

June 30, 2010

Mr. Keith H. Christie, D. Phil
Assistant Deputy Minister, Global Issues
Department of International Relations and Foreign Trade
125 Sussex Drive
Ottawa, Ontario K1A 0G2

Mr. Des Mahon
Manager, Access and Benefit Sharing
Ecosystems and Biodiversity Priorities, Environmental Stewardship Branch
Strategic Priorities Directorate
Environment Canada
Place Vincent Massey, 12th Floor
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Gatineau, QC K1A 0H3

Re: Draft Access and Benefits (ABS) Protocol and Domestic ABS Position

Dear Mr. Christie and Mr. Mahon:

On behalf of BIOTECCanada, Canada's Research-Based Pharmaceutical Companies (Rx&D), CropLife Canada, and the Canadian Chamber of Commerce (collectively the "Canadian Industry Stakeholders"), we would like to thank you for seeking our comments on the Draft Access and Benefits (ABS) Protocol being negotiated under the framework of the United Nations Convention on Biodiversity as well as the Canadian position on *Managing Genetic Resources for the 21st Century*. Although not widely known to or understood by many Canadian industry and non-industry stakeholders, we believe that the development of both the international and domestic ABS regimes will have significant implications for the development of the Canadian economy.

Our comments on both perspectives of ABS are guided by the principle that robust intellectual property (IP) protection regimes are absolutely critical to the development of innovative industries in Canada. As Canada strives to position itself in an increasingly competitive global economy, innovation has become critical to Canada's continued success. As participants in a knowledge-based economy, Canadians have a vested interest in their Government striving for a best-in-class IP protection regime domestically, and that we vigorously promote and defend IP rights internationally. Care must be taken in both areas to ensure that the policies that are developed enable the ability of research-based companies to invest in the research, development and commercial application of new biotechnology and biopharmaceutical innovations.

International Perspective: The Draft ABS Protocol

Support for CBD Objectives. Canadian Industry Stakeholders would like to reiterate our support of the objectives of the Convention on Biological Diversity (CBD) – to provide a legal framework for the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising out of the utilization of Genetic Resources (GR). We also support the

development of a workable International Regime (IR) based on the draft (Cali) protocol. While the drafts have improved through the negotiation process, a number of concerns remain outstanding.

Patent Related Disclosure Requirements. As we have previously emphasized, mandatory patent or IP disclosure requirements will not counteract “bio-piracy.” Rather, imposing such mandatory requirements will create significant uncertainty within the patent system and reduce investment in biotechnology and biopharmaceutical companies and in the use of genetic resources to create innovative products needed to address the largest threats to biodiversity, including climate change. This will have negative consequences for holders of genetic resources who wish to benefit from providing access. The World Intellectual Property Organization (WIPO) has a mandate for text-based negotiation on matters relating to IP and genetic resources, and therefore any such proposals should be discussed in WIPO. We recommend that the reference to disclosure requirements (Article 13) be eliminated.

Scope. The IR must not go beyond the scope of the CBD. The ABS provisions of the CBD (e.g., Art. 15) are limited to “genetic resources.” References to the broader category of “biological resources” in respect of access and benefit-sharing should be deleted, and must not include human genetic resources (consistent with COP Decision II/11). References to derivatives or products from genetic resources (Articles 4(2) and 13(a)) should be deleted as they reach beyond the definition of genetic resources.

Retroactivity. The IR should only apply to genetic resources acquired or accessed after the entry into force of the IR and its ratification in the provider country. The IR should not apply to pre-CBD or pre-IR transfers of genetic resources and should have no impact on existing (pre- or post-CBD) material transfer agreements. We recommend that the scope of the IR be clarified to reflect that the protocol only applies to genetic resources accessed following the entry into force for each provider country.

Application of Foreign Laws. The IR should not provide an obligation to interpret and apply foreign laws: We believe that provisions such as those in Article 12 have the potential to cause significant uncertainty and trade disruptions and should be eliminated from the IR. The suggestion that countries determine or interpret compliance with the national laws of another country raises significant issues for stakeholders that may utilize or distribute genetic resources in multiple jurisdictions.

Certificates System is Premature. We continue to believe that it is premature to mandate a certificate system in the IR and further deliberation is necessary on this point. If a certificate system is to become part of the IR then we believe that it should be available, on a voluntary basis, as prima facie evidence demonstrating compliance with national laws. In addition, the lack of a certificate should not be considered to be evidence of non-compliance with national laws, and the provision of certificates should not become a requirement in regulatory regimes such as the IP system.

Domestic Perspective:

While Canadian Industry Stakeholders understand the motivation behind the Government of Canada’s interest in the establishment of a domestic regime for ABS, and appreciate the fact that you have asked for our comments early in the process, it remains unclear to us whether a domestic

ABS regime is truly needed at this point in time. However, assuming that the Government moves forward, we have identified several key concepts that must be taken into consideration.

Simple and Facilitative: If the Government concludes that there is a need for a Canadian ABS policy, it should be consistent with the Bonn Guidelines in that it must be simple, predictable and national in scope. Parties seeking to utilize Canadian GR cannot reasonably be expected to negotiate with the Government of Canada, in addition to several provinces and territories, First Nations, and other GR holders. There must be a “single-window” approach to accessing these resources, or else Canadian GR will simply not be utilized, to the ultimate detriment of potential users and holders, and Canadian economic development. Canada’s federal, provincial and territorial jurisdictions must agree on ownership issues prior to implementation of any domestic GR policy. Moreover, any Canadian ABS policy should create a facilitative framework which encourages access to GR to the benefit of users, holders and taxpayers, rather than creating bureaucratic or cost obstacles to usage. Consistent with our comments regarding international perspectives on ABS, any policy should emphasize bilateral contractual agreements between users and holders, who are ultimately in the best position to assess the value and importance of specific GR resources.

Forward-Looking: Any new Canadian policy on ABS must have a clear starting date. The Government should not seek to enforce the new policy on GR that was accessed prior to its coming into force, since this would create business uncertainty and be highly inequitable. Any new policy should therefore “grandfather” rather than impose new burdens on holders and users that already have agreements in place to access GR.

Do No Harm: Consistent with our international position above, Canadian Industry Stakeholders do not support any form of patent disclosure mechanism (even of a voluntary nature) in relation to a domestic ABS policy. We also note that several Canadian companies are currently accessing Canadian GR in a variety of industries under agreements from various levels of government. We would encourage the Government of Canada to consult with these companies to learn what best practices might be employed in the creation of a national ABS policy, and to ensure that any new policy does not result in additional regulatory burden on these companies and other companies who may be interested in developing GR resources.

Conclusions:

The Canadian Industry Stakeholders greatly appreciate the position that the Government of Canada has taken to date in these international negotiations in opposition to the inclusion of new disclosure requirements within the patent system specifically. We ask that the Government of Canada maintain this reasonable and defensible position in opposition to any proposals that would seek to undermine the current balance of rights and obligations that exist within the Trade-Related Aspects of IP Rights Agreement and related international agreements. With respect to domestic ABS discussions, we believe that the general concepts set out above should guide the Government with respect to both its internal deliberations, and in its discussions with other Canadian governments and stakeholders.

The Canadian Industry Stakeholders appreciate the Government of Canada’s continued collaboration and consultation with our respective industries on this important topic. We look forward to working with the Department of Foreign Affairs and International Trade, Environment Canada, Industry Canada and other federal departments, P/T governments, and other stakeholders to help

provide practical solutions and an industry perspective on both international and domestic ABS related issues.

Sincerely,



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BIOTECanada



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Chief of Staff and Vice President, Legal Affairs
Canada's Research-Based Pharmaceutical Companies (Rx&D)



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The Canadian Chamber of Commerce

cc: Mona Frenedo, Industry Canada
Anne Daniel, Department of Justice