BIO Comments on Public Consultation N°66 of October 16, 2012
December 19, 2012

About BIO and the Biotechnology Industry

BIO is a not-for-profit trade association representing more than 1,100 companies, academic centers and research institutions in 30 nations worldwide involved in the research and development of innovative biotechnology products and services. Ninety percent of our members are small and medium sized enterprises (SMEs) working to develop and commercialize cutting-edge products in the areas of healthcare, agriculture, energy, and the environment. Simply put, this global industry would not exist without a stable, predictable and transparent intellectual property system that enables researchers and their sponsors to manage the risks of biotechnology innovation.

Developing a biotechnology product is a lengthy and expensive endeavor. In the health sector, on average, it takes US$1.2 billion over a period of more than a decade to bring a new biopharmaceutical to market; for agricultural biotechnology it takes hundreds of millions of dollars and over a decade to develop a new product. Biotechnology companies, whether in the United States or in Brazil, choose to make this investment when there is a reasonable expectation of a return on investment.

That is why intellectual property is so important. To raise the significant capital required for research and development, companies must first be able to assure investors that their patent portfolios are not at risk from competitors.

Government policies that support innovation are critical as the biotechnology industry seeks to develop innovative healthcare, agricultural, industrial and environmental biotechnology products and provide them to users all around the world. Innovation requires not only scientific research and commercial expertise, but also supportive and dynamic governments that help facilitate the expensive and risky process by which that science is turned into new products. Brazil has recognized the value of innovation in maintaining a robust, diversified economy that can compete in the 21st century, and declared biotechnology a national priority. A symbiotic relationship between Brazil and the biotech industry results in high paying jobs, a healthier, more productive workforce, and positive externalities benefiting society as a whole. While Brazil has made significant strides over the last decade and established ambitious goals, opportunities abound for additional policies to further support the ecosystem of innovation and put the country at an even stronger competitive advantage in the global economy.

With this background, BIO respectfully submits both questions and comments for the National Health Surveillance Agency's (ANVISA) consideration on the proposed rules.

ANVISA's Proposed Rules:

BIO appreciates ANVISA's desire to clarify their role in the review of patent applications for pharmaceutical products and processes. BIO understands that ANIVSA issues these rules as a follow up to the Inter-Ministerial Working Group to clarify the cooperation that

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will occur between ANVISA and INPI. Finally, BIO understands that ANVISA wishes to remain compliant with the Brazilian Constitution, the Federal Attorney General's opinions of 2009 and 2010, and with international law. With this understanding, BIO has the following questions and comments regarding the proposed rules.

General Comment:

As a general matter, BIO remains concerned with Article 229-C of the Brazilian Patent law, which provides for the additional layer of review by ANVISA with respect to pharmaceutical patent applications before they are reviewed by INPI and that is the subject of these draft guidelines. This additional layer of review directed to a specific technology class does not appear consistent with practices in other jurisdictions and with international norms. Until that law is reconsidered, however, we ask that the draft regulations be clarified to address the comments below in a manner that ensures the role of ANVISA is limited to appropriate public health concerns, does not undermine patent law principles in Brazil, and does not cause unreasonable burdens on patent applicants.

Structure:

BIO members' interpret the definition of "contrary to public health" as requiring that both subsections I and II be met for ANVISA review to occur and request clarification to confirm this interpretation.

Subsection I:

"Art 4: §1: It is considered that the patent application is contrary to public health when:

> I – The pharmaceutical product or process contained in the patent presents a health risk."

BIO and its members wish to inquire how ANVISA defines a "health risk." Any pharmaceutical compound would be expected to have both risks and benefits. Whether a pharmaceutical compound's health risks outweigh its health benefits only becomes clear after years of clinical and toxicological testing. However, patent applications on new pharmaceuticals are often filed long before such data are available.

As a practical matter, further clarification is needed so that companies may be capable of providing the information required. The current draft regulations leave several questions unanswered. For example, how would ANVISA decide whether a pharmaceutical compound presents a "health risk" if the results of clinical and toxicological studies are not yet available? Would this only apply to technologies whose only application is so dangerous that it would always outweigh any possible benefits? Would this requirement also include drugs or processes that have multiple uses of which one use constitutes a "risk to public health?" Further clarification would be helpful to determine what type of patents would fall under this section.

Subsection II:

"Art 4: §1: It is considered that the patent application is contrary to public health when:

> II- The patent application of the pharmaceutical product or process is of interest to the policies regulating the universal access to medicine and pharmaceutical assistance as provided for under SUS – Universal Public Health System – and that do not meet the patentability requirements and other criteria as established in the IP Law 9.279/1996."

BIO members seek clarification on how ANVISA will determine whether the patent is "of interest to the policies regulating the universal access to medicine and pharmaceutical assistance as provided for under SUS – Universal Public Health System?"

BIO members understand this language to refer only to those medicines on the approved SUS drug list. Thus, BIO understands that ANVISA would only review patent applications that claim a pharmaceutical product or process that is included in the list of SUS approved and reimbursed medicines as of the time the patent application is being reviewed. This interpretation of the rule is the most practical way for ANVISA to distinguish its role from INPI. This interpretation is also consistent with the plain language of the rule.

Expanding this rule's interpretation to patent applications on experimental or development-stage pharmaceutical products and processes would invite legal uncertainty as any ANVISA analysis would be trying to predict which patents will cover drugs that will be approved in the future and which patents will not. Such an approach would also waste ANVISA's resources on patents that ultimately are not relevant to its public health role. Limiting the scope to SUS approved medicines is a more feasible and practical role for ANVISA.

Patentability Requirements:

BIO members note the language of Article 1, §1 (II), which states that a patent application is considered contrary to public health when a patent application does not "*meet the patentability requirements and other criteria as established in the IP Law 9.279/1996.*" BIO members propose that clarification be added that that the determination of patentability requirements will be made by the INPI which is solely empowered under the law, including in article 2 of Law No. 5.648/70 to perform such a function. Such clarification would ensure full compliance with the decisions of the Federal Attorney General, Opinions 210 of 2009 and 337 of 2010.

Moreover, ANVISA would not appear to need to analyze such factors to determine whether an application is "contrary to public health." Conceptually, an invention could be new, involve an inventive step and industrial application, but ANVISA could still conclude that its commercial exploitation must be prevented in order to protect human or animal health (e.g., that the product may be deemed unsafe and therefore should not

be subject to commercial sales in the Brazilian market – TRIPS Article 27:2). BIO members are confused as to why ANVISA would chose to participate in the technical review of the patent application when it has no bearing on the public health exception reflected in both TRIPS and Brazilian Law.

Additional Questions:

BIO members also wish to understand how the process will work when ANVISA approves a pharmaceutical patent. Will there be reasonable review criteria, timelines and mechanisms for communication with Applicant? Will INPI also have to conduct a patentability analysis? Has the Brazilian government examined whether these rules, which appear to treat a certain class of inventions differently from others, comply with TRIPS obligations including the obligation under Article 27 Section 1 stating that "patents shall be available and patent rights enjoyable without discrimination as to … the field of technology"?

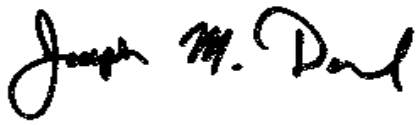
BIO members also wonder whether there is another way for Brazilian ministries to comply with the law. As BIO understands Brazilian law, ANVISA is required to provide prior consent before the grant of the patent. As noted above, the determinations in respect of public health do not appear to require ANVISA to consider typical patentability criteria such as novelty, inventive step, and industrial application. These proposed rules seem unnecessary, particularly in light of the fact that such determinations fall within the competency of INPI.

Finally, ANVISA needs to consider how these rules will affect innovation in Brazil, including impacts on both domestic innovative industry as well as foreign investment. Innovative industries need certainty that their patent applications will be reviewed under uniform legal and administrative standards. There should be clarity in the proposed rules to avoid the improper interpretation that ANVISA is a patent examining authority on the basis of patentability criteria or that INPI somehow has a limited role that excludes patents related to the biopharmaceutical industry. Such a dual system in which pharmaceutical patent applications are examined by a different agency would lead to nonuniformity, drift, and divergence in the interpretation of patent laws.

Conclusion:

ANVISA must carefully consider how the legal uncertainty created by these proposed rules could impact biopharmaceutical innovation in the Brazilian marketplace. Unpredictability in patent law is a great disincentive to investment-intensive innovation wherever it occurs. Accordingly, BIO believes that the proposed rules should more clearly reflect an ANVISA role limited to reviewing public health criteria (e.g., whether preventing the commercial exploitation of the product in order to protect human health) in a manner that does not impinge on the effective implementation of the patent laws in Brazil and which provides a better environment for innovation in Brazil and for the dissemination of this innovation, e.g., innovative cures and treatments, to the general population.

Respectfully submitted,



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