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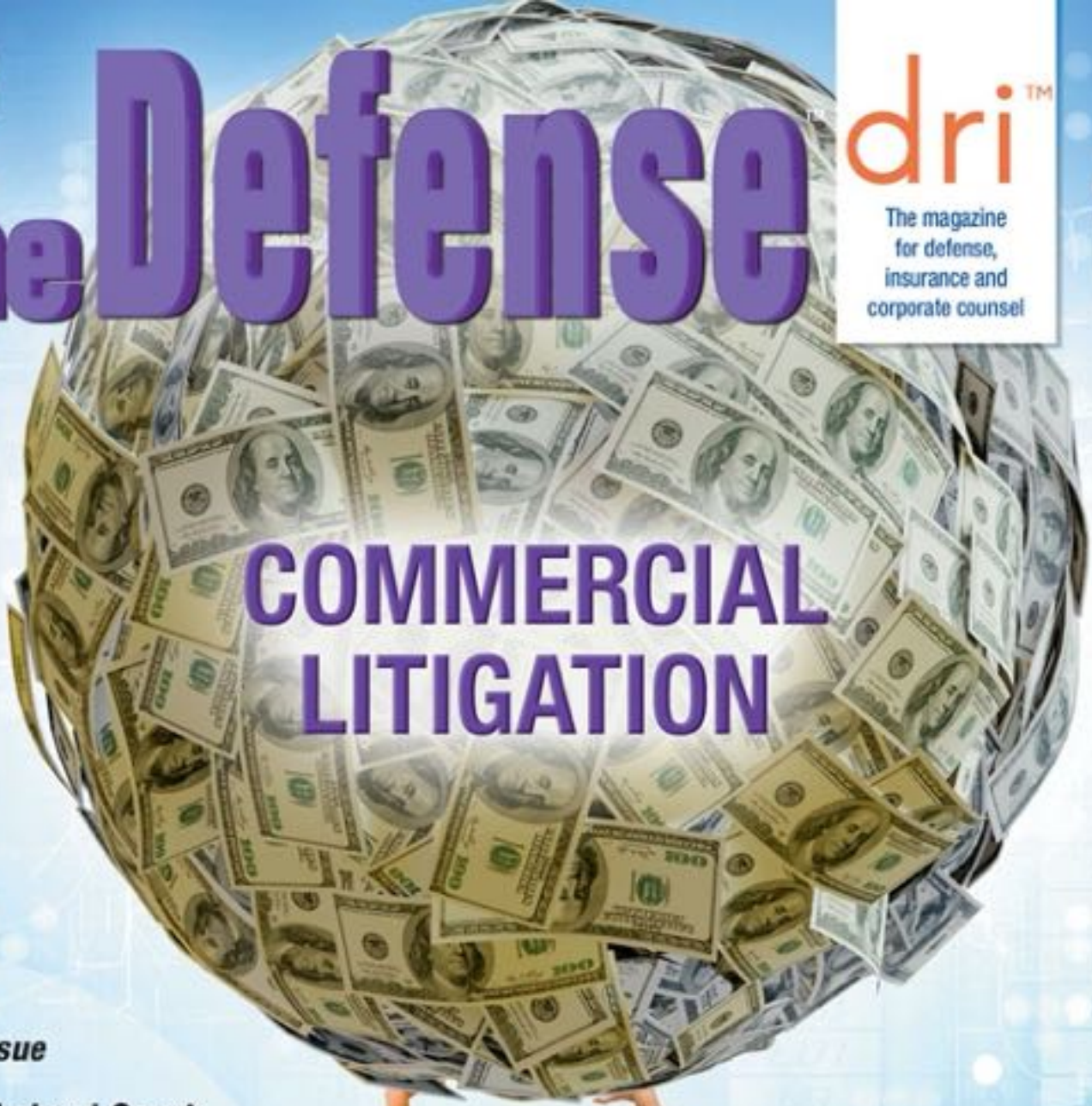

COMMERCIAL LITIGATION

Also in this issue

- **Relaxing Federal Court Jurisdiction for MDLs**
- **Brazil in the Market of Cannabis-Derived Products**
- **A Tool to Eclipse Class Action Litigation**
- **The Effect of Police Registries on *Monell* and Negligent Hiring Claims Litigation**

And more

Regulatory Framework and What to Expect Next

Brazil in the Market of Cannabis-Derived Products

By Rosangela Delgado and Renata Fialho de Oliveira



The current litigation scenario in Brazil is a direct consequence of the lack of authorization for cultivation of cannabis.

In December 2019, with the publication of Resolution No. 327/2019 of the National Health Surveillance Agency ("ANVISA"),

Brazil joined the group of countries that approved the prescription and use of medicinal cannabis. ANVISA's Resolution No. 327/2019 came into force on March 9, 2020.

Regulatory Framework

ANVISA's Resolution No. 327/2019 regulates the manufacture, prescription, importation, and sale of canna-





■ Rosangela Delgado Barreto is a partner of Veirano Advogados in Rio de Janeiro (**rosangela.delgado@veirano.com.br**), where she focuses her practice in the area of complex litigation that includes product liability, commercial, contractual, general civil and regulatory litigation. She has significant expertise in the consumer products, automotive, transportation, publishing, marine, ride hailing, press manufacturing and hotel industries, counselling several top-tier Brazilian and international corporations. Ms. Delgado Barreto serves as Brazil Country Chair for DRI International and is an active leader within the DRI Product Liability Committee. Renata Fialho de Oliveira is a partner in the São Paulo office of Veirano Advogados (**renata.oliveira@veirano.com.br**), where she represents pharmaceutical and medical device companies in transactional matters in relation to M&A and divestitures, joint ventures and strategic alliances, outsourcing projects, product development and licensing agreements. She also advises private equity and strategic investors in a wide variety of transactional matters in the healthcare industry. The authors would like to thank Caio Andrade for his assistance in the researching and drafting of this article.



bis sativa-based products and sets forth the rules for monitoring and inspecting products containing this active ingredient for medicinal purposes.

The cultivation of cannabis remains forbidden (a separate resolution in that regard has been vetoed and archived). Some attribute this prohibition to the current evangelical parliamentary group; some to the difficulty authorities would face in inspecting the crops and ensuring they would be destined to medicinal use only. There is, however, a bill of law under discussion that would aim to allow the cultivation of cannabis in the country. While such bill of law does not become a law, the active ingredient must be imported in bulk, phytopharmaceutical, or industrialized, in the form of vegetable derivates, exclusively for medicinal purposes.

Cannabis-derived products must be registered with the authorized entities under the applicable law. These products, however, will be subject to rules applicable to a new class of sanitary-inspected products that the resolution has created, which is "cannabis-based products" instead of "medicines." As a result of the creation of this new category, cannabis-based products and medicines must comply with different regulatory frameworks.

In addition to establishing the requirements that companies must fulfil to manufacture or import cannabis-based products, the regulation contains further rules on labeling and quality control, distribution, and sale in pharmacies and drugstores.

The resolution expressly sets forth that cannabis-derived products may be pre-

scribed—only by duly licensed physicians—when no other therapeutical option is available in the Brazilian market. Advertisement of cannabis-derived products is forbidden.

Even if Resolution No. 327/2019 could have been less restrictive and affirmative on cannabis-based products, its approval represented a significant disruption of the prior legal regime, when only the direct import by the patient for personal use was allowed.

The uncertainty of future rules has been pointed out as one of the reasons why the expansion of the Brazilian cannabis market has not been even greater so far.

Among the novelties arising from the resolution, one may note the national production of cannabis-derived products by local pharmaceuticals, local inventory of cannabis derived products, and increase in the sale and broader acceptance of such products by the medical community for treatment of patients, among others. Shortly after the resolution entered into force, in April 2020, the ANVISA granted the first marketing authorization for a cannabis-based product.

Resolution No. 327/2019 is transitory and must be reviewed within three years of its publication. The uncertainty of future rules has been pointed out as one of the reasons why the expansion of the Brazilian cannabis market has not been even greater so far.

Discussions Around Cannabis-Derived Products and Precedents

Litigation about the medicinal use of cannabis precedes the recent regulations approved by ANVISA, but has recently had a new wave due to the contradictions arising from Resolution No. 327/2019. This is because, as discussed above, on the one hand, it allows the manufacture and sales of cannabis-based products for medicinal use, but, on the other, it prohibits the cultivation of the plant and the importation of raw parts of it.

There are currently hundreds of lawsuits across the country that directly or indirectly deal with the medicinal use of cannabis, both from the criminal and civil perspectives. Below is a brief overview of the main types of litigation, what is at stake, and how the cases may shape future prospects for the cannabis market in Brazil.

Constitutional Challenges to the Drugs Act

The lawsuit with the most comprehensive scope is pending before the Supreme Federal Court (STF), Brazil's highest court. ADI 5708/DF is a constitutional challenge filed by the Cidadania Party in 2017 that seeks to declare certain articles of Law No. 11,343/06—commonly known as the "Drugs Act"—unconstitutional. In its complaint, the plaintiff requests that several articles of the Drugs Act be given an interpretation in accordance with the constitution to set aside the understanding that it constitutes a crime to "plant, grow, harvest, store, transport, prescribe, administer and acquire Cannabis for medicinal purposes and therapeutical wellbeing." The complaint also asks the STF to, "in the absence of proper regulation, set aside the need of prior government authorization for planting and cultivating Cannabis for medicinal treatments or scientific research." The Cidadania Party also asked the court for an injunction immediately authorizing the cultivation of cannabis in the above-mentioned cases, but the STF is yet to rule on such request.

Brazil's attorney general, whose intervention is mandatory in constitutional challenges filed before the STF, has issued an opinion in 2019 in favor of partially granting the request to assign the federal government and ANVISA a term to regulate the cultivation of *Cannabis sativa* for medicinal purposes. According to this opinion, the regulation in force at the time (prior to Resolution No. 327/2019), which only authorized the importation of finished cannabis-based products by individuals for personal use, was excessively expensive and bureaucratic, allowing only people with higher incomes to have access to those products.

Since 2017, several institutions—from research institutes and patient associations to law schools and the Brazilian Bar Association—have asked and/or been admitted in ADI 5708/DF as amici curiae. However, the case has been moving very slowly and, at the moment, there are no clear expectations as to when the STF will rule on its merits.

Also pending at the STF is a constitutional appeal (RE 635659/SP) filed by an individual against a decision rendered by the Court of Appeals of the State of São Paulo that sentenced him to two months of community service after he was found with three grams of marijuana. The STF recognized that the case's legal controversy (the unlawfulness of carrying drugs for personal use) was one of "general repercussion"—a legal requirement for the appeal to be analyzed by the court. The judgment has already started and, so far, three of the STF's eleven justices have voted to grant or partially grant the appeal to decriminalize the personal use of marijuana. As in ADI 5708/DF, various institutions are participating as amici curiae. Although the factual background in RE 635659/SP is not related to the medicinal use of cannabis, the decision in this case—which seems to be moving faster than ADI 5708/DF—will end up either allowing people to possess cannabis-based products (for recreational or medicinal use), or even to cultivate the plant at home, which will undoubtedly influence the legality of growing cannabis for medicinal purposes, at least at an individual scale.

In view of the STF's delay in deciding ADI 5708/DF and RE 635659/SP—which could provide a nationwide orientation on the medicinal use of cannabis—patients, their representatives, and associations have been forced to go to court to obtain individual authorizations for cultivating cannabis in Brazil. As to be expected when the highest court in the country has not given a definitive interpretation of the law, courts have decided in various directions. This is further complicated by the fact that Brazil has thirty-two different courts of appeals

that can deal with cannabis related litigation—the courts of appeals of the twenty-six states and the federal district (TJs), plus five federal courts of appeals for the five regions in which the country is divided (TRFs).

Individual Lawsuits

A significant number of the individual lawsuits pending are preventive habeas corpus that aim to obtain safe-conducts for the cultivation of cannabis for medicinal use without being prosecuted by law enforcement authorities. In general, the courts of appeals have been sensitive to the arguments and, in most cases, granted plaintiffs' request to import *Cannabis sativa* seeds and to cultivate the plant at home for medicinal purposes. Despite that, courts usually establish limitations on the number of seeds a person can import and on how many plants one can grow simultaneously. They also subject the authorization to a valid medical prescription.

The reasoning behind these decisions, which are setting aside the crimes provided for in article 33 of the Drugs Act, are usually related to the principle of human dignity and the State's duty to promote health, both of which are inscribed in the 1988 federal constitution. Article 33 considers as crimes, for example, a long list of eighteen actions: "import, export, send, prepare, produce, manufacture, acquire, sell, expose to sale, offer, have in deposit, transport, carry, store, prescribe, administer, deliver for consumption or provide drugs," subjecting the offender to five to fifteen years of imprisonment.

A May 2020 decision by the Federal Court of Appeals of the First Region (with jurisdiction over thirteen states and the federal district) considered that in cases such as the ones brought to the court (a victim of a bike accident with chronic pain caused by a fracture of the elbow), "the Judiciary must, even as a matter of humanity, protect the constitutional premises of the citizen's right to his well-being, to his own health, to the inviolability of the right to life and respect for human dignity." In this case the court authorized the plaintiff to import cannabis seeds and grow the plant exclusively for medicinal purposes without suffering the criminal consequences foreseen in the Drugs Act.

In some other decisions, courts have ruled that the regulation issued by ANVISA creates a situation where only people with higher incomes can access cannabis-based medication. That is because, as discussed above, until 2019 ANVISA authorized only the importation of cannabis medicines directly by patients. Even after the new 2019 rules, the agency still forbids the growing of cannabis in Brazil, despite authorizing pharmaceutical companies to manufacture and sell the products for medicinal use.

Although a slight majority of these individual cases have been decided favorably for plaintiffs, there is a significant number of precedents that show courts are worried about the effects their decisions may have on the control of drugs that are still considered illegal in the country. A November 2020 decision by the Federal Court of Appeals for the Fourth Region, which encompasses Brazil's three southernmost states, denied a preventive habeas corpus, stating that "the required authorization for the importation of 'marijuana' seeds characterizes a clear violation to the express wording of the law, that considers said conduct a crime" and that the high cost for importing cannabidiol "or even the fear that the state bureaucracy will delay the authorization to import said substance" are not sufficient to grant safe-conducts. According to the decision, those aspects can be dealt with through the proper request to the judiciary to grant access to those medicines under Brazil's free and universal public health system (the Unified Health System, more commonly known by its Portuguese acronym SUS).

Other decisions deny individual preventive habeas corpus on the grounds that plaintiffs do not have the necessary knowledge to extract the medicinal substances from the cannabis plant. A December 2020 decision by the Court of Appeals of the State of Minas Gerais denied a habeas corpus on the grounds that "the extraction of oils containing cannabidiol demands a complex process in order for pharmaceutical quality substances to be extracted, so that one cannot admit that laymen perform such conducts without any regulation or control, given the risk to their own health as well as to their communities." Similarly, in February 2021, the Court of Appeals of the State of São Paulo also rejected a preventive habeas corpus, stressing that "artisanal production [of cannabis-based products] demands expertise and sanitary control" and that there is no "effective form of control or supervision of said artisanal production, generating a risk of undue use of the plant, even by third parties,"

In a March 23, 2021, decision, the Superior Court of Justice (STJ), Brazil's highest court for non-constitutional federal law violations, rejected an appeal in a preventive habeas corpus in which plaintiff asked for a safe-conduct to "plant, grow and possess" cannabis for individual treatment. Despite rejecting the appeal, the STJ gave a Solomonic decision. On the one hand, the STJ noted that superior courts already have a firm jurisprudence recognizing that "importing small quantities of marijuana seeds does not fall under the crime set forth in article 33 of the Drugs Act," but rather under the crime in article 334-A of the Penal Code ("to import or export forbidden merchandises"), which, in any case, should not be applicable due to the insignificance of the conduct. On the other hand, the court concluded that "the authorization sought by the appellant depends on the analysis of technical criteria that are not the responsibility of criminal courts, but, rather, of Anvisa." Based on that, the court rejected the appeal, but "recommended that Anvisa analyze the case and decide if it is viable to authorize the appellant to cultivate and possess *Cannabis sativa L.* plants for medicinal purposes."

In short, while the majority of individual cases are still favorable to the plaintiffs, the above-discussed recent STJ ruling may change this trend.

Non-Individual Lawsuits

Another battle front for the right to grow cannabis plants in Brazil for medicinal purposes is being led by patients' associations and pharmaceutical companies. In 2017, a Brazilian association for patient cannabis support filed a class action against the federal government and ANVISA to obtain the right to grow, within its property, cannabis plants to extract the substances needed for the treatment of its associates. The plaintiffs were granted injunctive relief to start growing the plants. The decision,

which was later confirmed by the judge, was grounded on the high cost of importing cannabis medicines, on the fact the SUS does not offer these medicines on a collective basis, and on ANVISA's delay in regulating the cultivation of cannabis for medicinal purposes. On April 8, 2021, the Federal Court of Appeals of the Fifth Region rejected ANVISA's appeal and upheld the plaintiffs' authorization to grow cannabis. The court of appeals criticized ANVISA's and the ministry of health's delay in regulating the cultivation of cannabis in Brazil and ordered that, until a regulation comes, they must oversee the association's cultivation of cannabis and production of substances.

Shifting from the patients' perspective to that of economic agents interested in the cannabis market, since ANVISA's Resolution no. 327/2019 (authorizing the manufacture of cannabis-based products in Brazil, but prohibited the growing of the plant), a few companies have gone to court to seek judicial authorization to grow cannabis. The grounds for these claims are that there is a clear contradiction in the regulation when it allows the manufacture and sale of cannabis-based products in the country and at the same time prohibits the cultivation and import of the plant. A biotechnology company that claims to have "large experience in the agriculture sector, controlled cultivation, development of seeds, biotechnology and genetic engineering of plants" filed a writ of mandamus to be authorized to grow industrial hemp and sell its fiber, leaves and seeds, either *in natura* or after processing (oil). The Third Federal Court of Curitiba (State of Paraná) denied the injunction request. After an appeal by plaintiff, the Federal Court of Appeals of the Fourth Region upheld the decision, adding procedural grounds to reject the injunction request. In March 2021, the trial court dismissed the case on the grounds that

> an ample authorization for the industrial exploration of Cannabis sativa, as intended by plaintiff, is a matter of eminently political nature, which, therefore, depends on deliberation by the Legislative and Executive branches. An intervention of the Judiciary in this field, as requested by plaintiff, whose claims, I repeat, are not limited to isolated cases (…) would violate the principle of separation of powers.

Another company, specializing in plant-based medications, filed a similar lawsuit, which was dismissed by the First Federal Court of Paranaguá (State of Paraná) on the exact same grounds. The plaintiff's appeal was also decided by the Federal Court of Appeals of the Fourth Region, which concluded that the arguments of the appeal were not sufficient to set aside the lower court's reasoning.

In short, the scenario in non-individual lawsuits is still unclear. Despite the relevant outcome of the patients' association lawsuit in the Federal Court of Appeals of the Fifth Region, with sharp criticism towards ANVISA, other courts seem to be deciding in the opposite direction. This divergence will certainly reach the Superior Court of Justice and even the Supreme Federal Court in the coming months.

Future Perspectives

The current litigation scenario in Brazil is a direct consequence of the lack of authorization for cultivation of cannabis. Both individuals and economic agents recognize that there is no reasonable justification for authorizing the importation of cannabis-based medicinal products and their production in Brazil while, at the same time, forbidding the importation of seeds and the cultivation of cannabis plants in Brazil.

The current regulatory framework ends up limiting access to cannabis-based products to those with higher incomes, who can either import cannabis-based products directly or pay the high price pharmaceutical companies are forced to sell these products for in Brazil as a result of not being able to perform all steps of the manufacturing process in the country (cannabis-based medicinal products may cost up to BRL 2,500, approximately USD 400–500).

This has also a negative effect on the country's economy. The current regulation hinders Brazil's self-sufficiency in the cannabis market and creates a barrier to the national and international agribusiness by prohibiting the cultivation of cannabis plants in the country and the importation of raw parts of the plant.

ANVISA's regulation also has a negative effect on the public healthcare system. As mentioned above, Brazil has a free universal health system and there are already several court precedents ordering the SUS to fund cannabis-based products for patients who do not have the means to import them directly or even to buy them in Brazil, now that pharmacies are allowed to sell them in the country. Without access to cheaper cannabis-based products, the SUS's already tight budget is expended on the purchase of costly products that could be significantly cheaper if cultivation of cannabis in Brazil or importation of the plant were authorized for medicinal purposes.

Courts seem to be pointing in the direction of flexibility. Many believe that the STF will decide to decriminalize possession of cannabis in RE 635659/SP, which may open the door for cultivation of the plant in Brazil. Some restrictions in ANVISA's Resolution No. 327/2019 have already been challenged, and decisions indicating a broader interpretation of ANVISA's rules have been issued: in March and April 2021, the Court of Appeals of the State of São Paulo granted injunctions in writs of mandamus to two pharmacies to compound products containing cannabis-based derivatives or phytopharmaceuticals, which was expressly forbidden by the resolution. The court concluded that ANVISA has exceeded its regulatory authority and violated federal legislation when it limited the sales of cannabis-based products to regular pharmacies only. Both decisions, however, are still subject to appeal and may be reversed. The STJ's recent decision urging ANVISA to evaluate the authorization for an individual to grow cannabis plants will also likely influence both how the agency approaches this matter and how lower courts decide similar cases.

Also, as discussed above, there is a bill of law seeking to authorize the cultivation of cannabis sativa in Brazil. Hopefully, this will point Brazil in the direction of reviewing its current regulations and allowing the cultivation and/or the importation of cannabis sativa for medicinal use in the country, following most countries in South America, which have already authorized it.

This will boost the Brazilian cannabis market, which indeed is one of enormous potential.