

July 31, 2006

**Comments of the American BioIndustry Alliance on WIPO Paper
WIPO/GRTK/IC/9/5, “The Protection of Traditional Knowledge: Revised
Objectives and Principles”**

Introduction and Summary

The American BioIndustry Alliance (ABIA) welcomes the opportunity to comment on document WIPO/GRTK/IC/9/5 (“The Protection of Traditional Knowledge: Revised Objectives and Principles,” January 9, 2006). ABIA members strongly support WIPO’s work and believe that continued focused efforts in WIPO will bring greater clarity to the needs of biodiverse developing countries that seek both social and economic benefits from the sustainable use of genetic resources and associated traditional knowledge. Traditional Knowledge Digital Libraries (TKDL), databases, and registries are an area of particular promise where the work of WIPO has already been helpful. Much more, however, needs to be done.

To that end, the ABIA urges WIPO to expand the work program on traditional knowledge (TK) of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) both to develop a universal system to harmonize existing TK databases and digital libraries and also to ensure that their benefits reach the smaller developing country members of WIPO.

The ABIA was established in September 2005 as a non-profit, non-government organization to provide focused advocacy in support of the full patentability of biotechnology inventions and seeks enabling conditions for biotechnology in developed and developing countries through sustainable, mutually beneficial Access and Benefit Sharing policies.

The ABIA believes that WIPO’s program to protect traditional knowledge (TK) should support measures that simultaneously (i) help all stakeholders achieve their Access and Benefit Sharing (ABS) objectives and (ii) provide incentives for research in provider countries. Countries as varied as Australia and Costa Rica have used this approach in developing measures that serve to leverage their rich biodiversity into a recognized capacity for innovation based on their GR and related TK assets

ABS Enforcement and the Patent System

The ABIA is of the view that enforcement of ABS should be separate from the administration of patent rights, which are critical to the generation of the potential benefits that all parties seek from any ABS scheme. The biotechnology industry

is united in the view that strong patent rights remain essential for the successful commercialization of new biotechnology products.

Additional, mandatory patent disclosure would not provide any positive incentives for research by provider countries, or create benefits for developing countries. Instead, a patent-centric system for the enforcement of ABS would create uncertainty; discourage the very patent-related activity that developing countries seek to benefit from; and, in any event, would not effectively address the issue of access and benefit sharing.

Positive Alternatives for TK Protection

ABS Agreements

Over the past year, the ABIA has engaged with other stakeholders in developing positive alternatives to the patent-centric enforcement of access and benefit sharing of GR inventions and related TK. Such alternatives would simultaneously protect TK and provide up-front benefits to provider countries.

Such solutions include a system of ABS agreements, made on mutually agreed terms, which provide front-loaded benefits to provider countries. Under this approach, provider countries can gain highly important non-monetary benefits that can have a positive impact on research budgets, staff training; empowerment of human resources; technology transfer/infrastructure support; and conservation efforts. In addition, they can gain legal certainty through protection of intellectual property, market-oriented policies and a commitment to science and research, all of which facilitate the transfer of technology from the North to the South. At the ABIA Side-Event held at the CBD Eighth Conference of the Parties (COP-8), representatives from Australia and Costa Rica explained how, consistent with the sustainable use of their GR and protection of TK, they had used such ABS agreements to gain social and economic benefits from their biodiversity.¹

Traditional Knowledge Databases, Registries and Digital Libraries

Another promising approach, which is the focus of this paper, involves the use of traditional knowledge databases, registries and digital libraries (TKDL). The issues related to TKDLs are complex. Yet, as explained in the United Nations University Institute of Advanced Studies report, The

¹ Additional information on all ABIA side event speakers and presentations referenced in this paper can be found at <http://www.abialliance.com/html/news.html>

Role of Registers & Databases in the Protection of Traditional Knowledge. TKDLs can play a substantial role in protecting TK.²

TKDLs provide patent examiners with a search tool to avoid the issuance of “bad” patents based on prior art, while at the same time preserving biotech patent standards needed to generate continued R&D investment. The dual purpose of the TKDL has been recognized by Dr. R. A. Mashelkar, Director General of India’s premier independent research institute the Council of Scientific and Industrial Research (CSIR):

To mitigate this problem [of non-original inventions], the creation of TKDL in the developing world would serve a bigger purpose in providing and enhancing its innovation capacity... It could act as a bridge between the traditional and modern knowledge systems. Availability of this knowledge in a retrievable form in many languages will give a major impetus to modern research in the developing world, as it itself can then get involved in innovative research in adding further value to this traditional knowledge.”³

The role of TK data bases and digital libraries in generating meaningful benefits to stakeholders from genetic resources and related traditional knowledge was the subject of a side event that the ABIA sponsored at the fourth meeting of the ABS Working Group of the CBD in Granada, Spain. Presentations made by Dr. Shakeel Bhatti of the World Intellectual Property Organization (WIPO) and Dr. K. Gupta of the Council on Scientific and Industry Research (CSIR) of India, focused on the role of traditional knowledge databases, registries and digital libraries in providing positive benefits to stakeholders and in preventing issuance of patents lacking novelty or an inventive step by ensuring access to prior art.

As Dr. Gupta explained, the TKDL database acts as a bridge between ancient verses in different local languages and patent examiners in other countries, since it provides information on modern as well as local names in a language and format understandable to patent examiners. He stressed that the TKDL does not seek to prevent scientific research in the area of medicinal plants; it only seeks to break barriers in language and format for existing codified knowledge available in the public domain. He concluded that the TKDL is an important tool both to prevent issuance of patents based primarily on prior art, as well as to promote new research.

² United Nations University Institute of Advanced Studies, The Role of Registers & Databases in the Protection of Traditional Knowledge, January 2003, page 38.

³ “Intellectual Property Rights and the Third World,” Current Science, vol. 81, No. 8, 25 October 2001.

The ABIA has contracted independent research on the role of the Indian TK Digital Library in encouraging innovative research by CSIR institutions on Ayurvedic and other traditional knowledge and/or medicinal plants. Between 1980 and 2005, TK-related innovation by CSIR scientists resulted in 725 granted or published US patents. Of the 161 non-biotechnological patents that were directly related to TK and GR, 123 were herbal/medicinal applications; 24 involved plants and 14 involved microorganisms related to bioremediation. CSIR's US patents were informed by the TDKL, which provided both a road map to CSIR scientists as well as information on prior art to US patent examiners.

At the ABIA Side-Event in Granada in February, 2005, Dr. Bhatti of WIPO confirmed that, beyond India, there are a number of other developing countries in all regions that have adopted databases and registries for traditional knowledge and genetic resources, both individually and through regional initiatives. Among the databases that he cited were the Traditional Chinese Medicine (TCM) Patent Database of China; the system of national and local registers established under Peruvian Law 27811; and the Biozulua Data Base in Venezuela, which covers native medicines, ancestral technology and traditional agricultural knowledge.

The development of TKDLs is not the exclusive domain of governments. For example, the American Association for the Advancement of Science Project on Traditional Ecological Knowledge, together with a group of non-profit foundations and other non government organizations, has established the Traditional Ecological Knowledge Prior Art Database (T.E.K.* P.A.D.), which is an index and search engine of existing Internet-based, public domain documentation concerning indigenous knowledge and plant species uses. According to information found on its website,⁴ TEK*PAD brings together and archives in a single location, various types of public domain data necessary to establish prior art. Data includes taxonomic and other species data, ethnobotanical uses, scientific and medical articles and abstracts, as well as patent applications themselves.

ABIA members recognize the concerns raised by some that a public system of TK databases or digital libraries would provide a "license to steal" by cataloging GR and associated TK in a way that would be accessible to commercial researchers and scientists. The ABIA views the argument that the mere availability of TKDLs will lead to increased biopiracy as misleading. Such a view may be based on the incorrect assumption that the mere knowledge of the GR and/or TK is itself patentable. In fact, any TK that is known to a community and/or included

⁴ <http://ip.aaas.org/tekindex.nsf>

in a TKDL would constitute prior art, and would thus not be patentable. This important and basic point is often overlooked in the TKDL debate.

In this regard, the ABIA wishes to stress that, to the extent that any TKDL system encourages new, innovative research in the country of origin that uses, as its starting point, existing knowledge about GR/TK, it will benefit the biodiverse developing countries themselves. The recent independent research on India commissioned by the ABIA and presented at the CBD ABS Working Group in Granada demonstrates that R&D and patenting by CSIR scientists increased as a result of the development of the TKDL. At the same time, the TKDL did not result in issuance of “bad” patents by the U.S. PTO on Indian GR/TK.

Experience at the national level with TKDLs demonstrates their importance and utility in informing and facilitating the patent examination process and thus preventing “bad” GR/TK-related patents. The ABIA believes that the logical next step is the development of an inter-operable, integrated and comprehensive system of national TKDLs. Such an internationally-integrated system, which, to some degree, would be publicly available, would make it easier for patent offices to prevent bad patent issuance. It is particularly important that there be a mechanism developed to benefit smaller countries so that they can “dock” to a larger TKDL system.

In this regard, the ABIA welcomes the recent submission of the Government of Japan⁵ that proposed such data bases as an affirmative alternative to patent disclosure. The Japanese submission reflects the growing recognition and support by developing and developed countries alike of the utility of TKDLs in the ABS debate.

The Japanese submission provides a thorough analysis of the relationship between the CBD and the patent system and comes to the conclusion that data bases related to GR and TK are “an effective solution . . . which is accessible by examiners in any country, in order to avoid the erroneous granting of patents for genetic resources and related traditional knowledge.” Such “access-friendly” data bases, the GOJ contends, would create an environment that would enable examiners to perform efficient searches on a research basis. The GOJ paper calls for a “one-stop” system where GR and related TK can be researched once and comprehensively, rather than for a “system in which each data base created by each country has to be searched separately.”

⁵ “The Patent System and Genetic Resources,” WIPO/GRTK/IC/9/13, April 20, 2006.

Conclusion

The ABIA recognizes that many WIPO members, especially among the smaller developing countries, do not currently have the capacity or expertise to establish TKDLs that would dovetail with existing systems found in countries such as India and China. It consequently urges the IGC to focus its efforts on assisting these countries to develop the necessary TKDL-related infrastructure and on providing a process for the ultimate development of interoperable systems. In that regard, the ABIA urges the IGC to use the points raised in the Japanese paper as the terms of reference for an expanded work program on TK both to develop a universal system to harmonize existing TK databases and digital libraries and also to ensure that their benefits reach the smaller developing countries.