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July 14, 2005

Ambassador Rob Portman
United States Trade Representative
600 17th Street, N.W.
Washington, DC 20508

Ref.: Biodiversity and Intellectual Property Rules in the Andean Free Trade Agreement

Dear Ambassador Portman,

This letter concerns the ongoing negotiations leading to a free trade agreement between the United States and Colombia, Ecuador and Peru (Andean FTA), three countries with some of the richest biodiversity in the world. The Andean region is a vast reservoir of genetic material and traditional knowledge, and the tropical areas of the Andean Community of Nations concentrate approximately one quarter of the planet's biological diversity. It is of the utmost importance that the intellectual property rules in the Andean FTA support the conservation and sustainable use of the unique biological resources of the Andean region. The Andean FTA should preserve the flexibilities of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and incorporate the concerns many developing countries, including Andean countries, have voiced in the multilateral context regarding the need for a mutually supportive relationship around international intellectual property rules, the conservation of biodiversity and the preservation of the rights of local communities and indigenous peoples.

Systems of Intellectual Property Protection: The Andean FTA should reaffirm the option granted to countries under Article 27.3(b) of the TRIPS Agreement to exclude plants and animals from patentability. The Commission on Intellectual Property Rights established by the government of the United Kingdom recommended that developing countries not require patent protection for plants and animals given potential restrictions on use of seed by farmers and researchers. Patents on life forms also raise ethical and moral issues for many countries, as well as concerns regarding the impact on biodiversity. Recent free trade agreements negotiated by the United States, however, include provisions obligating Parties to undertake efforts to provide patents for plants. It is of critical importance that the Andean FTA not follow these negative examples; rather, the Andean FTA should support the options and flexibilities recognized at the multilateral level.

The Andean FTA should reaffirm the flexibility recognized by Article 27.3(b) regarding the use of *sui generis* systems of protection. For plant varieties, *sui generis* systems can mediate the impact of intellectual property protection on seed prices; safeguard farmers' traditional practices of saving, exchanging, and planting seeds; support public agricultural research institutions; and promote the development of varieties tailored to local conditions. In addition, the Andean FTA should not require Parties to ratify or adhere to UPOV 1991, a system of plant variety protection conceived for large scale, mechanized agriculture, which fails to recognize farmers' rights and limits access to germplasm for research purposes.

Disclosure of Origin, Prior Informed Consent and Benefit-sharing: The Andean FTA should obligate Parties to require patent applicants to disclose the source and country of origin of genetic resources and traditional knowledge used in the invention, as well as evidence of prior informed consent and fair and equitable sharing of benefits. Although international law recognizes the sovereign rights of States over genetic resources, the lack of concrete disclosure requirements in international patent rules has resulted, in several cases, in the patenting of inventions involving genetic material and traditional knowledge without adequate recognition of the country of origin of those resources or the indigenous or other local communities that identified their properties and/or conserved them through the years.

The case of *Uña de Gato* illustrates how disclosure requirements could ensure the equitable sharing of benefits derived from traditional knowledge and genetic resources. US patent 4,844,901 (oxindole alkaloids having properties stimulating the immunological system) relates to a substance containing an extract from root parts of the *uncaria tomentosa*. Native Peruvians have been using this plant against tumors and inflammations for years. Klaus Keplinger, one of the inventors mentioned in the patent and the assignee of the patent, utilized this traditional knowledge in his research and discovered that the plant could be used for stimulating the immunological system. It is doubtful that Keplinger would have been able to develop his invention if he had not been guided by the traditional knowledge of native Peruvians. Unfortunately, that *uncaria tomentosa* is but one example among many, including the Maca plant in Peru, the Ayahuasca vine of the Amazon, the neem tree and turmeric of India, and the Hoodia cactus of Southern Africa.

The contribution of traditional knowledge must be recognized and protected through disclosure requirements, prior informed consent and benefit-sharing. It is also crucial to acknowledge the difference between the concept of knowledge in the public domain in the U.S. patent system and the way that knowledge is developed and shared in traditional communities in other countries. Traditional knowledge cannot simply be regarded as public domain information; its holders have the right to prior informed consent and to benefit from its use. Additionally, prior informed consent from the country of origin of the genetic resource is also necessary to ensure respect for domestic laws regarding access and benefit-sharing.

These intellectual property requirements would improve the quality and transparency of patents related to genetic resources and traditional knowledge; assist patent-granting authorities in developed and developing countries in prior art searches and assessing claims of inventiveness and novelty; and reduce the misuse of the intellectual property system. In addition, they would mitigate the obstacles faced by developing countries in identifying and challenging patents related to genetic resources or traditional knowledge taken illegally from their territories. Such requirements would also be useful for disputes on inventorship, entitlements to a claimed invention, and infringement cases. This promotes legal certainty and win-win situations for all parties involved: countries of origin, communities and inventors.

Technology Transfer: Recognition that the Andean FTA should promote technology transfer is also critical, as is concrete language requiring the United States to grant incentives to industry providing effective access to the relevant technology. The TRIPS Agreement refers to the transfer and dissemination of technology "to the mutual advantage of producers and users of knowledge and in a manner conducive to social and economic welfare" as one of its objectives. Additionally, the Convention on Biological Diversity recognizes that "both access to and transfer of technology, including biotechnology, among Contracting Parties are essential elements for the attainment of the objectives" of the agreement.

Enforcement: Finally, to date, FTAs negotiated by the United States have included the commitment to effectively enforce environmental laws, which directly relates to intellectual property rules regarding the protection of genetic resources and associated knowledge. At the international level, the Andean countries are all parties to the Convention on Biological Diversity and therefore committed to its decisions and guidance on the issue, including the ongoing negotiation of a regime on access and benefit-sharing. Regionally, through the Andean Community these countries are bound to several decisions relating to genetic resources, intellectual property, plant varieties as well as patents and the nature of inventions. These obligations and their integration into relevant national law should be recognized and upheld by the FTA given their environmental nature and implications. Insensitivity to this body of law, to the need to preserve biological diversity in one of the world's most mega-diverse areas, and to the misappropriation of genetic resources and traditional knowledge would do immense harm to the United States' image and values both in the Andean Region and more broadly in Latin America and the world.

We hope that the U.S. government embraces our concerns. If you have any questions, please contact the undersigned for further discussion.

Sincerely,

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