

## Views on the International Regime

By SUSAN FINSTON



Just as CBD Parties intensified efforts on elaboration of an international regime for Access and Benefit-sharing (ABS) following COP-7, biotechnology companies sought greater engagement on biodiversity and benefit sharing issues. American companies launched the American BioIndustry Alliance (ABIA) in September 2005 to provide focused advocacy relating to access and benefit-sharing and international patent standards.

ABIA members – which include some of the largest companies active in the life sciences, and some of the smallest – share a heightened awareness of and commitment to biodiversity initiatives [1]. ABIA is company-driven, with member companies determining ABIA positions and activities.

### Positive alternatives

ABIA works closely with CBD Parties and other stakeholders to provide positive alternatives to the patent-centric enforcement of ABS of genetic resource inventions. The ABIA organizes side-events at major multilateral meetings to present positive alternatives to mandatory patent disclosure obligations, and plays a collaborative and coordinating role with other leading industry groups and research institutions. Most ABIA positions have developed through interactions and collaborations with delegations from developing countries, other NGOs and international research organizations, including Codes of Conduct, Model Material Transfer Agreements, Trade Marks/Regional Certifications, and Traditional Knowledge Digital Libraries.

*“Non-discriminatory treatment is needed to provide positive incentives for foreign direct investment and to ensure a fair rate of return, with transparent, predictable and durable procedures at the national level”*

The positive role of Codes of Conduct was explored at the ABIA/BIO Side Event held at the fifth meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing (October 2007). ABIA members have a proven record of compliance with the ABS obligations laid out in the *Bonn Guidelines*, including meaningful Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) for commercialization.

Based on extensive experience in the Food and Agriculture Organization (FAO) International Treaty on Plant Genetic Resources (ITPGR), ABIA members believe that Material Transfer Agreements (MTAs) may provide legally-binding instruments to define the access and benefit sharing terms and conditions up-front and establish milestone events triggering either compensation or additional negotiations and could also provide the context for critical capacity building. The former Secretary General of the International Seed Federation provided an overview of the practical benefits for MTAs at the ABIA/BIO/CLI side-event held on the margins of ABSWG-6.

In 2006 at COP-8 in Curitiba, the Public Interest Intellectual Property Advocates (PIIPA) Survey provided identified trademarks, regional certifications and other doing-business IPP issues as leading areas of need for developing country entrepreneurs. Ethiopia has since adopted a trademarks/regional certification systems to promote a return from genetic resources to local communities. Through appropriate capacity building programs for local communities and indigenous groups, trademarks and regional certification could be implemented at the national level to provide immediate benefits for ABS stakeholders.

ABIA members have also learned a great deal from the pioneering work of India on the development of the Traditional Knowledge Digital Library (TKDL) for efficient prior art searches to prevent the issuance of patents for inventions based on prior art, *i.e.*, lacking novelty or an inventive step. TKDLs provide positive incentives for research and investment in the commercialization of genetic resources. India, Malaysia, Venezuela, China and others, have already implemented TKDL variants. These databases add transparency about the origin of genetic resources, the related traditional knowledge and any indigenous groups from whom prior consent should be obtained. 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 ABSWG-4 in Granada, Spain (1 February 2006).

ABIA / BIO / CLI side event at COP-9

28 May, lunchtime, BMU / room 1.130

1423

### Red lines

Throughout the last three years, the ABIA has raised consistent concerns about primarily defensive and negative approaches to ABS, including mandatory patent disclosure.

- Clean title through patent protection for all life sciences inventions without additional disclosure obligations remains critical to industry's ability to make long-term investments.
- Complex and burdensome bureaucratic systems have led to stagnation of innovation and product development in the natural products area, discouraged international investment and collaboration with developing countries.
- Non-discriminatory treatment is needed to provide positive incentives for foreign direct investment and to ensure a fair rate of return, with transparent, predictable and durable procedures at the national level.
- Inclusion of indirect products or derivatives of any genetic resource would create enormous uncertainties for industry as technically even apples and oranges could be swept into the net of ABS-related activities as by-products of biodiversity.
- There has been a marked inability to reach international agreement on an accepted definition of TK. TK should be addressed in the elaboration of an ABS International Regime consistent with the scope of CBD ABS obligations and the Bonn Guidelines, and should go no farther.

ABIA members have learned a great deal from heightened engagement since 2005 and recognize that more hard work lies ahead. We appreciate the opportunity to work with CBD Parties and other stakeholders in the continuing work of the CBD's mandate to the ABS Working Group, as it completes its work in 2010 for the consideration of COP-10.

[1] Members include Avanti Therapeutics, Bristol Myers-Squibb, Eli Lilly and Company, Excel Life Sciences, General Electric, Hana Biosciences, Millennium Pharmaceuticals, Pfizer, Procter & Gamble, Tethys Research and ToxEM LLC. Membership is open to any company with U.S. operations active in the life-sciences, agriculture (inputs, related products and foods), forest, pulp/paper, plant, other industrial enzymes and/or environmental biotechnology applications.

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