Comments of the Biotechnology Industry Organization (BIO)
to the National Institute of Industrial Property (INPI) of Brazil

February 1, 2013

Re: Guidelines for Examination of Patent Applications in Biotechnology

About BIO and the Biotechnology Industry

As a global organization, the Biotechnology Industry Organization (BIO) welcomes the opportunity to make this submission in response to the proposed *Guidelines for Examination of Patent Applications in Biotechnology (hereinafter "Guidelines") issued in November 2012 by the National Institute of Industrial Property (INPI).*

BIO is a not-for-profit trade association representing more than 1,100 companies, universities, research institutions, investors, and other entities in the field of biotechnology. BIO's members hail from 32 countries, including Brazil. Numerous BIO member companies conduct business and research activities in Brazil on a regular basis. The vast majority of our members are small- and medium-sized enterprises that do not have products on the market, but have as their principal assets the intellectual property on innovative research and development. As a result, they are heavily dependent on private investment from venture capital funds and other similar sources to launch and continue their expensive research and development activities.

BIO members are committed to the Brazilian market and have a strong interest in the protection and enforcement of intellectual property rights. Robust intellectual property protection is critically important to fostering the development and commercialization of new biotechnological products. Our members focus their innovative efforts in the areas of healthcare, agriculture, energy, and the environment, researching and developing cutting-edge products and technologies that are helping to feed, fuel, and heal the world. Our members are developing cures and other therapies for life-threatening diseases, as well as agricultural innovations to boost crop yields, farm incomes, and overall agricultural sustainability. BIO members are also developing the next generation of biofuels and other renewable energy sources in order to reduce climate change and dependence on fossil fuels, while still others are focused on bio-based products and other technologies to help clean and sustain our global environment.

All of these critical areas of biotechnology innovation rely on the patenting of nucleic acid and other biological discoveries from humans, plants, animals, and other living organisms. Discovering and developing innovator biologics is a highly complex and risky business. Within the past few decades, the time and costs of drug development have soared. From original idea to the launch of a finished product, biopharmaceutical innovation is a complicated process that can take ten to fifteen years and cost in excess

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of US$ 1.2 billion.[1] A typical biotechnology invention starts in a laboratory where a scientist may discover a gene or other biological component of particular interest. Based on the function and characteristic of this discovery, the scientist can determine its potential for practical application and produce an isolated and purified form useful for such purpose. This represents only a start. For every 5,000 discoveries in pre-clinical testing, an estimated one to five products are approved for human use.[2] A product that looks promising at the discovery phase can fail at several points in drug development, as it undergoes tests for toxicology and efficacy, initially in animals and then in humans. One of the largest costs in drug development comes when side effects occur at the toxicology point. Even for compounds that proceed to clinical trials, approval is not guaranteed. The success rate for approval of biotechnology products is estimated at only 30 percent.[3]

In addition, the complexity of the biologic manufacturing process will also impose significant investment costs. Companies involved in developing innovative biologics must employ advanced techniques, such as recombinant DNA, and mammalian expression techniques. The production of most biologics requires cell culture facilities that can take three to five years to build with costs up to US$ 500 million.[4] Moreover, the facilities must comply with strict regulatory requirements to ensure the safety and purity of the commercialized product. Finding and identifying impurities in biologics is difficult as simple tests do not exist. Thus, additional costs are associated with preventing impurities from entering into the production market. Finally, the cost of materials to manufacture biologics is estimated to be 20 to 100 times more than small molecule drugs.[5]

Getting new biotech plants to the market also requires a tremendous investment. From discovering a new genetic trait, field testing, and meeting intense regulatory requirements to ensure environmental and human safety, agricultural biotechnology is time consuming and costly. First, the initial discovery phase can take years as the trend in the number of candidate genes being screened in order to develop one trait is increasing. Second, the time from the initiation of a discovery phase to commercial launch is on average thirteen years for most crops.[6] Moreover, the overall

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[1] Joseph A. DiMasi and Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?* 28 MANAG. DEC. ECON. 469, 470 (2007).
[2] Peter Gwynne and Gary Heebner, *Drug Discovery and Biotechnology Trends*, 2004, available at http://www.scinecemag.org/site/products/ddbt_0207_final.xhtml.
[3] Tufts Center for the Study of Drug Development, *Average Cost to Develop a New Biotechnology Product is $1.2 Billion*, November 9, 2006, available at http://csdd.tufts.edu/NewsEvents/NewsArticle.asp?newsid=69.
[4] See e.g., Alison McCook, *Manufacturing on a Grand Scale*, *The Scientist*, February 14, 2005, available at http://www.thescientist.com.
[5] Henry Grabowski, Iain Cockburn, and Genia Long, *The Market For Follow-On Biologics: How Will It Evolve?*, *Health Affairs,* September/October 2006.
[6] See Phillips McDougal, *The Cost of New Agrochemical Product Discovery, Development & Registration and Research & Development Predictions for the Future*, January 2010, available at www.croplife.org/PhillipsMcDougalStudy.

cost of discovery, development, and authorization for a new plant biotechnology trait is estimated at US$ 130 million.[7]

The biotechnology business model is based on making significant investments, often hundreds of millions of dollars, in early stage research and development with the hope that some of these efforts will yield a commercially successful product. It is only by taking these risks that breakthrough innovations are developed and commercialized. These risks are even more pronounced for a large majority of the biotechnology industry, which comprises small, unprofitable, privately funded start-up companies without reliable revenue streams. These companies are heavily dependent on private capital to support their research and development activities. They must bear not only the enormous costs and high degree of uncertainty of their product development, but must also seek additional investment of private capital to pursue their innovative research and development work.

The key to the success of the biotechnology industry—across all of its sectors—is a business model that is based on taking significant risks to develop products based on innovation. This business model requires a stable patent system that rewards the discovery, characterization, and isolation of useful genetic material. Patent protection has, time and again, proven to be critical to the decision making process of those providing funding for this research and development. Accordingly, eliminating the possibility of obtaining patents on isolated biological materials would likely slow the progress of much-needed advancements in healthcare, agriculture, food safety, and renewable energy. Moreover, it would have an adverse impact on existing and new biotechnology enterprises in Brazil.

Innovators and their investors can only take this significant risk when key markets like Brazil provide strong protection for fundamental biotechnology inventions such as nucleic acids.

General Comments

BIO commends the INPI for their efforts to devise guidelines for examining biotechnology related inventions. Given the technological advances and the innovation that spurs it are the primary drivers of economic growth in the modern era, it is critical that patent laws and practices properly motivate and reward innovation. While BIO agrees with many of the proposed Guidelines, BIO is concerned that several of the proposed Guidelines would not achieve this objective with respect to biotechnology inventions.

BIO is concerned that aspects of the Guidelines, if adopted, would have significant consequences in all sectors of biotechnology and for patients and consumers in Brazil. Most troublesome, the proposed Guidelines would exclude from patent

[7] Ibid.

protection any isolated and/or purified biological material, whether a gene or otherwise, that may have the same sequence as naturally occurring biological material, despite the fact that the isolated and/or purified biological products are manmade and are structurally and functionally different from their natural counterparts. In addition, several Guidelines interfere with the ability of innovators to obtain meaningful protection for their genetically engineered innovations. Implementation of these proposals would prevent the patenting of a vast amount of biological innovations, to the detriment to the people of Brazil.

Moreover, there are several proposals that BIO believes require further clarification and others that BIO believes depart from the principle that patent applications must be evaluated on a case-by-case basis. Furthermore, BIO remains concerned about patentability requirements mandating disclosure of the source and origin of biological materials.

The following comments by BIO raise these issues in more detail and provide our perspective on some of the specific provisions within the proposed Guidelines.

Specific Areas of Concerns

A. Patentable Subject Matter

1. Isolated and/or purified biological products are manmade inventions that are significantly different from their natural counterparts.

At the outset, naturally occurring products, whether of biologic or chemical origin, are not patent eligible subject matter. Isolated and/or purified products, however, are not naturally occurring products. Instead, they are derived from natural products and are significantly different from their natural counterparts.

Proposed Guideline 4 contains an unqualified exclusion from patentability for isolated and/or purified biological products. Specifically, Guideline 4.2.1.1 of the proposed Guidelines excludes from patentability "the whole or part of biological products, even if isolated or produced synthetically, which have naturally occurring correspondents and which cannot be distinguished from the latter." Guideline 4.1 defines "biological material" broadly to include "all or part of living organisms, plus extracts, lipids, carbohydrates, proteins, DNA, RNA, and parts or fragments thereof." In this regard, the Guidelines essentially disregard the human ingenuity involved in the purification and isolation of biological materials to create new and distinct products.

This interpretation of Article 10 of the Brazilian IP Law is deeply concerning for the biotechnology industry for several reasons.

First, Guideline 4 presumes that isolated and/or purified biological products are not inventions eligible for patent protection because they are the mere "isolation" or

"purification" of naturally occurring substances, rather than newly identified substances. However, this premise is incorrect.

Synthetic preparations of biological material, such as DNA molecules, are typically transformed by human intervention into something that is structurally and functionally different from its natural counterpart. Isolated and/or purified biological molecules are often freestanding chemical compounds that do not occur in nature, but are new substances created in the laboratory. In contrast, genetic material in its natural or "native" form exists as part of structures called chromosomes. A gene is a discrete segment of DNA on a chromosome, which typically includes thousands of genes. A gene in nature thus never occurs as a standalone molecule, but is merely a subunit of a chromosome. Each gene controls the expression of one or more traits by specifying the structure of a protein or proteins it encodes. Naturally occurring genes have three functional parts: (1) one or more regulatory regions; (2) protein encoding regions; and (3) non-protein encoding regions.

In the case of isolated and purified DNA sequences, they are not simply a segment of a strand of DNA; rather, they are physically and chemically separated from the chromosome and other cellular components during the process of isolation. First, the desired sequence is excised from the rest of the chromosome by breaking the covalent bonds between the chromosome and its DNA. By definition, chemical changes induced by the separation create a new molecule, which does not exist in nature.[8] Next, the excised DNA is amplified (reproduced million-fold) and separated from other genomic DNA through various laboratory techniques. In the end, the isolation process transforms the DNA sequence into a new form with distinct properties and uses compared to naturally occurring genes.

Isolated DNA sequences have different chemical structures because the regulatory regions present in naturally occurring genes are removed during the isolation process. As a result, isolated DNA sequences that lack their regulatory regions have different structures than the genes from which they are derived.

Isolated DNA sequences also have a host of new functions not found in naturally occurring genes. For example, when the protein-encoding portion of genes is separated from its natural regulatory regions, the expression of isolated DNAs can be controlled by researchers. This means that isolated DNA molecules can be introduced into a host cell expression system to produce a variety of biological products. In addition to other benefits, this permits a large-scale production of biological products, including drugs and vaccines, which are very difficult to isolate and purify. The removal of naturally occurring regulatory regions also enables scientists to investigate the effect of a

[8] The difference between a physical change and a chemical change is **composition**. In a chemical change, there is a change in the composition of the substances in question. Because chemical changes take place on a molecular level, a chemical change always produces a new substance. In contrast, in a physical change there is a difference in the appearance, smell, or simple display of a sample of matter without a change in composition.

particular gene on cells in new and innovative ways that are not possible with genes in their natural state. In contrast, naturally occurring DNA cannot be used in these ways. In conclusion, scientific evidence supports the principle that isolated DNA molecules yield new products that have distinct uses compared with native DNA.

In addition to Guideline 4, Guideline 6 specifically addresses the patentability of proteins and protein fragments based on naturally occurring amino acid sequences. According to Guideline 6.4.3, if an amino acid sequence is found in the prior art, as part of a naturally occurring protein, a claimed protein/protein fragment is not patentable because it is considered "biological material found in nature." Example 32 of Guideline 6.4.3 further explains that even if the applicant can show that the claimed protein can be distinguished from the natural one on the basis of "folding, spatial conformation, aggregation and physiochemical properties," the claimed subject matter is not patentable.

In many cases, claims covering proteins and/or fragments can be distinguished from their naturally occurring counterparts, e.g., by identifying new three-dimensional structures or deletions in the amino acid sequence. In these cases, modifications to existing protein structures or their amino acid sequences transform the protein/fragment into a new substance with distinct properties and uses. As such, these proteins are no longer "natural biological products," but the result of human ingenuity.

In summation, BIO submits that isolated and/or purified products are clearly distinguishable from their naturally occurring counterparts.

Second, BIO and its Members believe that implementation of the proposed Guidelines would harm, not promote innovation. Patents on isolated genetic material have led to numerous advancements across all sectors in biotechnology. For example, it was the cloning and subsequent patenting of the human insulin gene that allowed researchers to synthesize genuine human insulin in the laboratory using recombinant DNA technology. This approach results in more reliable insulin and reduces complications than can occur from a reaction to animal insulin. Since then, DNA-based innovations have led to numerous advancements in the treatment of many conditions and diseases, including cancer, growth deficiency, hepatitis, rheumatoid arthritis, and hemophilia.

In addition to the healthcare industry, the most significant breakthroughs in agriculture are coming from research into the structure of genomes and the genetic mechanisms behind economically important traits. Researchers continue to work on ways to feed more people at lower cost and with less environmental impact by identifying and using genetic markers-- identifiable DNA sequences-- associated with natural resistance to insects and diseases, resistance to environmental stresses such as drought and temperature fluctuations, and improved characteristics such as lower nutrient use and higher yield.

The importance of DNA-based inventions to the food supply is not limited to the farm. DNA probes can detect harmful or lethal microorganisms in the food supply. When a problem is detected, DNA fingerprinting can be used to trace products back to their source and enable appropriate remedial steps.

Patents on isolated DNA molecules are also important for industrial, energy, and environmental applications. For example, DNA-encoded biocatalysts, such as enzymes, can decrease energy use, replace harsh chemicals in industrial processing, and produce biofuels and green plastics without the use of petroleum-based products, helping to reduce dependence on "dirty" energy sources and mitigate global climate change.

In the realm of renewable energy, genomic research is revolutionizing approaches to creating alternate sources, such as biofuels. Scientists are studying DNA mutations in algae and *E.coli* in the hopes of increasing reproductive efficiency, producing oil that is easier to extract, and creating more attractive fuel options. Other advances focus on ways to break down cellulosic materials, such as isolating genes from termites and enzymes that those genes produce. Because of the copious amounts of sugar contained in cellulose, cellulosic ethanol technology continues to be vigorously pursued by the biotechnology industry.

Third, BIO also believes that excluding isolated and purified biological products from patentability contravenes Brazil's obligations under the TRIPS Agreement. Article 27.1 of the TRIPS Agreement provides that "patents shall be available for any inventions, whether products or processes, to all fields of technology, provided they are new, involve an inventive step and are capable of industrial application." The same paragraph of Article 27 also requires that "patents shall be available and patent rights enjoyable without discrimination as to the … field of technology." Under these obligations, Brazil may not refuse to grant patents on new, useful, and distinct chemical compounds, such as DNA and protein molecules, simply because the compounds are derived from biological sources. Yet, this is exactly the kind of discrimination that is proposed. By singling out a particular field from patent eligibility, the proposed Guidelines raise questions about Brazil's commitment to neutral application of its patent laws.

For the foregoing reasons, virtually every developed economy recognizes the patentability of isolated and synthetically produced biological products. Emerging economies, such as China and Russia, also have adopted similar practices. BIO urges that the proposed Guidelines be revised to reflect that isolated and synthetically produced biological products are inventions that can be distinguished from their natural counterparts due to their significantly different structures and uses.

2. Patents should be available for plant and animal inventions.

The proposed Guidelines declare plants, animals, and their parts unpatentable. Guideline 7.1 provides that even when the invention is the result of human intervention, plant and animal inventions are not patentable according to Article 18(III) of the Brazilian IP Law. Moreover, Guideline 7.2 confirms that "transgenic plants and parts

thereof (for instance, transgenic cell, transgenic tissue and transgenic organ) are not considered patentable."

BIO is concerned that the proposed Guidelines result in an overly broad interpretation of Article 18 (III). Excluding parts of plants and animals from patent protection may run afoul of Brazil's obligations under the TRIPS Agreement. Article 27.1 obligates Brazil to provide patent protection for "any inventions, whether products or processes, to all fields of technology, provided they are new, involve an inventive step and are capable of industrial application." While Article 27.3 of the TRIPS Agreement permits Members to exclude from protection plants and animals, the extension to "parts thereof" is beyond the scope of the TRIPS Agreement. BIO notes that "parts thereof" could be interpreted broadly to include such products as DNA sequences, transgenic cells, and plant and animal extracts. Such extracts often form the basis for a variety of useful products ranging from pharmaceuticals to detergents.

In addition, BIO remains concerned that transgenic plants and animals are not eligible for patent protection in Brazil. While BIO recognizes that Article 18 of the Brazilian IP Law prohibits patents on plants and animals, BIO would like to take this opportunity to express its views that genetic engineering has opened new avenues to modify plants and animals, providing new solutions to solve specific needs. For instance, there is great potential for genetic manipulation of crops to enhance productivity through increasing resistance to diseases, pests, and environmental stress. Transgenic plants are also becoming drug-delivery devices, with both HIV and rabies vaccines being synthesized in plants and bananas engineered to produce edible vaccines. Plant factories are also being designed for high volume production of pharmaceuticals and other beneficial chemicals. Similarly, much effort has gone into the development of animals that can produce various proteins, which are used to treat various conditions, such as cystic fibrosis, emphysema, and blood clots. In addition, animals are also being developed for testing purposes, i.e., evaluating new therapies and vaccines.

While great strides are being made, the development of new features in plants and animals using microbiological methods is a long, difficult process with no guarantee of success. Patent protection is necessary to stimulate private investment and encourage further research and development. BIO urges that the current exclusion from patentability for plant and animal innovations be eliminated.

B. Disclosure Requirements

1. <u>Disclosure requirements should be based on objective standards.</u>

a. Sufficiency of disclosure is based on whether skilled artisans can reproduce the invention.

BIO is concerned that proposed Guideline 2.2 will lead to highly subjective standards in determining whether a claimed invention is sufficiently enabled. For

example, it is unclear how subjective criteria, such as when "the invention is dependent on chance" or when the "embodiment of the invention is inherently impossible," will be applied by INPI. In contrast, example 6 of Guideline 2.2 instructs examiners to employ the well-accepted rule that a specification is sufficiently disclosed if "a person skilled in the art is able to reproduce the invention." Because the Guidelines are unclear as to the precise disclosure obligation imposed on applicants, BIO requests clarification on this issue.

BIO emphasizes that the disclosure requirement set forth in Article 29.1 of the TRIPS Agreement provides that a patent specification "disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art." Thus, whether a patent has disclosed enough to place the invention within reach of the public depends on whether a person ordinarily skilled in the art can reproduce the claimed invention. Under Article 29.1 of the TRIPS Agreement, a WTO Member is not permitted to impose stricter or different disclosure requirements by requiring applicants to provide information beyond that needed to show a person of ordinary skill how to make and use the claimed invention.

Accordingly, BIO strongly encourages the adoption of a single objective standard for determining sufficiency of disclosure, i.e., whether skilled artisans are able to arrive at the claimed invention. Illustrative examples should provide further guidance as to how this standard would be applied, so as to promote transparency and consistency in examination.

b. A claimed invention is adequately supported by a specification that demonstrates the inventor was in possession of the claimed invention.

BIO is concerned that the proposed Guidelines regarding adequate support in the specification may be applied in an overly stringent manner so as to deny patents on inventions that are adequately described and supported by the specification. Specifically, proposed Guideline 2.3 would require applicants to "provide technical input capable of supporting the claimed matter." Because this Guideline does not provide objective rules for what constitutes adequate support in the disclosure, BIO is concerned that applicants would be required to provide working examples for all embodiments in a claimed invention.

BIO submits that a sufficient specification is one that would convey with reasonable clarity that the inventor was in possession of the invention, i.e., that the inventor did invent the invention being claimed. Possession of the invention is shown by describing the invention with adequate specificity such as by words, structures, figures, and formulas. In many cases, this requirement can be met by enumerating a representative number of examples to show that the inventor was in possession of the claimed invention.

BIO recommends adoption of an objective standard for what constitutes adequate support in the specification, i.e., a description of the invention in sufficient terms to allow those skilled in the art to know what was invented. In addition, illustrative examples are needed to provide further guidance as to how this standard would be applied by INPI.

2. Claims should be evaluated on their individual merits in determining compliance with disclosure requirements.

The Guidelines declare that certain claim formulations, as a general rule, are not acceptable because they lack sufficient disclosure and/or clarity. First, the Guidelines suggest that claims that identify genetic material by functional characteristics are not acceptable because they would not meet the clarity and precision requirement of Article 25 of the IP law. For example, the examples set forth in Guideline 6.1 illustrate that claims that rely on functional descriptions will not be accepted by INPI. In a similar fashion, Example 28 of Guideline 6.4.1 declares "the characterization of protein sequences only through their properties, such as three-dimensional structure, function, or biological activity, chemical properties will not be accepted in claims."

BIO submits that instead of evaluating each claim, as a whole, to determine whether the claims comply with the clarity and precision requirement of Article 25 of Brazil's IP law, the Guidelines presume that claims with functional descriptions are not acceptable. In practical effect, the approach articulated in the Guidelines forecloses an independent merit-based analysis. Under the proposed approach, patent examiners must presume that all claims directed to functional descriptions of genetic material must be found per se to be unclear and imprecise.

BIO firmly believes that claims covering biological materials can be adequately described by functional characteristics. For instance, when coupled with a known disclosed correlation between function and structure, functional characteristics can adequately define the claimed invention. An example is given in guidelines issued by the United States Patent and Trademark Office of a functional claim to an antibody.[9] In that example, the specification teaches the purification of antigen X by standard techniques and provides a clear protocol by which antigen X is isolated, but fails to teach antibodies that bind to antigen X. The example emphasized that because the knowledge in the art of antibodies against well characterized antigens was routine, skilled artisans would have recognized the spectrum of antibodies which bind to antigen X. In addition, when a claim covers a genus, the disclosure requirement can be satisfied by describing a representative number of species falling within the scope of the claim or structural features common to the members of the genus so that a skilled artisan can "visualize or recognize" the members of the genus. Accordingly, BIO submits that compliance with

[9] See Example 13 of Written Description Training Materials, March 25, 2008, available at http:www.uspto.gov/web/menu/written.pdf.

disclosure requirements must be assessed on a case-by-case basis based on the disclosure, knowledge in the art, and other facts specifically relevant to the claims presented for examination.

As a further illustration of our concerns, Guideline 6.1 suggests that a claim to a DNA sequence encoding a peptide having a specified sequence would not meet the clarity requirement. This should not be the case. Although only one DNA sequence that encodes a protein may be disclosed, skilled artisans could readily envision all of the DNA sequences capable of encoding the protein by using a genetic code table. Thus, one of ordinary skill in the art can conclude that the applicant was in possession of the genus based on the specification and the general knowledge in the art concerning the degeneracy of the genetic code.

For these reasons, BIO urges INPI to reject the notion that claims employing functional description of material lack clarity and precision. BIO recommends that the Guidelines be revised so that claimed inventions employing functional descriptions are evaluated based on their individual merit.

Second, the proposed Guidelines indicate that claims directed to protein or nucleic acid sequences that contain a specified percent homology or identity with another sequence are not acceptable. The justification articulated in Guideline 6.2 is that not only is "the characterization of the object of protection is unclear and imprecise, in violation of Article 25 of the Brazilian IP Law," but also "the specification does not provide sufficient information to allow the reproduction of all the multiple sequences covered by such a definition, in violation of Article 24 of the Brazilian IP Law."

BIO believes that claims directed to protein or nucleic acid sequences that share a percent homology or identity with another sequence should not be categorically rejected. Instead, BIO submits that such claims should be examined on a case-by-case basis to determine whether they are sufficiently enabled and described. For example, BIO asserts that claims directed to a nucleic acid sequence that encodes a polypeptide with a specified percent identity to a known sequence should be permitted because with the aid of a computer, one could identify all of the nucleic acids that encode a polypeptide with the claimed percent identity. Accordingly, BIO recommends that the proposed Guidelines be revised to permit claims directed to biological material that share a percent homology or identity with another sequence.

Third, the proposed Guidelines require that claims to monoclonal antibodies be characterized by their specific hybridoma. According to Guideline 6.4.6, claims to monoclonal antibodies that are not characterized by their original hybridomas are not acceptable, "[a]s they do not clearly and precisely define the antibodies for which protection is sought" in accordance with Article 25 of the Brazilian IP Law.

While BIO recognizes that a monoclonal antibody can be characterized by their specific hybridoma, BIO advocates that a monoclonal antibody can be characterized by other means, such as their specific amino acid sequence. BIO urges that the proposed

Guidelines permit monoclonal antibodies to be characterized by means other than their specific hybridomas.

3. The deadline for the deposit of biological material should be the filing date in Brazil.

Guideline 2.2.1.2 suggests that if there is a priority claim in a given patent application, the deposit of biological material should be before or up to the date of priority claimed. BIO submits that applicants should be permitted to deposit biological materials up to the filing date of the Brazilian or corresponding PCT application. This approach provides applicants with enhanced flexibility and does not unduly prejudice applicants for failing to deposit biological materials as of the foreign priority date. Accordingly, BIO requests that the deadline for deposits should be before the filing date of the application in Brazil, and not by the priority date.

C. Genetic Resources

The patent system is not the appropriate vehicle for regulating access to genetic resources.

Although BIO recognizes that INPI does not regulate access to genetic resources, BIO would like to take this opportunity to express its views regarding Article 31 of Provisional Measure #2186-16/01, which establishes that the grant of an intellectual property is conditioned upon compliance with measures to disclose the origin of genetic material. BIO has always supported the access and benefit sharing (ABS) goals of the Convention on Biological Diversity (CBD). To this end, BIO has always advocated that an effective ABS regulatory system based on mutually agreed terms between the provider and user of genetic resources is the best mechanism to further the ABS objectives of the CBD. BIO firmly believes that regulating access of traditional knowledge and genetic resources should focus on promoting research, economic development, and the sharing of benefits from the holder of the resource and the consumer.

In BIO's view, Provisional Measure #2186-16/01 does not meet the goals of the CBD. BIO submits that the IP system is not the appropriate instrument for regulating access to Brazil's genetic resources. Requiring, as a condition of patentability, the disclosure of genetic resources and evidence of prior-informed consent and benefit sharing will do nothing to ensure that prior informed consent or benefit sharing actually occurs. When a patent is not granted, inventions are not commercialized, no sharing of economic benefits occurs, and the consumer and holder of the genetic resource does not gain anything. On the other hand, contractual systems to regulate access and benefit-sharing now exist that ensure that benefit sharing occurs in the event of any commercialization of products based on genetic materials to which access is provided, whether or not those products are the subject of patents. Suits for breach of contract can result in court orders for specific performance or for damages. Contracts can also specify how any disputes that arise under the contract will be handled. Criminal

penalties can be applied for violation of laws regulating access. Patent requirements cannot do these things.

BIO also believes that Brazil's requirement, as a condition to patentability, to disclose the source of biological resources used in the claimed invention would be inconsistent with the TRIPS Agreement. The TRIPS Agreement does not permit WTO Members to impose substantive patentability requirements in addition to those specified in the Agreement. Specifically, Article 27.1 of the TRIPS Agreement only permits Members to require that an invention be new, involve an inventive step, and be capable of industrial application. Similarly, the TRIPS Agreement does not permit a WTO Member to impose special or additional disclosure requirements for an invention beyond those specified in Article 29.1. With respect to the disclosure of the invention, WTO Members may only require that the patent applicant "disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application." Consequently, any requirement to disclose additional information for inventions based on genetic resources would be inconsistent with Brazil's obligations under Articles 27.1 and 29.1 of the TRIPS Agreement.

For these reasons, BIO respectfully calls for the elimination of requirements that condition the grant of patent rights to the disclosure of genetic resources and evidence of prior-informed consent.

Setting aside our substantive concerns with Article 31 of Provisional Measure #2186-16/01, BIO seeks clarification regarding the procedures for complying with Article 31. Guideline 8 provides that applicants must provide information concerning the origin of the material through petitions established by INPI: "a petition for access information and another for stating that the application does not involve access." Currently, it is our understanding that a single petition informing INPI that the invention does not involve access to components of Brazilian genetic heritage has been sufficient. BIO seeks clarification as to whether a single petition is sufficient or the proposed Guideline imposes an additional obligation on applications by requiring more than one petition.

Guidelines Requiring Clarification

BIO would also like to take this opportunity to make the following comments on proposed Guidelines that BIO believes require further clarification.

A. Industrial Applicability

The proposed Guidelines introduce a new standard for determining if an invention has industrial applicability. Specifically, proposed Guideline 1.1 states that "any method of private and personal nature is not susceptible of industrial application." (Example 2 of Guideline 1.1)

BIO submits that the proposed Guideline fails to provide a meaningful definition of when an application is of a "private or personal nature." Moreover, the examples offered in the proposed Guideline do not provide the necessary guidance as to the application of this new rule. BIO encourages INPI to explain the meaning and use of the expression "private and personal nature" in the context of determining the industrial applicability of an invention. BIO also respectfully requests that INPI provide additional examples so that applicants can have a more comprehensive understanding of how INPI will implement the rule that methods of a private and personal character are not industrially applicable.

B. Unity of Invention

The proposed Guidelines set forth the standard for determining unity of invention. Guideline 2.1 provides that a patent application "must refer to a single invention or to a group of inventions so interrelated as to compromise a single invention."

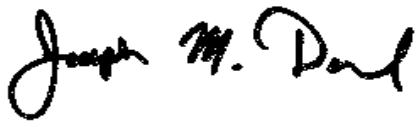
BIO submits that the brief explanation and single example offered by the Guidelines does not adequately explain how unity of invention will be determined. BIO respectfully requests that INPI provide additional guidance and examples of how determinations for unity of invention will be made.

C. Microorganisms

Proposed Guideline 5 provides a list of suitable formulations for claims covering microorganisms. BIO submits that the list of suitable microorganism claims should not be exhaustive, but merely representative of acceptable claims. BIO seeks clarification that the list of acceptable claims is open ended and not an exclusive listing of microorganism claims.

BIO thanks INPI for considering these comments and welcomes further discussion of its views and positions.

Respectfully submitted,



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