

## DISCUSSION PAPER

### Relevance of Genetic Resources to the Pharmaceutical Industry<sup>1</sup>

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#### Introduction

For most of the developing world, it may be an understatement to note that intellectual property (IP) protection is viewed with trepidation and suspicion. Despite the documented developmental benefits of IP,<sup>2</sup> it has become a source of debate and polarization in multilateral fora, including the World Intellectual Property Organization (WIPO), the World Trade Organization (WTO) Trade Related Aspects of Intellectual Property Rights (TRIPS) Council, and the Convention on Biological Diversity (CBD).<sup>3,4</sup> With the widely-held perception within the developing world that WIPO and WTO discussions tilt towards the interests of Western, more developed economies (such as the U.S. and Europe), developing countries increased their presence and engagement in biodiversity-related issues which culminated in the negotiations that established the CBD in 1992.

If WIPO and the TRIPS Agreement within the WTO are viewed by anti-IP activists as primarily benefiting the developed world, the CBD was intended to be a direct counter-point that would ensure that developing countries and their indigenous peoples retained sovereignty and control over natural resources and related bio-diversity found in greater concentration in developing countries.<sup>5</sup> Concerns about the negative tone of countries on intellectual property

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<sup>1</sup> Susan Kling Finston, with research assistance from Paul Hanna, MPP, University of Michigan Ford School of Public Policy (expected Spring 2005). This article is based on a presentation initially made at the International Society of Environmental Biotechnology, Seventh Biennial Symposium, June 21, 2004, in Chicago, IL. A draft of this paper was subsequently presented at the 5<sup>th</sup> Princess Chulabhorn International Science Congress: Evolving Genetics and its Global Impact, August 17, 2004, in Bangkok, Thailand.

<sup>2</sup> Zavín, Jonathan, et al. 1997. *The Value of Intellectual Property Rights Enforcement in Developing Countries. Economic Perspectives*. June 1997. [<http://usinfo.state.gov/journals/ites/0697/ijee/ej7com1.htm>]. Taking the real-world case of Mexico. Since the adoption of strong intellectual property for medicines, Mexico has eradicated Smallpox and Polio; developed "State of the Art" vaccines, like those to prevent meningitis, gastrointestinal and respiratory infections, and increased average life expectancy increased in Mexico from 52 to 74 years, including a reduction by more than 50% in the rate of early childhood mortality. See the 2004 Annual Report, *Asociación Mexicana de Industrias de Investigación Farmacéutica* (AMIIF). See also George G. Korenko, 1999. *Intellectual Property Protection and Industrial Growth, A Case Study*, The Journal of World Intellectual Property, January 1999, No. 1, pp 47 – 75, which found that patent protection transformed the pharmaceutical industry into one of Italy's leading industries, with annual average growth of more than 5.4% at a time when average GDP growth overall was only about 1.5%. For more recent data on benefits of intellectual property for middle-level developing countries, see, Ryan, M.P. and Shanebrook, J., 2004. *Establishing Globally-Competitive Pharmaceutical and Bio-Medical Technology Industries in Jordan: An Assessment of Business Strategies and the Enabling Environment*, International Intellectual Property Institute and the AMIR Project, August 2004.

<sup>3</sup> *Brazil rejects proposal for global patent. Gazeta Mercantil Online (Brazil)*. Oct 2, 2002.

<sup>4</sup> Hirano, Ko., 2003. *U.S., Poor Nations remain apart over WTO drugs row. Japan Economic Newswire*. Feb 15, 2003.

<sup>5</sup> *Convention on Biological Diversity*. Article 3. June 5, 1992. (<http://www.biodiv.org/convention/articles.asp>)

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protection, expressed primarily by key developing countries during the negotiations, contributed to the U.S. decision to defer ratification of the CBD,<sup>6</sup> notwithstanding that most European and other WIPO/WTO members had adopted and implemented the CBD.<sup>7</sup>

Most recently, at the Seventh Conference of the Parties (COP-7) of the CBD, Ministers agreed to undertake the most ambitious and possibly the most far-reaching negotiations in the history of the Convention. These negotiations will deal with the issue known as Access and Benefit-sharing (ABS) relating to “genetic resources” (all non-human, i.e. plant, animal or microbial materials). While far from definitive, the COP-7 Ministerial Declaration left open the possibility of the establishment of a mandatory international ABS regime that would have a chilling effect on patent rights for biotechnology inventions. This Declaration demonstrates the continuing ambivalence of much of the world’s governments to the ability of current IP protection systems to meet their developmental needs, and the corresponding fear that developed states are using IP in an unfair way to take advantage of the so-called “mega-diversity” in the developing world without providing commensurate benefits.

On a regular basis, the media reports allegations of “bio-piracy,” e.g. assertions that Western scientists have appropriated biological specimens without adequate compensation for developing countries or their indigenous peoples. These assertions resonate with the public, but unfortunately create a misleading and incorrect impression about the prevalence of this activity. More troubling, this implies that most corporations and scientists fail to comply with CBD-based rules, such as prior informed consent and benefit-sharing. As a rule, while U.S. and European corporations follow current voluntary CBD ABS guidelines, the increasing intensity of the focus on ABS issues has had the overall effect of reducing interest in natural products as a source for the research and development activities of multi-national corporations.

What this means is that, despite the potential that may exist in natural products that could yield benefits for consumers and patients around the world, the increasingly negative focus on ABS by developing countries is driving down interest among the commercial sector to evaluate natural products for potential R&D efforts. This has resulted in a decreasing level of activity in this field by the biotech and pharmaceutical industries. International research-based bio-pharmaceutical companies have largely downsized R&D efforts focused on natural products, preferring instead to advance work in synthetic drug development. Despite the efforts of many developing countries to establish bio-technology hubs as a focal point for development in the 21<sup>st</sup> century, the absence of predictable and transparent ownership for biodiversity-related natural resources has led to a dearth of investment in biotechnology outside of the U.S., with even European markets falling short of predicted investment.<sup>8</sup> This is an unfortunate situation for all concerned: patients around the world, indigenous populations in developing countries and the international research based bio-pharmaceuticals industry.<sup>9</sup>

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<sup>6</sup> Coughlin Jr., M. D., 1993. *Using the Merck-INBio Agreement to clarify the Convention on Biological Diversity*. Columbia Journal of Transnational Law. 31 (2): 337-75 (1993).

<sup>7</sup> As of May 25, 2004, there are 188 parties to the CBD and 168 signatories (<http://www.biodiv.org/world/parties.asp>)

<sup>8</sup> Griffith, Victoria, 2003. *Biotech reaches a turning point in its evolution*. *Financial Times* 17 December 2003: 16.

<sup>9</sup> For an early discussion of the risks of increased politicization of genetic resources for commercialization of natural products research, please see: *Biotechnology, Globalization and Intellectual Property*, WIPO Industry Advisory

Twenty-five years ago, the U.S. faced a similar situation, in which the U.S. Government had invested heavily in biotechnology research, only to see industry fail to commercialize with few resultant benefits for US taxpayers. In the late 1970's, the U.S. failed to provide clear and exclusive rights in biotechnology inventions for scientists and corporations. Through a series of legislative initiatives, the U.S. established new forms of public-private rights-sharing agreements that revolutionized biotechnology in the U.S. and the rest of world. The U.S. experience of twenty-five years ago is especially relevant for CBD members, who are about to embark on an open-ended negotiation to establish a framework for internationally binding commitments in genetic resources relating to biotechnology inventions - which could raise even more questions about the future viability of natural products R&D. It is critical, at this point before the ABS negotiations begin, to get the questions right before settling on pre-determined answers. The well-being of patients and future prospects for biotechnology in developing countries depend on those questions.

### **Developing Country Interest in Access and Benefit-sharing (ABS) within the CBD**

Developing countries came together at the 1992 United Nations Conference on Environment and Development, also known as the Rio Earth Summit 1992, to form the Convention on Biodiversity (CBD) and in large part to act as a counterweight to the binding intellectual property (TRIPS) obligations that were then being negotiated within the WTO. Unlike the WTO, which was perceived by some as providing disproportionate benefits to the West, the CBD declared the sovereignty of the developing world and their indigenous peoples over their bio-diverse resources, based on an assumption that developing countries environments provide unique benefits for natural products R&D.

The stated objectives of the CBD were:

- The conservation of biological diversity;<sup>10</sup>
- The sustainable use of biological diversity;<sup>11</sup> and
- The fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including access to these resources and the transfer of relevant technologies.<sup>12</sup>

The latter objective focused on an ill-defined but critical commitment to ensure that benefits from the commercial development of new products related to bio-diverse resources would also flow back to developing countries. This became known as Access and Benefit-sharing, or ABS.

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Commission (Third Session, May 4 and 5, 2000), Attachment VII DOC.B. This presentation presaged many of the developments outlined in this paper.

<sup>10</sup> Convention on Biological Diversity, Article 15 (June 1992), accessed at:

<http://www.biodiv.org/convention/articles.asp>

<sup>11</sup> Ibid.

<sup>12</sup> Ibid.

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Developing countries have continued to demonstrate a serious commitment to formulating systems for ABS both within the CBD and in the WTO and WIPO.<sup>13</sup> The ABS goals of these countries have been articulated in multiple fora, including the group of 12 Like-Minded Megadiverse Countries, the WIPO Patent Cooperation Treaty and Substantive Patent Law Treaty talks, and in numerous submissions to the TRIPS Council.<sup>14,15</sup>

The Cancun Declaration of Like-Minded Megadiverse Countries is illustrative of these objectives:

[We] seek the creation of an international regime to effectively promote and safeguard the fair and equitable sharing of benefits arising from the use of biodiversity and its components. This regime should contemplate, inter alia, the following elements: the certification of the legal provenance of biological materials, prior informed consent and mutually agreed terms for the transfer of genetic material, requirements for the application and granting of patents, strictly in accordance with the conditions of access agreed by the countries of origin.<sup>16</sup> [emphasis added]

The Cancun Declaration added fuel to the concerns of bio-pharmaceutical companies that CBD members seek to encumber patent rights for biotechnology. Implicit in the foregoing, as well as in the structure and formation of the CBD, is the developing country fear of illegitimate “bio-prospecting” - the idea that pharmaceutical companies will harvest natural material from the developing world and reap great profits from these materials without reimbursing the host country or its indigenous populations. This fear is misplaced, given that the likelihood of a blockbuster product originating from a discovery in a rain forest or jungle is much more remote than conventional wisdom would suggest.<sup>17</sup> And, more importantly, the examples of “bio-piracy” frequently cited by activist groups rest on a shaky factual foundation.

New voluntary principles associated with ABS were codified in the Bonn Guidelines, adopted formally by CBD members in April, 2002, closely tracking a number of the goals outlined in the Cancun Declaration. The main provisions of the Bonn Guidelines are:

- *Prior Informed Consent (PIC)*: Private or public enterprises seeking to acquire biological material should attain consent from the country within which the material resides prior to collection;

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<sup>13</sup> For discussion of the early involvement of WIPO in the debate over binding legal obligations relating to genetic resources, see Intellectual Property and Genetic Resources – An Overview, WIPO/IP/GR/00/2, March 24, 2000; demands by developing countries for a binding regime under the authority of WIPO have been made repeatedly in the intervening years (Committee’s Fifth Session, WIPO/GRTKF/IC/5/15, paragraphs 16, 22, 80 and 126, as well as WO/GA/30/8, Report of the WIPO General Assembly, paragraph 65 to 92, passim).

<sup>14</sup> See, *Submission by Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru Thailand, and Venezuela for the TRIPS Council meetings*, IP/C/W/403. 24 June, 2003.

<sup>15</sup> Joint communication from the African Group for the TRIPS Council meeting. IP/C/W/404. 26 June, 2003.

<sup>16</sup> Cancun Declaration of Like-Minded Megadiverse Countries. 18 Feb. 2002.

[[http://www.unido.org/file-storage/download/?file\\_id=11803](http://www.unido.org/file-storage/download/?file_id=11803)]

<sup>17</sup> Macilwain, C., 1998. *When rhetoric hits reality in debate on bioprospecting*. *Nature* V. 392 (1998): 535-540.

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- *Certification of Origin/Legal Provenance*: A certificate from the provider of genetic material, whether it be a university, ministry, or other organization, that notes the origin of the material and can be used to track the material;
- *Disclosure*: Countries may consider measures to encourage disclosure of origin of biological materials or traditional knowledge in patent applications;
- *Technology Transfer*: As stated in the CBD, the “appropriate transfer of relevant technologies” used in the collection and/or study of genetic material;<sup>18</sup>
- *Benefit Sharing*: As required by the CBD, “fair and equitable sharing of the benefits arising out of the utilization of genetic resources”;<sup>19</sup> and
- *National Focal Point*: Each CBD Members may designate one national focal point to inform applicants for access to genetic resources on how to follow PIC and Benefit-sharing guidelines, as well as informing the applicant of relevant indigenous and local community stakeholders.

The Bonn Guidelines outline considerations that CBD members should consider in the formulation of national ABS regimes, as called for in the CBD. The CBD Secretariat has recently reported that very few CBD members have implemented integrated and effective ABS regimes at the national level.<sup>20</sup> Now that the COP-7 has called for the negotiation of a broader International Regime (IR) for ABS, some CBD members have expressed concern that planned negotiation of a comprehensive IR may remove any incentive for the timely and appropriate implementation of the Bonn Guidelines, and may further delay the implementation of appropriate ABS measures at the national level.

Missing in the CBD debates is a clear understanding of the important and positive role of intellectual property protection to support and encourage investment by private companies, which is essential for the successful commercialization of natural products derived from genetic resources. The technology transfer in biotechnology that is specifically called for in the CBD necessitates substantial long-term investment by industry. Private sector investment on this scale, however, is only possible with clear exclusivity periods, like those provided by patents. As David Schwartzman points out: “*without patents the return from investment in pharmaceutical research and development would fall to zero, and private companies would no longer engage in research and development*”.<sup>21</sup> The case of penicillin provides an instructive lesson of how development is delayed in the absence of patents. Penicillin was first discovered in 1928, yet no patent on penicillin or its manufacture was taken out until 1948. As a result, penicillin remained wholly unutilized until WWII, where the mass casualties due to infection necessitated large scale manufacturing of the drug.<sup>22</sup>

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<sup>18</sup> *Convention on Biological Diversity*. June 5, 1992. (<http://www.biodiv.org/convention/articles.asp>)

<sup>19</sup> *Ibid.*

<sup>20</sup> *National Implementation* paper presented by Valerie Norman, Programme Officer, Access and Benefit-sharing, Convention on Biological Diversity Secretariat, at the ABS International Expert Workshop on Access to Genetic Resources and Benefit-sharing, Cuernavaca, Mexico, October 25, 2004.

<sup>21</sup> Schwartzman, D., 1976. *Innovation in the Pharmaceutical Industry*. Baltimore: Johns Hopkins Press, 1976.

<sup>22</sup> Public Broadcasting Service: *A Science Odyssey: People and Discoveries*. (<http://www.pbs.org/wgbh/aso/databank/entries/dm28pe.html>)

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As a result of growing antipathy toward patent rights within the natural products community, and due to global competition for foreign direct investment associated with drug discovery, international research-based pharmaceutical companies have drastically reduced their natural products or even eliminated them.<sup>23</sup> Merck and Lilly, for example, have both cut programs for collecting samples and isolating extracts from natural biological sources.<sup>24</sup> David Newman, a senior chemist working at the natural products branch of the National Cancer Institute, is not surprised by this development, stating that "Industry is not doing that much [with natural products], compared with what it used to do". He estimates that natural drug discovery faces extremely long odds, calculating that only one sample in 250,000 will eventually yield a commercial drug, although many more samples may provide leads for other drugs.<sup>25</sup> At the same time, combinatorial chemistry blossomed during the 1990's as the preferred method of creating and examining new molecules. It was cheaper, faster, and provided more clarity with respect to intellectual property rights than natural product development.<sup>26</sup> Today, 5000 assays can be done at a time using thousands of slightly different molecules.

Improvements in chemical synthesis, occurring against a backdrop of hostility toward patent protection and commercial enterprises relating to natural product development in general, has led to the questioning of the need for natural products R&D altogether. David Galas, president of Darwin Molecular, a biotechnology company, believes that natural products are now left "completely high and dry". He goes on to say that "the idea of exploiting the rain forest to find wonderful drugs is, quite frankly, not credible".<sup>27</sup> However, others believe that the science merits further R&D. R. Murray Tait, Cerylid's Vice President for drug discovery, says "It's a shame that many of the big pharma companies got out of natural products just when technology was so dramatically improving the process".<sup>28</sup> As scientists argue both sides of the debate between combinatorial chemistry and natural products, private corporations are left trying to balance risks and costs, particularly those associated with developing country ABS regimes. If the risks and potential benefits were brought back into balance, at least some of these companies would have an incentive to venture back into natural product exploration.

Despite the CBD's ambiguities with respect to intellectual property, most major corporations in the US and Europe continue to meet the obligations laid out by developing countries. In fact, even before the CBD, pharmaceutical companies voluntarily entered into benefit-sharing agreements with developing nations in the early years of commercial biotechnology. Some of these pre-CBD partnerships between developing countries and public-private institutions led to positive benefit-sharing among all parties involved. The Merck/INBio agreement in 1991 is a case in point. The National Biodiversity Institute (INBio) of Costa Rica provided Merck with

<sup>23</sup> Rouhi, A. M., 2003. *Betting on Natural Products for Cures*. CENEAR, 81 41 (2003): 93-103.  
[<http://pubs.acs.org/cen/coverstory/8141/8141pharmaceuticals3.html>]

<sup>24</sup> Ibid, see also Macilwain, C., 1998. *When rhetoric hits reality in debate on bioprospecting*. Nature V. 392 (1998): 535-540.

<sup>25</sup> Ibid.

<sup>26</sup> Rouhi, A. M., 2003. *Rediscovering Natural Products*. CENEAR, 81 41 (2003): 77-91.  
[<http://pubs.acs.org/cen/coverstory/8141/8141pharmaceuticals.html>]

<sup>27</sup> Macilwain, C., 1998. *When rhetoric hits reality in debate on bioprospecting*. Nature V. 392 (1998): 535-540.

<sup>28</sup> Rouhi, A. M., 2003. *Betting on Natural Products for Cures*. CENEAR, 81 41 (2003): 93-103.  
[<http://pubs.acs.org/cen/coverstory/8141/8141pharmaceuticals3.html>]

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plant, animal, and soil samples in exchange for short-term, exclusive rights to study the samples as well as proprietary rights for any innovative product created from the INBio samples. In return, the company agreed to pay the Government of Costa Rica US\$1 million and a percentage of the royalties obtained from any innovative products derived from INBio resources. Merck also provided INBio with relevant laboratory equipment. The Government of Costa Rica committed to using the proceeds from royalties toward conservation of biological diversity. This agreement illustrates the benefits of a non-statutory, contract-based approach to ABS. Clear patent rights and access to genetic material were provided to Merck, while Costa Rica benefited from investments of cash and technological equipment, with money earmarked for conservation. Such an agreement could fulfill the major objectives that developing countries later included in the CBD.

Another example of an early benefit-sharing arrangement was the agreement between the State Government of Sarawak and Medichem Research, which established Medichem-Sarawak Pharmaceuticals as a joint venture company. A Cooperative Research and Development Agreement (CRADA), which enumerated the benefits including royalties, technology transfer, training and participation in scientific and biotechnology research, was established.<sup>29</sup>

The case of Pfizer, Phytopharm, the South African Council for Scientific and Industrial Research (CSIR), and the San people of South Africa concerning the Hoodia plant, known as P57, is often cited, erroneously, as a case of inequitable benefit-sharing with respect to biological material and traditional knowledge. In fact, Pfizer had no relationship with the San people, and had no knowledge of the rights of the San tribe at the time that it entered into its contractual relationship with Phytopharm. P57 was originally patented by the CSIR. In 1997, Phytopharm, a British biotech company, engaged in a licensing agreement with CSIR to further develop and commercialize P57. In 1998, Pfizer licensed P57 from Phytopharm to develop it into a commercial product. However, the San people had been using the Hoodia plant for its appetite suppressing qualities for hundreds of years, and it was their use that led CSIR researchers to the Hoodia plant. CSIR filed the patent without informing the San tribe. When Pfizer acquired the license for P57 from Phytopharm, they had no contact with the San and actually were led to believe that the San tribe had died out. It was not until the San brought a case against the CSIR that they were recognized as an existing tribe. A benefit-sharing program has now been worked out between the CSIR and the San people, in which the San will receive a percentage of royalties Phytopharm receives on the commercial sales of pharmaceuticals containing P57.<sup>30</sup> Given this uncertainty, the potential users of bio-diverse resources may benefit from dealing with a national focal point, as called for in the Bonn Guidelines that provide meaningful assurances as to potential stakeholders.

The adverse experiences of companies like Pfizer and increasing bureaucratization of ABS obligations in developing countries both have contributed to the reduction in investment in natural products. Ironically, while it has led to reduced technology transfer and investment,

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<sup>29</sup> ten Kate, K. & Wells, A. 1998. *The access and benefit-sharing policies of the United States National Cancer Institute: A comparative account of the discovery and development of the drugs Calanolide and Topotecan*. Executive Secretary of the Convention on Biological Diversity. 1998. ([www.biodiv.org/doc/case-studies/abs/cs-abs-nci.pdf](http://www.biodiv.org/doc/case-studies/abs/cs-abs-nci.pdf))

<sup>30</sup> Bio e-News. 2003. *The CSIR and San sign benefit-sharing agreement in the Kalahari*. March 2003. ([www.csir.co.za/biochemtek/newsletter/mar/benefit\\_sharing.html](http://www.csir.co.za/biochemtek/newsletter/mar/benefit_sharing.html))

the expanding universe of ABS guidelines within the CBD “has done little to quell poor nation’s fears of exploitation”.<sup>31</sup> As described above, the CBD has fundamentally failed in its primary objective, as it has not provided an effective framework for public-private partnerships. Rather, it has actively precluded “the anticipated bioprospecting bonanza”.<sup>32</sup>

Given the current environment, it may be helpful to look for new models for global biotechnology development, and to review how the U.S turned around a similar challenge and developed its current biotechnology IP regime, which is credited with the launch of the biotechnology revolution. It is particularly important at this time to seek a new model, given the imminent launch of new ABS negotiations aimed at establishment of international obligations in the CBD.

### The U.S. Experience

Nearly 25 years ago, the U.S. faced a similar challenge to that encountered currently in the CBD-ABS negotiations. In the 1960’s and 1970’s, there was a major concern in the United States that, despite increased funding for basic research by the U.S. Government, industry was adopting very few of the new technologies for commercial development of new products.<sup>33</sup>

In 1980, fewer than 5% of the 28,000 patents for which the U.S. Government held title were developed into commercial products by industry.<sup>34</sup> Companies faced a difficult and time-consuming process when they tried to obtain exclusive rights to U.S. Government inventions.<sup>35</sup> U.S. law only provided for the granting of non-exclusive rights, but this failed to encourage companies to invest in the application and development of new products. In short, “taxpayers were supporting the federal research enterprise, [but] they were not benefiting from useful products or the economic development that would have occurred with the manufacture and sale of those products.”<sup>36</sup>

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<sup>31</sup> Dalton, R. 2004. *Bioprospects less than golden*. *Nature*, V. 429 (2004): 598-600.

<sup>32</sup> Ibid.

<sup>33</sup> The Bayh-Dole Act: A Guide to the Law and Implementing Regulation. Council on Government Relations (COGR), 1999, (<http://www.ucop.edu/ott/bayh.html>)

<sup>34</sup> Ibid, citing the U.S. Government Accounting Office (GAO) Report to Congressional Committees entitled “Technology Transfer, Administration of the Bayh-Dole Act by Research Universities,” May 7, 1998.

<sup>35</sup> “[B]y the late 1970s there was a growing dissatisfaction with federal policies on patenting the scientific knowledge resulting from the research. Many government officials, for example, believed that federal laboratories were keeping information away from those who could make use of it. There was also a concern that because the government had retained title to inventions, no one was bothering to advance the research. There was no incentive to do so. Further, with the maze of bureaucracy caused by lack of a uniform policy, made companies reluctant to deal with the government, even if they were interested in the research.” Speech: Anything Under the Sun Made by Man, Lila Feisee, Director for Government Relations and Intellectual Property, Biotechnology Industry Organization, Delivered at the Conference - Biotechnology in Northeast Ohio, Current Plans and Visions for the Future, At The Case Western Reserve School of Law, Law-Medicine Center, April 11, 2001 [<http://www.bio.org/news/041101.html>]. See also: *Innovation’s golden goose*, The Economist, December 12, 2002, noting that “inventions and discoveries made in American universities, teaching hospitals, national laboratories and non-profits institutions sat in warehouses gathering dust.”

<sup>36</sup> The Bayh-Dole Act: A Guide to the Law and Implementing Regulation, Council on Government Relations (COGR), 1999 (<http://www.ucop.edu/ott/bayh.html>). The Economist notes that, “although taxpayers were footing

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The resultant legislation, known as the Bayh-Dole Act of 1980, together with other related legislation, enabled universities and research institutes to engage in the commercialization process by owning inventions and to work with industry to bring products to market. Bayh-Dole allowed for the exclusive licensing of inventions, with regulations that ensured that products were developed diligently and for the public good. University-industry partnerships allowed researchers to participate in the development of a product or process, speeding up commercialization.<sup>37</sup> Under Bayh-Dole, the inventor, the university and the industry all shared in the royalties resulting from the invention. Income derived by the university went back to fund additional research. The U.S. Government also benefited broadly by seeing scientific advances translated into products that benefited U.S. taxpayers.

The Economist magazine notes that, as a result of the Bayh-Dole Act, America experienced “a flowering of innovation unlike anything seen before.”<sup>38</sup> The return on investment in terms of improved health under the Bayh-Dole system has been estimated to be 15 times the annual investment in NIH research.<sup>39</sup> Bayh-Dole has generated continuing streams of income for universities and research institutes, leading to increased funding for scientific research.<sup>40</sup> In the fiscal year of 2002, more than 37 billion dollars in total funding was distributed to over two hundred research institutes in the U.S.<sup>41</sup> In 1999 alone, the licensing and development of these discoveries added \$40 billion to the U.S. economy and supported more than a quarter of a million jobs.<sup>42</sup>

The primary social benefit of these two developments was the launch of the biotechnology revolution that has brought so much hope of new cures and therapies for diseases in our lifetime. Most of the commercialization of scientific breakthroughs under Bayh-Dole have taken place in the life-sciences, where products and processes reduce pain and suffering and save lives.<sup>43</sup> It has been estimated that there are thousands of new products on the market due to Bayh-Dole. These include technologies instrumental to the biotechnology industry such as recombinant DNA technology, the process for inserting DNA into cells, new and more effective tests and therapies for cancer and osteoporosis, new vaccines, environmentally sound technologies and even safer guardrails for highways.<sup>44</sup>

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the bill for 60% of all academic research, they were getting hardly anything in return”. In *Innovation’s golden goose*, The Economist, December 12, 2002.

<sup>37</sup> *Bayh-Dole Act*, Cornell Research Foundation, Inc. (<http://www.crf.corell.edu/bayh-dole.html>)

<sup>38</sup> *Ibid.*

<sup>39</sup> *The Benefits of Medical Research and the Role of NIH*. U.S. Congress Joint Economic Committee (JEC). May 2000.

<sup>40</sup> “Running royalties on product sales were \$1.005 billion”, in FY 2002, according to Patricia Harsche Weeks, 2003 – 2004 President of the Association of University Technology Managers (AUTM), and Vice President, Planning and Business Development, Fox Chase Cancer Center, Philadelphia, PA, A Message from the President, AUTM Licensing Survey, FY 2002.

<sup>41</sup> AUTM Licensing Survey, FY 2002, p.1

<sup>42</sup> *Id.*

<sup>43</sup> *The Bayh-Dole Act: A Guide to the Law and Implementing Regulation*, Council on Government Relations (COGR), 1999 [<http://www.ucop.edu/ott/bayh.html>]

<sup>44</sup> *Ibid.*, Op. Cite.

### Relevance of Bayh-Dole for future ABS Framework

One way to measure the success of the Bayh-Dole Act is the level of private sector investment in the commercialization of biotechnology and the development of the U.S. biotech market relative to the market outside of the United States:

[T]he U.S. dominance is clear on virtually any measure. By end-2002 its biotech sector had 10 times the market capitalisation of Europe's.....and the U.S. spent three times more on research and development. This year the gap has widened. In the U.S., biotech has once again found favour with venture capitalists, raising \$8.52bn so far, says research group Windhover Information. The rest of the world raised \$1.37bn.<sup>45</sup>

The relatively low level of investment in biotechnology outside of the U.S. and Europe may have parallels to the area of natural product development in the developing world. It is not clear, to say the least, how bio-diverse developing countries plan to foster successful indigenous biotechnology industries without doing more to attract foreign direct investment, which is currently being drawn to the U.S. due to the strength of its private rights, including intellectual property rights. The U.S. experience in launching the biotechnology revolution should not be dismissed as irrelevant to the task facing CBD negotiators meeting next year in Bangkok, Thailand. They may want to revisit their current assumptions and positions and move to an "International Bayh-Dole" model as the way to actually advance their development goals and improve economic growth prospects for natural products research and development.

Recent patent data<sup>46</sup> confirms the inadequacy of current incentives for private industry, whether in the U.S., Europe or the developing world, to lower the risk and enable substantial capital investment needed for natural products R&D, including technology transfer and capacity building in CBD developing country members. The International Bureau of WIPO reports that during the calendar year 2002 alone, it received 114,048 applications filed worldwide, with nearly 45,000 from the U.S. alone.<sup>47</sup> Of these, only a total of 156 patents published over the two-year period between January 2002 and November 2003<sup>48</sup> were for international applications for medicinal substances derived from plants.<sup>49</sup> Despite overall developing country gains in the international use of the Patent Cooperation Treaty (PCT), it

<sup>45</sup> Griffith, V. 2003. *Biotech reaches a turning point in its evolution*. Financial Times, December 17, 2003: 16.

<sup>46</sup> Actual patent applications are an independent indicator of commercial R&D.

<sup>47</sup> Yearly Review of the PCT: 2002, WIPO [[www.wipo.int/pct/en](http://www.wipo.int/pct/en)]

In the narrower category of high-technology patent applications, the U.S. Patent and Trademark (PTO) (over 100,000 patent applications) the European Patent Office (EPO) (over 20,000 applications) and the Japan Patent Office (JPO) ( 85,000 applications) receives the lion's share of total applications for so-called high technology patents for calendar year 2002 (including but not limited to biotechnology patent applications) [[http://www.european-patent-office.org/tws/tsr\\_2002/pdf/high\\_tech\\_applic-10.pdf](http://www.european-patent-office.org/tws/tsr_2002/pdf/high_tech_applic-10.pdf)]

<sup>48</sup> Ibid.

<sup>49</sup> International Patent Classification sub-classes A61K 35/78, 35/80, 35/82 and 35/84), cited in WIPO/GRTKF/IC/6/6, November 30, 2003, p. 12. While the number of patents filed in a given year is not directly related to the number of published patent applications during that same time period, this does provide a strong indication of patent trends over time.

should concern bio-diverse countries that WIPO reports very low rates of filing for international patent applications for medicinal substances derived from plants.<sup>50</sup> Essentially, the bio-diverse developing countries are facing today the same situation that the U.S. faced in the 1970's. They possess a tremendous unexploited potential value in natural products R&D, although without the proper legal framework needed to ensure the commercial development of actual products, their economic development and health objectives will not be realized.

### **Conclusion: More questions, few answers**

This is a story in search of an ending. The next chapter may be written in Bangkok, Thailand, early in 2005, when CBD Members are scheduled to meet for as yet undefined ABS negotiations. At this juncture, all CBD members have a new opportunity, as well as an obligation, to attempt to change the current negotiating dynamic, which has led to the current stalemate over the commercialization of natural products R&D. To the international research-based industry, this means looking beyond patent-based ABS systems for a transparent, predictable and reliable approach (possibly non-statutory) that would provide sustainable, mutual benefits to CBD members, scientists, indigenous peoples and industry.

It remains to be seen whether the North-South rhetoric of past CBD negotiations, which have not led to any meaningful benefits, will continue to trump the interests of indigenous peoples living in mega-diverse environments, who would gain from greater commercial investment in natural product development. It is hard to over-estimate the importance of this and other related questions for the development of biotechnology hubs in the developing world. As noted above, patent-disclosure approaches adopted to date have failed to bring any benefits to CBD members, and in fact have helped to drive down industry demand for natural products.

Questions that remain include: How will CBD negotiators in the ABS talks view the private sector as an important stake-holder, given the unique role of companies in commercializing science, as demonstrated by the role they played in the U.S. Bayh-Dole biotechnology revolution? Will the ABS talks strengthen accountability and the rule of law systems, like patentability for genetic resources (needed to attract foreign direct investment and encourage technology transfer), or will they lead to a greater understanding of the need for predictability and transparency as a condition for economic growth and stability? The international research-based industry supports a positive approach to ABS that will provide sustainable mutual benefits, through the greater use of contracts that would provide early benefits in the form of technology transfer and capacity building for developing country CBD members. In order to better define operational mechanisms that could bring real benefits, greater dialogue and interchange is needed between all relevant ABS stakeholders.

Before coming to any conclusions or even defining the desired outcomes for the negotiations, it is important that all CBD members be willing to pose the right questions. As Lewis Carroll

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<sup>50</sup> International Patent Classification sub-classes A61K 35/78, 35/80, 35/82 and 35/84), cited in WIPO/GRTKF/IC/6/6, November 30, 2003, p. 12.

III. Specific Issues for consideration in the elaboration of the IR:  
Measures to ensure compliance with CBD and access legislation

noted, if you do not know where you are going, any road will get you there.<sup>51</sup> Now more than ever, it is important for the developing country members of the CBD to identify their destination in terms of their strategic commercial interests, and map out a strategy for reaching their goals.

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<sup>51</sup> Lewis Carroll, *Alice in Wonderland*. (“One day Alice came to a fork in the road and saw a Cheshire cat in a tree. Which road do I take? she asked. Where do you want to go? was his response. I don't know, Alice answered. Then, said the cat, it doesn't matter.”)