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Microbial consortium: How to obtain patent protection in Brazil

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For centuries, humans have unknowingly used natural microbial consortia to transform raw materials into valuable products. Long before the identification of microorganisms, these complex microbial communities played a crucial role in food and beverage production (e.g., beer, wine, cheese, and bread), soil fertility, and even early medicinal preparations. As scientific knowledge expanded, researchers began to understand the intricate interactions within these groups of microorganisms, revealing their vast potential for various applications.

Microbial consortia are diverse communities of microorganisms from different species that coexist and interact, often exhibiting cooperative behavior that enhances their collective functionality. Unlike single-strain cultures, these naturally occurring or engineered communities can perform complex tasks more efficiently by complementing each other's metabolic functions. In nature, microbial consortia play a key role in vital ecological processes, including nutrient cycling, waste degradation, and plant growth promotion. Nowadays, they are harnessed for applications such as wastewater treatment (e.g., degradation of antibiotics and azo dyes), degradation of complex compounds (e.g., petroleum hydrocarbons and plastics), bioprocessing (e.g., biofuel production), probiotics (e.g., gut colonization and metabolic complementation), bioinoculants (e.g., increasing crop tolerance to drought and enhancing phosphorus availability in soil), and synthetic biology (e.g., bioremediation and sustainable chemical synthesis).

Advances in biotechnology have facilitated the design and optimization of microbial consortia for industrial, agricultural, environmental, and medical applications. The construction of artificial microbial consortia generally follows two approaches: top-down and bottom-up. The top-down approach involves selecting a naturally occurring microbial community from an environment relevant to the target application (e.g., soil, wastewater, or the gastrointestinal tract), followed by the elimination or suppression of undesired species and the optimization of interspecies interactions through genetic engineering, environmental modifications, or selective enrichment. In contrast, the bottom-up approach involves assembling a microbial consortium from individual species, selecting microorganisms with specific metabolic capabilities, engineering strains as needed to enhance functionality, and cultivating the consortium under controlled conditions to optimize stability and interspecies interactions.

Engineering microbial consortia aims to facilitate the division of functions among different strains,

with each member performing a specific task that contributes to the overall system's functionality. Interaction mechanisms play a crucial role in selecting microorganisms that ensure optimal performance. Cooperative relationships, such as mutualism and commensalism, are advantageous, while minimizing parasitism, competition, amensalism, and neutralism is essential for maintaining stability and functionality.

Beyond division of functions and cooperative interactions, microbial consortia are increasingly used to drive complex processes more efficiently. For instance, microbial consortia engineering can enhance metabolic pathway efficiency, as demonstrated in the conversion of cellobiose into isopropanol using two strains—one expressing an enzyme to break down polysaccharides from cellobiose, and the other converting the resulting products into isopropanol. Another example is the use of engineered biofilms, a type of engineered living material (ELM), to enhance biofilm production for applications such as aquaplastic manufacturing. Microbial consortia are also employed in biosensors, where genetically modified microorganisms detect environmental contaminants such as arsenic, mercury, and copper by generating fluorescence. Additionally, microbial consortia can be used in product formation, where one strain produces a molecule and another detects it.

Microbial consortia also hold promise for therapeutic interventions. For instance, fecal microbiota transplantation has been explored as a treatment for various conditions. However, the risk of pathogen transmission and the lack of complete characterization of fecal material have limited its widespread clinical use. As an alternative, microbiome-directed therapeutics offer a promising strategy to restore microbial balance. One promising approach involves the use of well-defined bacterial consortia designed to restore a balanced and beneficial microbiota composition.

A growing area of research focuses on the genetic modification of obligate anaerobic gut bacteria. Advances in genetic engineering of Bacteroidales, a major bacterial group in the human gut, have opened new possibilities for microbiome-based therapies with greater specificity and effectiveness. Additionally, CRISPR-Cas9-based platforms have been developed to delete genes responsible for producing metabolites that may harm the host. By preventing the synthesis of these compounds, their absence reduces interaction with the intestinal epithelium, mitigating potential inflammatory responses, dysbiosis, or other adverse physiological effects. These approaches also enable the engineering of gut bacteria to selectively modulate metabolite production, promoting beneficial host-microbiome interactions and improving therapeutic outcomes.

Patent Protection for Microbial Consortia in Brazil

Article 10 (IX) of the Brazilian IP Statute (Law No. 9,279/96) establishes that natural living beings, in whole or in part, are not considered inventions and, therefore, are not eligible for patent protection in Brazil. Non-natural living beings are also considered to fall under these provisions if they cannot be differentiated from their natural counterparts. However, transgenic microorganisms—defined as microorganisms that express, through direct human intervention in their genetic composition, a characteristic not normally achievable by the species under natural conditions—can be patented. Therefore, while some microbial consortia may not be considered inventions in Brazil, protection is possible for those involving genetic manipulation or for combinations of strains that would not naturally coexist without human intervention. However, if such a combination is later found to occur naturally, the granted patent may be subject to annulment.

Furthermore, the use of natural microbial consortia, processes for their preparation, and products comprising them may be patentable, provided the products do not merely represent a dilution of the natural material. In other words, the components must contribute to the final function, which is to provide the natural product in a suitable formulation, such as probiotics formulated with excipients related to capsules or tablets.

Compliance with Enablement Requirements

A key aspect of prosecuting patent applications in biotechnology is compliance with the enablement requirement. In some cases, it is necessary to submit a sequence listing and/or the biological material deposit number upon filing, as these may be considered essential for enabling a person skilled in the art to reproduce the invention. If a microbial consortium is obtained through random mutagenesis leading to increased production of a product, depositing the microbial consortium with a depositary authority recognized by the Budapest Treaty is required. On the other hand, if the activity of the microbial consortium depends on a particular heterologous gene, a sequence listing elucidating the nucleotide sequence is necessary for sufficient disclosure. This also applies to inventions where the consortia are not the primary object but are essential for their reproduction (e.g., a method using a microbial consortium to treat wastewater).

Examples of BRPTO's Examination of Microbial Consortia-Related Applications

Despite restrictions in the Brazilian IP Statute and BRPTO's guidelines, it is possible to obtain protection for microbial consortium-related inventions. However, understanding the invention and developing tailored strategies are crucial to securing the best possible protection. We've selected four cases to demonstrate how the BRPTO examines such applications:

- **Agrinos As (BR 11 2012 032040 8)** sought protection for a microbial composition comprising a microbial consortium, only defined by its acronym, and excipients. The BRPTO found the claims lacked clarity and written description. The patent was granted after the applicant amended the set of claims to specify the deposit number of the microorganisms.
- **Rinagro B.V. (BR 11 2015 015767 0)** was initially rejected as the BRPTO deemed the claimed consortium to be of natural occurrence and, thus, not eligible for patent protection. The patent was granted only for the use use of the consortium, for a method for the reduction of ammonia and/or methane emission in manure or soil, and for the use of manure comprising a microorganism consortium as an organic fertilizer.
- **Superbac Biotechnology Solutions S.A (BR 10 2016 029351 0)** obtained a patent for a process for preparing micro-encapsulated microbial consortia. Since the consortium itself was not the key element of the claimed process, defining it by deposit number was not required by the patent office. However, the BRPTO objected to two dependent claims that referred to modifications in the composition of the consortia without specifically defining the modifications and the final "product", and generically mentioned that the consortia could be used to "certain agricultural application" without specifying it.
- **Sustainable Community Development, LLC (BR 11 2020 013227 6)** faced objections regarding clarity and precision of the claims. The BRPTO required the applicant to explicitly define the microorganisms in the claimed composition, instead of defining the consortia by the function of the microorganisms.

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