinal and industrial uses by May 2025.

- This would well-position Brazil to develop pharma inputs and industrial cannabis

IPRs and the Cannabis **Industry - Patents**



Allowed

- Cannabis-based formulations
- Extraction/purification methods
- Innovative therapeutic uses

× Not Allowed:

- Cannabis plants or parts
- Natural substances (CBD, THC)
- Biological reproduction processes

IPRs and the Cannabis Industry -**Patents Challenges**



Cultivation not allowed = limited R&D



BPTO requires high inventive step



X Example: Myalo patent annulled by BPTO

IPRs and the Cannabis **Industry - Trademarks**

Terms like "cannabis", "hemp" under Art. 124, III

Trademarks aligned with Anvisa-regulated products

IPRs and the Cannabis Industry – Geographical Indications - GIs

product tied to regional quality, tradition or a consolidated reputation or traditional knowledge tied to a specific Brazilian region.

Not yet viable: cannabis cultivation not legally authorized

Future potential: regional hemp or medical strains

Plant Breeders' Rights (PBR)

Legal framework for PBR exists (Law 9.456/97)

Prohibition of Cultivation: Currently, the cultivation of cannabis for medicinal or industrial purposes is not broadly authorized in Brazil, limiting the practical application of PBRs in this sector.

Future: regulations may enable variety protection

The Future of Cannabis in Brazil

Regulation → Local innovation & investment

IP strategy → Market access & competitive edge

© Cultivation approval → Unlocks R&D and exports

Thank you!



