BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

March 18, 2004

Dr. MacDonald Netshitenzhe
Director: Commercial Law and Policy
Department of Trade and Industry
PRETORIA
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Via Electronic Mail and Facsimile

Sir,

We offer the following remarks in response to Notice 227 of 2004 concerning certain proposed amendments to the Patents Act, 1978.

We offer these remarks on behalf of the Biotechnology Industry Organization (BIO).

The Biotechnology Industry Organization is a trade association representing more than 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations in the United States and 33 other nations. BIO members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products. The vast majority of our members are small companies that are involved in researching, identifying and developing products that will utilize biotechnology to improve public health, agriculture and industry. These companies offer the best hope known for developing new drugs and medical technology to address unmet medical needs afflicting South Africans. These companies are also identifying ways of diagnosing diseases, which assists doctors and health-care providers in managing public health.

Agricultural biotechnology is similarly improving the lives of South Africans by vastly improving the viability and yield of crops, particularly those planted in South Africa and on the continent. These crops are hardier, more drought-resistant, have higher yields and can even provide a more balanced nutritional profile than their unimproved counterparts.

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Biotechnology is a transformative technology that benefits a country in other ways as well. Specifically, South African researchers who become proficient in the basic techniques of biotechnology can use these new skills to develop products and services that address needs in their immediate environment. Whether those skills are applied in the public sector, through state-based or university-run research enterprises, in private companies started to develop new biotechnology products or services, or in collaborations among these entities, South Africa benefits—through more high-quality jobs, educational enrichment and new solutions to local medical, agricultural and industrial problems.

The biotechnology industry also has enjoyed a mutually beneficial relationship with the public research community. Many biotechnology companies were started to commercially develop a promising technology invented by one or more individuals in a university lab. The nature of our industry and its business model requires collaborations to be forged among and between companies, universities, public research organizations and the like. As a consequence, our industry is particularly sensitive to ensuring that the priorities and needs of our partners in development are respected and enforced.

We believe it is important to keep these points in mind when evaluating the desirability and necessity of the proposed changes to legal protection afforded to inventions within South Africa. The present request seeks comments on a series of changes to the South African Patents Act. In general, we believe these changes will diminish the protections afforded to biotechnology inventions in South Africa and inhibit, rather than promote, collaborations involving the biotechnology industry. Moreover, the changes would introduce immense and impractical burdens on patent applicants with no corresponding public benefit.

Observations on the Premise for the Patents Act Amendment

The stated motivation for the proposed amendments is identified in the "Explanatory Memorandum" to the notice. This memorandum states:

> Genetic and biological resources all over the world are being patented. The patenting of these resources happens without the knowledge of the states who have sovereignty over them and without the knowledge of indigenous peoples who might have contributed immensely towards the patent invention.

Before addressing the proposed amendments, we must first take issue with this unfounded and inaccurate characterization of the motivation for these changes.

As you must certainly appreciate, there is an important distinction between a "genetic or biological resource," on the one hand, and an "invention" on the other hand.

Under Section 25 of the South African Patents Act, an invention "which involves an inventive step and which is capable of being used or applied in trade or industry or agriculture" may be patented. A "mere discovery" is not eligible to be patented under Section 25(2)(b) of the act. In contrast, "biological or genetic resources" are undeveloped naturally occurring organisms, such as plants, bacteria or animals. The distinction is critical. If the premise of the proposed legislation is to prevent the patenting of "genetic or biological resources," we submit that such legislation is unnecessary, as the patenting of such things is already prohibited under the South African Patents Act.

However, if the intent of the proposed amendments is to prevent the patenting of *inventions* that may have been made, in part, through utilization of a genetic or biological resource, or of indigenous knowledge in relation to such resources, we have further concerns. In particular, the explicit purpose of the Patents Act is *to grant* patents on inventions that meet the requirements for novelty, inventive step and industrial application and are adequately disclosed to permit others to practice the invention. Provided that these requirements are met, the South African law appropriately rewards the innovator with a patent. If the premise of the proposed amendments is simply to prevent the patenting of otherwise eligible inventions, we take serious issue with this as a legitimate motivation.

It is established beyond doubt that if there is no way the developer can make a reasonable commercial return on his investment, inventions that require substantial up-front investments, substantial commercial risk and significant effort will never reach the market in the form of products and services. In the various fields of biotechnology, this is absolutely the case. The reason is clear. If the South African law permits a party to copy a product that can be manufactured for a fraction of its development cost, no company has a financial incentive to introduce new products. This not only frustrates the purpose of the Patents Act, but also harms the South African consumer, and even the party that wishes to copy the product. For, as is well established, patents are to give exclusive rights for a fixed period, after which the invention may be exploited without restriction. Thus, if there is no prospect for a biotech company to enjoy market exclusivity for some period of time, it will pursue other opportunities.

Accordingly, if the sole justification for the proposed amendment is the belief that patents should not be granted on the inventions the Patents Act currently permits to be patented, we believe an appropriate justification for the amendments is wholly lacking.

The proposed amendment also seeks to punish a party that fails to disclose certain information in the patent application. The punishment is loss of the patent right, by either refusing to issue a patent or revoking the patent. One could thus assume that the purpose of these sanctions is not to prohibit the use of genetic or biological resources to develop inventions or to use information provided by the member of an indigenous community to develop an invention that qualifies under the Patents Act, but to ensure that such uses are

publicly disclosed and done with the consent of the appropriate parties. If this is the motivation for the amendments, again, we have several concerns.

First, we are aware of no evidence suggesting that parties that develop inventions out of genetic or biological resources or by working with indigenous communities are not complying with their obligations to disclose such uses and, more importantly to obtain informed consent before such use occurs and to share benefits as agreed upon mutually agreed terms. Indeed, the members of our organization are on record as fully supporting the principles of the Convention on Biological Diversity that prevent unauthorized exploitation of genetic or biological resources or knowledge held by indigenous communities. We think it particularly unwise to attempt to make such dramatic changes to the Patents Act upon such an insubstantial foundation.

Second, if the intent of the South African government is to entirely extinguish any interest by commercial or academic entities in the study, evaluation and potential commercial exploitation of inventions made using the knowledge gained from study of genetic or biological resources, this legislation will help the country reach that goal. Given the structure of the proposed amendments, however, it does not seem that this is the intent of the amendments. Rather, if we assume correctly that the amendments are proposed to *ensure transparency,* we must assume that the South African government perceives value in the study, evaluation and potential commercial development of inventions from the study of genetic and biological resources and that the government of South Africa wishes to promote such activity. In this respect, we believe the amendments, if enacted, will precisely frustrate that objective. Biotechnology companies participate in an extremely competitive environment. In particular, since so few biotechnology companies have any products or services that produce revenue, there is an intense and ongoing competition for funding from investors. Investors, in turn, must see that there are manageable and predictable risks to balance against the potential return from their investment. A biotechnology company, accordingly, must select carefully the focus of its research and development activities.

In the particular case of this legislation, the proposed amendments will extinguish interest by biotechnology companies in the study, research upon and use of biological and genetic resources within South Africa. Moreover, it will also diminish the interest such companies may have to collaborate with and attempt to establish business development within South Africa, as the risks of losing patent rights in South Africa far outweigh the potential commercial returns. To provide a concrete example, the draft proposal will make it much more difficult, if not impossible, for University of Cape Town researchers studying the Resurrection Plant, to find support to harness their findings to improve the drought tolerance of South African crops.

If the true motivation of the proposed amendment is to create a transparent environment where uses of biological and genetic resources or the use of knowledge

provided by an indigenous community can be readily identified and regulated, we respectfully submit that a direct regulation of such activity would be a far more effective path without the detriments of the present approach. For example, we note that only a small percentage of genetic or biological resources studied in research and development actually result in inventions that seek patent protection, and fewer still clear the substantial barriers of patentability. Thus, if this is the system that the government of South Africa employs to regulate use of its genetic and biological resources, it will—by definition—fail to induce reporting of such uses except when they result in patentable inventions, a small fraction of the potential uses that might occur. More significantly, however, by putting at risk patents that use genetic or biological resources, BIO members will not use those resources.

Specific Observations and Questions Regarding the Proposed Amendments

The motivation and premise for the proposed amendments raise serious questions and concerns, as noted above. In addition, we have specific concerns with the form of the proposed amendments. These concerns can be summarized as follows:

(i) The *nature* of the information that must be disclosed in the application is not identified.

(ii) It is unclear *which* "genetic or biological resources" will trigger disclosure obligations—those that led directly to the invention, those that were evaluated but did not contribute to the invention, those that clearly did not lead to the invention, etc.

(ii) The *relationship* of the required information to the invention that is being claimed in the patent is not identified. For example, if an applicant *has* disclosed the necessary information for genetic resources actually used to make the invention, but does not disclose information about unrelated genetic resources, can the patent still be refused or revoked?

(iv) It is not clear what the term "origin" is intended to mean. Is this the *actual location* from which a resource was obtained, such as a collection or a particular geographical location? Or must a patent applicant deduce and disclose the absolute *biological origin* of the resource by conducting evolutionary biology research on the material? If the latter, to what year in history is the research to be conducted? If the research discloses multiple origins (as of the historical date in question), must all or some of those origins be disclosed? If a legitimate error is made in conducting this research such that some but not all "origins" are identified in the application, the law would still appear to apply the sanction of loss of the patent right. Is this the intent of the legislation?

(v) If a party has failed to disclose information as required by the act, but nonetheless has publicly disclosed its use of the materials, fully discharged its obligations to share benefits, provided informed consent in use of the material and is otherwise fully complying with the expectations of the South African government in relation to use of genetic or biological resources, why should any party have the capacity to invalidate the patent for not properly disclosing information in a patent application?

In addition, we believe these obligations appear to be inconsistent with prevailing international standards governing patents. Indeed, we seriously doubt that the proposed amendments would be consistent with the obligations South Africa has undertaken by its participation in the Paris Convention for the Protection of Industrial Property and the Agreement on Trade-Related Aspects of Intellectual Property Rights.

Conclusions

For the reasons noted above, we believe the proposed amendments are not based upon a legitimate foundation and suffer from serious flaws in drafting. More significantly, however, we believe the proposed amendments, measured in part by the stated reason for making the changes, will send a very negative signal to the biotechnology community. As a consequence, the industry will redirect its interests to developmental opportunities outside of South Africa. We strongly urge the government to reconsider the need for and form of the proposed amendments.

Please contact Lila Feisee at 202-962-9502 should you have any questions regarding these comments.

Sincerely,

L. Val Giddings, Ph.D.
Vice President for Food and Agriculture

cc:
Jocelyn Webster, Executive Director, AfricaBio

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