



October 14, 2010

To: Members of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing of the Convention on Biological Diversity

Cc: Convention on Biological Diversity Secretariat

From: The Heads of Biotechnology Associations: Asia, Europe and the Americas

On behalf of the more than 2,000 biotechnology/biopharmaceutical enterprises worldwide, we would like to thank you for the opportunity to comment on the *Draft Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity*. Our members support the agreed objective of the Protocol and the greater goal to establish a practical and workable international regime governing access to genetic resources and the fair and equitable sharing of benefits arising therefrom. The industry stands ready to do its fair share in the conservation and sustainable use of biodiversity.

The biotechnology industry is poised to be a critical player in the quest for innovative technologies in a variety of sectors, including medical, agricultural and industrial arenas. The industry is uniquely suited to collaborate and partner with organizations and institutions around the world including in the developing world, which in turn may provide benefits and increases capacity for these countries. The biotechnology industry is working in the medical sector to produce the next generation of vaccines and medicines, largely focused on currently unmet medical needs such as a variety of cancers, Alzheimer's disease, multiple sclerosis, and diabetes. In the agricultural field, biotechnology innovations are growing the economy worldwide by simultaneously increasing food supplies, reducing pesticide applications, conserving natural resources of land, water and nutrients, and increasing farm income. Biotechnology companies are also leading the way in creating alternative fuels and various chemicals and pharmaceuticals from renewable sources without compromising the environment. And yet, even with all of the advancements in the field, we have only just begun to realize the full potential of this powerful technology.

It is clear that many areas of development in biotechnology would further the long-term goals of the ABS Protocol. Indeed, we understand that the greatest threats to biodiversity are the



potential ramifications from unchecked global climate change – threats that biotechnology innovation is critical to satisfactorily address. Achieving success in pursuit of the Convention’s goals requires the effort and cooperation of all stakeholders. CBD Parties can help promote such cooperation by better understanding the industry and the role that incentives – particularly strong and predictable patent protection – play in driving its innovative activities.

The vast majority of our members are small- and medium sized-enterprises that have innovative technologies and products in various stages of development. Many of these companies are not profitable – however, the industry as a whole invests tens of billions of dollars developing ideas into cutting-edge products, which may include the next generation of treatments for chronic and infectious diseases, and new crops and technologies for clean water and clean energy to meet the growing demands of the world’s population. In order for our companies to do their part to sustainably develop biotechnology products, they must attract funding from private investors to exist and continue their R&D operations. Our companies do this by demonstrating that their technological innovation has promising commercial applications that can be protected and can deliver a strong return on the enormous amounts of investment needed in this endeavor. In our experience, the four pillars for biotech innovation are:

- sufficient research capacity – both in terms of capital and human resources, to initiate the quest for novel technologies;
- an efficient mechanism to transfer basic research from laboratories into the hands of those who can further develop it through innovation;
- a transparent and strong intellectual property system to incentivize the development of these technologies; and
- an enabling, science-based regulatory environment for the development of new products.

The Draft ABS Protocol expressly recognizes the first of these important pillars by mandating that Parties cooperate in capacity building, including “strengthening of human resources and institutional capacities.” Consistent with the notion of development of “endogenous research capabilities” in draft 18, this capacity will, in turn, empower countries to create their own innovative technologies. In addition, universities and research institutions, which are also at the table in these discussions, will play a role as engines for innovation and economic growth. It has been our experience that stakeholders can be encouraged to participate in these activities through funding, capacity building and education.

The draft Protocol also touches upon the second pillar, by including a provision on technology transfer, and specifically mentions collaboration in technical and scientific research and development, including “biotechnological research activities.” The same provision also mandates Parties to promote and encourage “access to” and “transfer of technology to developing country Parties.” In order to make this a reality, the appropriate incentives must be in place to stimulate basic research, to transfer that research to others who can further develop it into commercial applications, and to facilitate transfers across borders.

However, the recognition of these two pillars is called into question by certain proposals made in respect of the third and fourth pillars. In particular, certain proposals made regarding intellectual property raise great concerns and, if adopted, would hinder, rather than promote, the access to, and transfer of, technology to developing countries – as well as hinder the generation of shared benefits in furtherance of the objectives of the Protocol.

Biotechnology product development often takes many years and millions of dollars of capital investment. This process is fraught with high risk and the vast majority of biotech products fail to reach the marketplace. In order to provide sufficient incentives for such a cost intensive, long-term and high-risk process, there is a critical need for strong and predictable intellectual property protection, and specifically patent protection. Certain provisions have been proposed in the Protocol such as patent disclosure requirements or including intellectual property offices as mandatory “checkpoints.” These proposals, if implemented, would add great uncertainty into the intellectual property system, undermine the incentives of that system for innovation and, consequently, undermine the generation of benefits from the use of genetic resources that may be fairly and equitably shared. These proposals reduce investment in innovative products, including those needed to address the largest threats to biodiversity, such as climate change and food security. The ABS Protocol has a unique chance to assist in creating a global regulatory environment in respect of genetic resources and associated traditional knowledge to overcome these barriers. But in doing so, it should not seek to modify and intervene in the international intellectual property system. Similarly, it should not seek to impair, in any way, the operation of existing ABS systems, such as the Food and Agriculture Organization’s International Treaty on Plant Genetic Resources for Food and Agriculture.

The Protocol can, however, enhance legal certainty regarding the establishment of an appropriate regulatory environment in CBD Parties when implementing their obligations under the Convention. Consequently, it is critical that the Protocol apply only to those genetic resources (or associated traditional knowledge) acquired after the application of the Protocol in the provider country – *i.e.*, the Protocol must avoid any retroactive application to those resources transferred previously, which could cause existing agreements, and research being performed thereunder, to be called into question. In addition, clarity of obligations at the time that resources are accessed is of paramount importance to successful implementation. Thus, the Protocol should provide that any obligations to share benefits must be based on mutually agreed terms reached at the time of access, where required in publicly available national laws.

The solutions to some of the world’s most pressing challenges are possible through biotechnology. Our companies are at the forefront of such innovation. With appropriate incentives and cooperation, our companies can help achieve the goals of providing greater access to innovative medicines and therapeutics, developing new innovative bio-based materials and enzymes for industrial processes, increasing crop yields and conserve natural resources through new agricultural advances, and addressing climate change by developing alternative fuel sources and other mitigation technologies, while at the same time providing for jobs and economic growth. We believe that an ABS Protocol that is practical, workable, and provides legal certainty can help us achieve these goals.

We would be pleased to elaborate on these views and hope that you will take them into consideration in your negotiation process. We are confident that, if the four pillars discussed above are fairly recognized, we can look forward to the establishment of an ABS Protocol at the upcoming Conference of the Parties that will achieve the goal of appropriate access and the fair and equitable sharing of benefits arising from the use of genetic resources that will result in innovative products for the betterment of mankind.

Sincerely,

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