Biotechnology Industry Organization

October 15, 2013

The Honorable Dr. Rob Davies
Minister of Trade and Industry
77 Meintjies Street
Block B, 1st Floor
Sunnyside
Pretoria, South Africa

Re: Comments on the Draft National Policy on Intellectual Property, 2013

Dear Minister Davies,

The Biotechnology Industry Organization (BIO) appreciates this opportunity to provide comments on the Draft National Policy on Intellectual Property, 2013.

BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations in more than 30 developed and developing nations. More than 90% of BIO's companies are small- and medium-sized enterprises. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products.

BIO members are expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment. South African scientists-- today working mainly outside South Africa-- are making important contributions to the advance of biotechnology and development of products that benefit society.

The biotechnology industry relies heavily on patents. The development of a single biotechnology product often takes scientists more than a decade to be commercialized, and hundreds of millions (and in the healthcare sector more than a billion) of dollars of capital investment, a significant amount of which comes from private sources.

Biotechnology product development is also fraught with high risk – the vast majority of biotech products fail to ever reach the marketplace. In addition, while biotech health inventions are entitled to the same patent term as all other inventions – 20 years from the time they are filed – they face the additional hurdle of a rigorous pre-launch regulatory review process during which they may lose between 8 to 10 years of the patent life.

Venture capital firms invest in capital-intensive, long-term, and high-risk research and development endeavors only if they believe that there will be an attractive return on their investment. Patents help provide this assurance.

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According to a patent survey conducted by researchers at the University of California Berkeley, 73% of the biotechnology entrepreneurs surveyed reported that potential funders, such as venture capitalists, angel investors, and commercial banks, etc. indicated patents were an important factor in their investment decisions.[1]

Without strong and predictable patent protection, investors will shy away from investing in biotech innovation, and will simply put their money into projects or products that are less risky – without regard to the great value that biotechnology offers to society.

For this reason, it is important for countries that would like to develop their biotechnology sector to carefully consider the types of patent laws and regulations they implement.

South Africa's Draft National Policy:

A national policy on intellectual property represents an important step in fostering domestic innovative capacity and infrastructure particularly in an IP intensive industry such as the biotechnology industry. In countries that have experienced a "brain drain" of scientific and medical talent, a world-class intellectual property system provides a critical cornerstone for retaining talent and building up national capacity.

BIO and its member companies are aware of the South African government's aspirations to develop its life sciences industry, a message that South African officials communicated clearly at the recent BIO International Conference in Chicago, USA, in April 2014. At that conference and in subsequent discussions, South African officials have sent strong signals that they intend to develop the Life Sciences sector, including biotechnology, to emerge as a global top 20 country by 2020.

While South Africa's Life Sciences and biotechnology industry are in a nascent phase, the country does possess significant building blocks to support a globally-competitive sector.

An OECD report found that South Africa, in 2009, had nearly 21,000 scientific researchers nationwide.[2] Leveraging and commercializing the innovative potential of these scientists requires pro-innovation policies that foster broad economic growth and inclusion emblematic of the biotechnology business model. The biotechnology business model is built on collaborations between universities, small biotechnology companies, and venture capital. The government supports this effort when it sends clear signals that indicate a willingness to protect innovation and fuel the economic potential of South Africa.

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[1] Graham, Stuart J. H. and Sichelman, Ted M., Why Do Start-Ups Patent? (September 6, 2008). Berkeley Technology Law Journal, Vol. 23, 2008. Available at SSRN: http://ssrn.com/abstract=1121224

[2] OECD, Main Science and Technology Indicators, Volume 2013 Issue 1 available at http://www.keepeek.com/Digital-Asset-Management/oecd/science-and-technology/main-science-and-technology-indicators/volume-2013/issue-1_msti-v2013-1-en#page78

BIO welcomes discussion of South Africa's proposal to transition from a patent registration system to a system that would search and substantively examine patent applications from all fields of technology. The establishment of a new cross-disciplinary corps of hundreds of patent examiners could be an important step in building regulatory and technological capacity to promote industrial and agricultural innovation through the issuance of strong patents.

If building a South African substantive examination capacity is deemed a proper use of budgetary resources, not unnecessarily duplicative of work done by other patent offices (in the case of applications that were also filed in other jurisdictions), with searching and examination done in a timely manner and according to international best practices, this endeavor may result in stronger patents and more certainty for innovators in all technology areas.

Any substantive examination system, however, requires sufficient technical capacity to fairly examine patent applications in reasonable time frames. South Africa should provide for mechanisms that protect the innovator from a potentially endless backlog that may likely occur as the patent office tries to build sufficient capacity during this time of transition. For example, some countries provide patent term restoration for examination delays beyond a reasonable time period. Other countries, such as Brazil, ensure a minimum period of protection (10 years from grant) to ensure equity and fairness in their system.

In general, BIO believes that a new South African patent examination system should follow international norms of globally accepted systems such as those in the United States, Europe and Japan. Aligning with such norms will ensure maximum uptake and development and new technologies in South Africa; significant divergences with global practices would only undermine South Africa's goals to enhance its technological development. The following comments are made with such global standards in mind.

The South African government's recognition of the need to expand technology transfer capacity represents another positive development. The government should continue its efforts to leverage South African innovation produced in its universities to bring new products to the world that result in economic benefits to the inventors and the community.

Restrictive licensing terms[3], however, or other efforts that undermine the transfer of this technology would discourage collaborations and private sector investment, and will only make it more difficult to commercialize South African innovation.

The South African government should carefully consider the negative consequences of introducing new mechanisms that are likely to delay access to essential new technology for South Africans. For example, duplicative mechanisms (e.g. pre-grant oppositions or

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[3] Beginning on Page 23 of Draft Policy document

multiple agencies reviewing patent applications) can significantly delay patent grant and may not comport with the principles of justice and due process for innovators. In addition, these mechanisms may violate international treaty obligations, and delay market entry of the life-changing products biotechnology creates. We note that recently in Brazil, courts have held that a system involving the health regulatory authority is onerous to innovators and unnecessarily duplicative because applications are reviewed by the patent authority in that country.

Patentability restrictions and exclusions designed to benefit one industrial non-innovative sector also undermine innovation. All science occurs incrementally. Restrictions against "new uses of known products" remove necessary commercial incentives for innovators to conduct further research on breakthrough products. Such research could include testing proven cancer medications for other potential cancer targets, transferring drought tolerant genetic traits from one type of grain to another, and other areas of incremental innovation where South Africa may command a competitive advantage.

Likewise, exclusions for plant breeders and seed-saving exclusions undermine incentives to commercialize plant biotechnology innovation. Investors will not provide the necessary capital to test and seek regulatory approval of new ideas and educate customers when others can easily copy and resell their technologies without taking risks or investing their own capital. The South African government should carefully consider patentability restrictions and exclusions that retard the commercialization of innovation.

Systems that protect innovation must also consider the science. For example, biologic pharmaceutical products are complex and challenging to manufacture. They present unique considerations relative to pharmaceutical products containing active ingredients made by traditional chemical synthesis. These distinctions translate into different kinds of challenges – both with respect to the regulatory approval of these products and how they can be effectively protected by intellectual property standards.

One important distinction also recognized by the World Health Organization[4], is that, unlike generic drugs, a biosimilar product is not identical to the innovator product. Among other things, this means there is greater uncertainty as to whether an innovator's patent rights will cover a biosimilar version of the innovator's product, as compared to a traditional generic drug. Without the certainty of some substantial period of market exclusivity, innovators will not benefit from the incentives needed to conduct the expensive, risky, and time-consuming work to discover and bring new biological products to market.

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[4] Guidelines on evaluation of Similar Biotherapeutic Products (SBPs). World Health Organization. Available from: http://www.who.int/biologicals/areas/biological_therapeutics/BIOTHERAPEUTICS_FOR_WEB_22APRIL2010.pdf [accessed 2012 Jun 18]

Patents and regulatory data protection, while complementary, serve two distinct purposes. Patents protect inventions ranging from the foundational inventions that underpin new drugs and biologics to the incremental advances necessary to bring those products to market and manufacture them at the scale needed by patients. Patents provide such protection even where a third party conducts its own, full research and development program to develop the same or similar product.

Data protection, on the other hand, is intended to incentivize biomedical innovators to invest the enormous amount of resources and time necessary to conduct the complex development work required to prove a new drug or biological product is safe and effective, and to secure regulatory approval of that new product. Data protection does so by requiring third parties seeking to gain approval of a same or similar product to independently generate the full range of pre-clinical and clinical evidence for their own product, or to wait a defined period of time before seeking a regulatory shortcut to approval based on the innovator's prior approval. Data protection thus prevents parties from unfairly "free riding" on the investments and efforts made by the innovator to secure original approval of its product.

Finally, BIO believes that measures aimed at increasing access through the use of compulsory licenses and parallel importation are misguided and will not solve South Africa's healthcare access problems. Incidentally, such measures would also have the effect of reducing incentives from global researchers and innovators to partner with companies or other parties in South Africa.

Indeed such measures often have the precise opposite effect. BIO's members with an interest in healthcare include a diverse mix of innovative small biotechnology companies, large integrated pharmaceutical companies, top-tier research institutions, and biotech investment firms – each with its own different expertise and experiences that can be used to address these unmet needs. Each biotechnology company also has its own unique business model, with varying approaches to R&D and commercialization depending on the products at issue and the markets for them.

At the heart of these business models, however, is respect for, and the need for, strong intellectual property rights. Further, each company must in the end remain – or become – profitable to be able to continue its investment in R&D activities and make products broadly available. Measures such as compulsory licensing and parallel importation would discourage such companies from a) investing in new and innovative technologies and products, and b) from launching cutting-edge technologies in the country in which such measures are in place.

BIO's members believe that the goals of increasing access to medicines, respecting intellectual property rights, and maintaining commercial viability are not mutually exclusive-- rather they are mutually supportive.

Based on our broad international experience and empirical evidence, BIO's members believe that many of the problems with access to medicines in the developing world are caused by factors outside the control of individual stakeholders, such as lack of adequate manufacturing, delivery and public health infrastructure, trade and tariff barriers, taxes and duties imposed on medicines, regulatory obstacles, lack of market incentives, local corruption, diversion of supply to more lucrative markets, and a chronic underinvestment in health in national budgets.

Nonetheless, BIO believes that all participants in this complex arena – including BIO's healthcare members – can work together collaboratively to help improve the lives of those suffering in the developing world from preventable or treatable conditions.[5]

In short, BIO believes that collaboration offers a superior and more sustainable approach than coercive measures that rely on confiscation of or limitations on intellectual property. Experience has shown that investors and innovators in biotechnology are far more likely to react enthusiastically to incentives and offers of partnership than policies that appear to be punitive in nature or otherwise undermine investor confidence.

BIO notes that there is a close correlation between competitiveness and investment flows, and that the globally-leading top 20-25 countries today rely on incentive-based (vs. coercive) policies to encourage investment and innovation in the sector[6].

Opportunities for Continued Engagement

BIO has appreciated the participation of the South African government in our annual International Convention where the global biotechnology community gathers. At these gatherings, typically 15,000 participants from more than 65 countries share information, partner, and seek investment to take their exciting discoveries to the market.

Likewise, high-level staff from BIO have participated in conferences in South Africa providing technical capacity on how to build a domestic biotechnology industry. A consistent theme in all of these events has been the importance of protecting intellectual property to ensure that small- and medium-sized companies, which often take the greatest risks in the development process, can attract the private funding they need to commercialize their inventions.

This concept is one that South Africa's nascent biotechnology sector recognizes. Organizations such as the Technology Innovation Agency are working closely with BIO to develop entrepreneurship programming for South African biotechnology innovators at the upcoming BIO International Convention, which will take place in San Diego CA, June 23-26, 2014. We hope to welcome dozens of young innovators, scientists and public officials from South Africa to this convention.

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[5] *See BIO's Options for Increasing Access to Medicines in the Developing World,* at http://www.bio.org/sites/default/files/Access_to_Medicines_Policy_Statement_Final.pdf

[6] Scientific American Worldview Scorecard 2014.

We believe that a clear signal from South Africa of its willingness to provide the necessary minimum level of intellectual property rights to sustain innovation will open the door for collaborations.

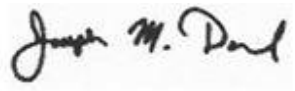
South Africa is nurturing a nascent biotechnology industry with immeasurable potential. We respectfully submit that revising the Draft National Policy on Intellectual Property to reflect BIO's comments will best help South Africa realize this potential.

BIO appreciates this opportunity to comment. We would be pleased to provide further input or clarification of our comments, as needed.

In coming months, we anticipate sending a high-level delegation to South Africa to discuss policies that would support development of the local biotechnology sector. That visit may offer a timely opportunity to discuss the Draft National Policy on Intellectual Property, and gain a better understanding of South Africa's aspirations in the life sciences sector.

We look forward to any opportunity to share the international experience and perspectives of our more than 1000 member companies and academic research centers.

Respectfully Submitted,



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