

USPTO
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USPTO Comments on WIPO/IP/GR/056/01
Entitled “Examination of Issues Relating to the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Rights Applications”

The United States Patent and Trademark Office would like to thank the International Bureau for the opportunity to provide comments on the document entitled “Examination of Issues Relating to the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Rights Applications.” Below are our comments and suggestions.

On page 19, following paragraph 51, please insert a description of U.S. national measures, as follows:

United States

The U.S. National Parks Omnibus Management Act of 1998 expressly authorizes “negotiations with the research community and private industry for equitable, efficient benefit-sharing arrangements” in connection with research conducted in national parks. The Act also mandates increased scientific research in the national parks and the use of science in park management decisions. The law encourages the national parks to be places for scientific study by public as well as private sector researchers, and mandates long-term inventory and monitoring programs that provide baseline information, and document trends relating to the condition of park resources. The law does so by requiring permits to collect samples in the national parks. In order to obtain a permit, parties seeking access must first negotiate a cooperative research and development agreement (CRADA) with the park system.

As an example, a CRADA was entered into between a company named Diversa and Yellowstone National Park in 1999. Under the CRADA, Diversa was allowed to take DNA samples from wolves in Yellowstone. In exchange, Diversa developed the first DNA pedigree for the endangered Yellowstone wolves at no charge to the U.S. government. This pedigree, which the Yellowstone National Park could not have afforded to pay for, helps in understanding the dynamics of the wolf population, assessing the genetic health of the park’s wolf population, identifying wolves that are killed illegally, detecting when wolves from other areas immigrate to Greater Yellowstone, and documenting breeding in the wild. This knowledge is used by Yellowstone staff in carrying out their charge to conserve the wildlife in the park for the enjoyment of future generations.

On pages 21-22, paragraph 57, please insert the following bullets, to reflect an additional underlying questions that must be considered with respect to new disclosure requirements:

- Is the patent law the appropriate vehicle for ABS?
- What impact would a new disclosure requirement have on innovation?
- Will the pursuit of ABS through the patent system cause greater harm than benefit?
- How would a new disclosure requirement transfer benefits?
- Have any of the disclosure requirements that have been implemented promoted ABS in an effective manner?
- How have new disclosure requirements affected rates of innovation in those countries?

On page 28, please change the title from “TRIPS Council Checklist of Issues” to “TRIPS Council.” Under this heading, please reflect that the TRIPS Council has decided not to structure its work based upon the proposed checklist. Please also note that another proposal was made by the United States to structure work upon widely shared objectives of WTO Members. These objectives consist of (1) ensuring authorized access to genetic resources, i.e., that prior informed consent is obtained; (2) achieving equitable sharing of the benefits arising from the use of traditional knowledge and genetic resources; and (3) preventing the issuance of erroneously issued patents. This approach is preferred by certain Members in order to ensure that the positions of all Members are fully considered, without prejudice to any particular position, in order to facilitate resolving differences between Members in that forum. Furthermore, this approach has generated significant discussion in that forum as evidenced by a number of papers engaging on that level (see IP/C/W/434 by the United States and IP/C/W/443 by India and Brazil) as well as comments by various Members.

Furthermore, the TRIPS Council, in response to an initial proposal by the delegation of Canada, has embarked upon a more “fact-based” discussion involving national experiences in trying to achieve progress in that area.

On page 31, paragraph 86, please insert a third option for model provisions, as follows:

(iii) maintaining, and not exceeding, traditional disclosure requirements, as these are the most constructive and least harmful model.

On page 33, after paragraph 89, please insert the following:

The submission of the United States pointed out that that new disclosure requirements may be inconsistent with, or may conflict with, WIPO-administered treaties such as the PCT and PLT, as well as the WTO-administered TRIPS Agreement.

On page 37, in the Summary of Options for Model Provisions, please insert a new subparagraph, as follows:

(f) The form or status of model provisions for new disclosure requirements is not relevant, as the best option is to not adopt a new disclosure requirement in the patent laws because a new disclosure requirement would not effectively facilitate ABS, and it would discourage innovation.