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Brazil: Understanding the New Bioinputs Regulation and Patent Landscape

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The Brazilian agricultural sector has long been a driving force in the global economy, contributing significantly to international and domestic markets. In 2022, for instance, Brazil was the world's fourth largest grain producer and second largest exporter, and in 2024, agribusiness products accounted for almost half of the country's total exports.

Innovation plays a pivotal role in the growth of this sector, and the importance of bioinputs—biological products used to enhance productivity and sustainability within agricultural, aquatic, and forestry systems—cannot be overstated. Reflecting this, the Brazilian Congress recently enacted a new regulatory framework for bioinputs. In parallel, the Brazilian Patent and Trademark Office (*Instituto Nacional da Propriedade Industrial* – INPI) has published two studies in the past year analyzing the innovation landscape for bioinputs and biofertilizers, shedding light onto patent trends and challenges in protecting hese technologies.

THE NEW BIOINPUTS LAW: REGULATION OF ON-FARM PRODUCTION

Enacted on December 23, 2024, Law #15,070/2024 establishes rules for the production, importation, exportation, commercialization, research, marketing, and use of bioinputs in Brazil, closing a regulatory gap.

A central feature of this law is the regulation of on-farm production—the practice of producing biological inputs directly on the agricultural site where they will be used, rather than sourcing them from commercial suppliers. This approach allows farmers to tailor bioinputs to their specific crop and soil needs. However, it raises concerns about the improper handling of bioinputs, resulting in products that are ineffective or even harmful, and the potential replication of patented formulations or processes, infringing on third-party intellectual property rights.

Law #15,070/2024 permits on-farm production exclusively for farmers' personal use, prohibiting commercialization. The bioinputs themselves are exempt from registration, but production units may be subjected to a simplified registration, at the discretion of the Brazilian Ministry of Agriculture and Livestock. The Ministry shall also establish which bioinputs for livestock and aquaculture cannot be produced for personal use.

The law also forbids the practice of multiplicating registered commercial products for personal use, with the exception of bioinput inoculant registered for that purpose. The multiplication of

registered commercial products consists of reproducing or propagating biological agents (such as microorganisms) from a registered bioinput product for on-farm use, rather than purchasing additional quantities from a supplier. Inoculants are a subset of bioinputs: microorganisms used to enhance plant health, growth, and nutrient absorption. They can be categorized into biofertilizers (promote plant growth and nutrient availability) and biocontrol agents (control pests and pathogens through non-chemical methods).

For bioinputs with microorganisms as active ingredients, the law establishes that on-farm producers are exempt from registering microorganism isolates, strains, or lineages in the National System for the Management of Genetic Heritage and Associated Traditional Knowledge, if the microorganisms are obtained from accredited germplasm banks or registered bioinput inoculants. Producers must document production details, such as dates, quantities, and the origins of the microorganisms for five years, while institutions and companies maintaining germplasm banks are required to maintain sales records for the same period.

Contracting third-party services and equipment rentals are permitted; however, importing bioinputs for personal use is not. The importation of bioinput inoculants for on-farm production, on the other hand, will depend on registration.

Overall, the law also provides that producers must adhere to good manufacturing practices and follow transport protocols when moving bioinputs between properties, ensuring traceability and safety.

In addition to the regulation of on-farm production, Law #15,070/2024 contains other important provisions pertaining to bioinputs. For instance, it foresees that the Brazilian Food and Drug Agency (*Agência Nacional de Vigilância Sanitária* – ANVISA) and the Brazilian Environmental Protection Agency (*Instituto Brasileiro do Meio Ambiente e dos Recursos Naturais Renováveis* – IBAMA) must provide input on the registration of new bioinputs intended for phytosanitary control. The registration process itself, however, is handled by the Ministry of Agriculture and Livestock.

Bioinputs intended exclusively for export are exempt from registration, requiring only prior notification to the Ministry of Agriculture and Livestock.

Simplified registration is allowed for bioinputs similar to those already registered. However, Law #15,070/2024 does amend Law #10,603/2002, which regulates data protection for veterinary and agrochemicals, to extend its protections to include bioinputs. With that, it ensures that test results and other non-disclosed data submitted for the registration of bioinputs are protected against unfair commercial use.

To stimulate the bioinputs sector, the law introduces incentives to encourage their research, development, production, and use, including tax and credit mechanisms, with priority given to microenterprises, cooperatives, and family farmers; reduced interest rates for producers and cooperatives adopting bioinputs; and public policies to support bioinput production in traditional and indigenous communities, recognizing their practices and integrating them into sustainable development strategies.

Overall, this new law represents a significant step forward in establishing a comprehensive legal framework for the production, registration, and use of bioinputs in Brazil. It clearly aims to promote innovation, sustainability, and accessibility by simplifying certain processes, supporting

small-scale producers, and incentivizing the adoption of bioinputs across various agricultural systems. However, the law still leaves several important aspects to be determined by subsequent regulations to be issued by the Ministry of Agriculture and Livestock, which will play a critical role in defining the practical application of its provisions.

From the IP standpoint, the lack of clear parameters defining the scope and scale of on-farm production, particularly regarding large producers who engage in the large-scale commercialization of agricultural products, is a cause for concern. Without limitations, these producers could exploit the on-farm production framework to create significant volumes of bioinputs for personal use, effectively lowering production costs for their crops while bypassing the regulatory and financial obligations associated with commercial bioinput production. The absence of robust oversight mechanisms may allow even the unauthorized replication of patented microorganisms, formulations, or production processes. Such practices could undermine the rights of innovators and discourage investment in R&D, ultimately harming the broader bioinput market and stifling technological advancements in sustainable agriculture.

PATENT TRENDS IN THE BIOINPUTS SECTOR

In 2023, the Brazilian PTO published a comprehensive report analyzing patent filings related to inoculants in agriculture, globally and in Brazil, from 2000 to 2023. These include technologies for fertilization and pest/pathogen control.

The report provides valuable insights into patent trends and technological advancements. In the analyzed period, 44,017 patent families related to inoculants were identified globally, with 954 applications filed in Brazil (82% of them are from foreign entities). China leads in patent filings, accounting for 75% of global patents, though mostly filed domestically. Other countries with significant patent activities include South Korea (2,271 families), United States (1,370), Japan (1,127), India, Germany, and Brazil, which ranks 10th in patent filings globally for inoculants, emphasizing categories like nitrogen fixation and nutrient solubilization.

Biofertilizers represent 80% of the patent families globally, with focus on nitrogen fixation, solubilization of nutrients, and addressing abiotic stress. Biocontrol agents account for 45% of the patent families, focusing on fungicides, bactericides, nematicides, and arthropocides. The overlap indicates multi-functional inoculants.

Bacteria predominate among the patented technologies. Key genera include *Bacillus*, *Pseudomonas*, *Rhizobium*, *Azospirillum*, and *Bradyrhizobium*. Among fungi, genera such as *Trichoderma* and *Penicillium* are frequently cited. Other microorganisms like algae, viruses, and protozoa are less commonly used but are emerging in innovative applications.

The report also sheds light on the patenting activity of key global players, showing that between 65% and 92% of international patent families from key global players (e.g., Bayer, Novozymes, BASF, Monsanto, among others) include filings in Brazil. These trends demonstrate the strategic role of Brazil as a key market for advanced agricultural technologies.

It is also mentioned that while in countries like Brazil, South Korea, and Russia government and academic institutions dominate patent applications, in USA and Germany corporations appear as the main applicants. Key Brazilian contributors to the innovation ecosystem include EMBRAPA, which is a national leader in agricultural research, and universities and public research institutes.

The Brazilian soy industry is highlighted as a significant success story in the application of inoculants, particularly through nitrogen fixation, which refers to the process by which certain microorganisms convert atmospheric nitrogen (N?) into a form usable by plants, reducing the need for synthetic nitrogen fertilizers. This technology is applied in 75% of the soybean cultivation area in Brazil, using microorganisms such as *Bradyrhizobium* (a genus of bacteria symbiotically associated with soybean roots) and *Azospirillum brasilense* (a bacterium that enhances nitrogen fixation and overall plant growth when co-inoculated with *Bradyrhizobium*).

The use of such inoculants provides several benefits, from economic savings of billions of dollars, due to reduced reliance on nitrogen fertilizers, to environmental benefits, as it reduces greenhouse gas emissions associated with the production of synthetic fertilizers and prevents contamination of water bodies and soils, which often results from excessive use of chemical fertilizers. Additionally, it improves soil health by promoting microbial diversity and natural nutrient cycling and enhances plant productivity while maintaining or reducing production costs.

This report on inoculants is complemented by another report published by the Brazilian PTO containing a strategic intelligence study on innovation focusing on fertilizers. According to this second report, there are globally 215,764 patent families related to fertilizers with filing date between 2010 and 2023. China accounts for 81% of them (175,000), with 57% of the filings focusing specifically on biofertilizers (100,000).

Among non-Chinese applicants, approximately 40,000 patent families were identified, with 64.5% focused on biofertilizers and 16.8% on traditional NPK fertilizers. The United States leads in non-Chinese patent applications for biofertilizers, followed by South Korea and Brazil, which ranks 7th globally.

In Brazil, 3,225 patent filings were identified between 2010 and 2023, with 61% focused on biofertilizers. The number of biofertilizer patent applications has shown a consistent annual growth rate of 5% during this period.

Biofertilizer patent applications in Brazil emphasize diverse aspects, such as microbial products (use of microorganisms for nutrient solubilization, plant growth promotion, and soil health improvement), organic waste utilization (processes for converting organic waste into biofertilizers), biological and organic inputs (innovations that incorporate natural molecules, enzymes, and organic residues for sustainable soil enhancement), and crop-specific applications (tailored for specific crops, such as soybeans, cereals, sugarcane, and horticultural products).

STRATEGIC CONSIDERATIONS

The new regulatory framework for bioinputs in Brazil provides significant opportunities for innovation and market growth, but it also underscores the critical role of intellectual property (especially patent law) in safeguarding advancements. For R&D-driven companies, the increasing adoption of bioinputs and the rise of on-farm production demand a strategic approach to protecting patented technologies while navigating Brazil’s regulatory landscape.

The allowance for on-farm production, while a progressive step toward sustainability, introduces potential vulnerabilities in patent enforcement. Without clear oversight mechanisms, there is a risk of unauthorized replication of patented bioinputs and production processes, which could dilute the value of innovations and undermine the incentives for further R&D investments. Companies must

therefore remain vigilant, employing robust monitoring systems and pursuing enforcement actions where necessary to safeguard their proprietary technologies.

On another note, the patent trends highlighted by the Brazilian PTO's recent reports reinforce Brazil's position as a key player in the bioinput innovation ecosystem. With foreign entities comprising the majority of patent filings in the country, Brazil offers a fertile ground for leveraging cutting-edge technologies, particularly in the areas of biofertilizers and biocontrol agents. However, to maximize their competitive edge, companies should consider tailoring their IP strategies to account for local nuances.

In the evolving regulatory and technological landscape, patent protection will remain central to the success of R&D-based companies in Brazil. By aligning innovation efforts with proactive IP strategies and leveraging Brazil's expanding regulatory framework, companies can secure their position in this rapidly growing market while contributing to the sustainable transformation of agriculture on a global scale.

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