



December 1, 2006

Mandatory Patent Disclosure of Source/Origin of Genetic Resources: The Law of Unintended Consequences

Introduction

Access and Benefit Sharing (ABS) has long been dogged by the law of unintended consequences. Time after time, states have sought to achieve development benefits through ABS policies, and instead have created disincentives for both conservation and natural product development, resulting in a situation where all parties were worse off.

This point was made during a discussion on the ABS enforcement through mandatory patent disclosure of source for genetic resource inventions at the working luncheon hosted by the ABIA in honor of the SIPO delegation that visited Washington, D.C. in September, 2006. At the luncheon, ABIA Members¹ agreed to provide SIPO with a written report on the broad spectrum of adverse unintended consequences that ABIA Members believe would frustrate the intent of the proposed Chinese Patent Law Third Amendments.

This paper will first review the record of those developing countries that have implemented patent disclosure schemes and will then seek to explain how these disclosure obligations were perceived by potential bio-prospectors and right holders.

Executive Summary

While ABIA Members support disclosure in patent applications to the extent necessary to operate the invention,² they oppose additional disclosure obligations in patent applications relating to biotechnology inventions, including mandatory disclosure of source for genetic resources as a condition of patentability. ABIA members support the equitable sharing of benefits from the commercialization of genetic resources and do not believe that the mandatory disclosure of source or origin will likely advance that goal.

The recent experience of several Latin American and Asian countries that have adopted mandatory patent disclosure regimes since 1996 demonstrates that such regimes have led

¹ABIA Members represented in the September 13, 2006 meeting with SIPO officials in Washington DC included GE, Lilly, Pfizer and Tethys Research.

² All patent laws require disclosure of information required to allow anyone “skilled in the art” to determine whether the invention is novel, non-obvious and includes a commercial application. This includes source or origin of any genetic resources or related traditional knowledge where relevant to demonstrate the “best mode” associated with an invention, source or origin.

to reduced ethnographic work, conservation and other commercial and non-commercial activities relating to genetic resources and traditional knowledge. In addition, because the patent disclosure schemes resulted in reduced commercial activity, the expected generation of benefits from the increased commercial activities failed to materialize. Most significantly, these countries experienced a break-down of trust and dialogue among stakeholders. Instead of providing certainty to all parties, the adoption of negative incentives has resulted in frustration and driven parties further apart.

Additional possible or potential adverse consequences for China under a mandatory disclosure regime include reduced biotechnology investment due to uncertainty from increased litigation or fear of litigation, greater difficulty for smaller, indigenous biotech entrepreneurs to gain access to foreign capital, and negative impact on commercialization of Chinese traditional herbal medicine.

In brief, the implementation of negative incentives has the clear effect of reducing the certainty of patent rights for genetic inventions. These problems are inherent in the concept of mandatory patent disclosure, and would not be mitigated by international adoption of patent disclosure. While there may be other substantial, sources of uncertainty for patent holders outside the area of ABS, this goes beyond the scope and remit of the ABIA, which is an organization providing focused advocacy for its members relating only to the issue of biotechnology patentability standards and ABS. ABIA members are well-represented by other organizations that provide broader advocacy on domestic U.S. patent issues.

The Track Record

1. Industry

Multinational corporations seek to comply with ABS norms under the CBD. This has been recognized by ABS experts, who also stress the superior benefits provided by “front-loaded” benefits when compared to patent-linked compensation and view patent-linked compensation, which relies on the successful commercialization of the patented invention, as unrealistic:

Benefit sharing varies by sector, but since adoption of the CBD standards for best practice in benefit-sharing have become widely accepted. This is a significant and positive achievement of the CBD and ABS policy dialogue. Although unscrupulous and ill-informed companies continue to by-pass these standards, the larger or more socially responsible companies today would not consider genetic resources freely available, or the ‘common heritage of mankind.’ The package of benefits typically includes a mix of monetary benefits like fees per sample, milestone payments, royalties on net sales, and licensing agreements, as well as non-monetary benefits like training,

capacity-building, research exchanges, supply of equipment, technology transfer, and joint publications. Groups with the most experience in benefit-sharing generally emphasize the importance of non-monetary benefits and “front-loading” benefit-sharing packages. “Front-loading” benefit-sharing packages ensures that provider countries receive a stream of benefits through the discovery and development phases, given the small odds of any one partnership yielding a commercial product and the fact that all products will not necessarily be billion-dollar “blockbusters,” generating large royalties, or that in most industries products rarely, if ever, achieve this status.³

ABIA members underscore their continuing commitment to the equitable sharing of benefits from the commercialization of genetic resources and to meeting ABS obligations mandated by CBD members. It is in this context that the ABIA submits, for the consideration of SIPO, the following information on the adverse consequences for China from the adoption of mandatory disclosure of the source of genetic resources as a condition of patentability.

2. Countries with National Patent Disclosure Regimes

The adverse experience of countries from adoption of mandatory disclosure of source and/or origin as a condition for the patentability of biotechnology inventions is well documented. Negative unintended consequences have included reduced domestic conservation; disincentives for both academic and commercial R&D on natural products; low rates of bio-prospecting, and little to no benefits to the indigenous or to the developing country itself.

- Brazil

Since the implementation of mandatory patent disclosure, Brazil has experienced a well-documented reduction in conservation, bio-prospecting and both academic and commercial R&D efforts relating to natural products. “Brazilian scientists claimed the 2001 rules hindered research on biodiversity by creating complex and time consuming procedures for those applying for research permits,” affecting both domestic research and international collaboration.⁴

The Government of Brazil’s undocumented assertions of biopiracy have created a climate of fear and intimidation, with critics of Brazil’s policy noting that: “the

³ “Commercial Uses of Biodiversity: An Update on Current Trends in Demand for Access to Genetic Resources and Benefit-Sharing, and Industry Perspectives on ABS Policy and Implementation,” Sarah A. Laird and Rachel Wynberg, distributed at CBD/ABS 4 as UNEP/CBD/WG-ABS/4/INF/5, 22 December 2005, p. 26.

⁴ “Brazil seeks public views on biodiversity research rules,” Wagner de Oliveira, 22 March 2005 <http://www.scidev.net/News/index.cfm?fuseaction=readNews&itemid=2005&language=1>

reality is that the search for the next miracle drug is being hampered by a deep Brazilian suspicion of ‘biopiracy.’”⁵ This has all but shut down both academic and commercial research in Brazil in favor of better operating environments in neighboring states: “... [S]cientists say the rules are so stringent and overzealously enforced that it has become impossible to ship samples abroad for analysis, *reducing research to a crawl and driving many scientists to move their research to Ecuador, Bolivia and Peru.*”⁶ (Emphasis added) This goes beyond commercial collaboration and has also shut down international cooperation between academic institutions and museums: “One of our masters students has been waiting for nearly two years for government permission to collect samples of plants that she is studying,’ says Ruy José Válka, curator of the herbarium of the National Museum, based at the Federal University of Rio de Janeiro . . . the herbarium, which houses more than half a million specimens of Brazilian plants, has had to virtually cease research collaborations with foreign institutions because of the current laws.”⁷

- The Philippines

Along with the Andean States, the Republic of the Philippines was the first to adopt stringent ABS obligations, which, according to UNEP, have “acted as deterrents to biodiversity research and bioprospecting.”⁸ Filipino officials acknowledge that the ABS system implemented in 1995 through Executive Order No. 247, and later implemented under the Wildlife Resources Conservation and Protection Act of July 30, 2001,⁹ has failed to have any positive impact. According to Paz J. Venavidez II, Philippine Government official and ABS negotiator, the ABS process developed by the Philippines Government under EO 247 was “considered a deterrent to research growth and development.”¹⁰ The Prior Informed Consent (PIC) requirements have also been viewed as bureaucratically burdensome for applicants; the required interagency approval as unworkable; and the benefit-sharing obligations as being problematic. Taken together, the Philippine ABS regime has all but eliminated bioprospecting in the

⁵ See “Biopiracy fears hampering research in Brazilian Amazon,” Michael Astor, Associated Press October 30, 2005, <http://news.mongabay.com/2005/1030-ap.html>

⁶ Ibid.

⁷ <http://www.scidev.net/News/index.cfm?fuseaction=readNews&itemid=2005&language=1>

⁸ UNEP, quin.unep-wcmc.org/resources/publications/pa_biodiv/key_issues.pdf, p. 46

⁹ “The Challenges in the Implementation of the Philippine ABS Regulations: Monitoring and Enforcement of Bioprospecting Activities in the Philippines,” Paz J. Benavidez II. Legal Research Consultant, Committee on Ecology, House of Representatives, Republic of the Philippines. See www.canmexworkshop.com/documents/papers/I.2.1.pdf

¹⁰ Ibid.

Philippines, as Philippine Government officials report: “Since 1995 we have had only one Commercial Research Agreement (CRA) and one Academic Research Agreement (ARA) that has been processed under EO 247.”¹¹ Although the 2001 Wildlife Act was intended to mitigate the major problems encountered under EO 247 (and does exempt non-commercial research from its scope), the bottom line is that, since 1995, bioprospecting and natural products R&D in the Philippines have all but dried up.¹²

- India

The Government of India adopted mandatory disclosure of the source of genetic resources and related traditional knowledge in 2002 as part of the Second Patent Amendments. The Biological Diversity Act of 2002 and Biological Diversity Rules, 2004 also play a significant role in India’s patent disclosure regime.¹³ Since the entry into force of the regime, India has made little to no progress in the approval of bioprospecting applications by the National Biodiversity Authority (NBA), which was established in 2004 to administer the approval process.

Some observers have noted that the mandatory patent disclosure and other elements of the domestic regime have created uncertainty and harm India’s interests in the area of natural products development.¹⁴ While the 2004/2005 Report of the NBA documents a number of interesting biodiversity educational and awareness programs, it fails to record any actual approvals of commercial bio-prospecting applications.¹⁵ The NBA website further reports that approval has been withheld from at least ten bio-prospecting applications.¹⁶ The patent disclosure regime has also created disincentives for IP protection of GR inventions in India: according to the NBA website, only four applications have been received for advanced approval of patent rights associated with GR/TK.¹⁷

As in Brazil and the Philippines, the political environment for industry in India has not improved with the advent of the patent disclosure regime. Critics of the

¹¹ Ibid.

¹² Ibid.

¹³ Additional inconsistencies have been raised between the Biological Diversity Act and Rules and the earlier Plant Variety Protection and Farmers Rights (PVPFR) Act of 2001. See <http://www.ias.ac.in/currensci/jan102006/15.pdf>

¹⁴ Presentation and comments by Dr. M. K. Nair, Hi-Tech Pune: Where IT Meets BT, October 27, 2006, Pune, India

¹⁵ [http://www.nbaindia.org/docs/annual_report\(04-05\).pdf](http://www.nbaindia.org/docs/annual_report(04-05).pdf)

¹⁶ http://www.nbaindia.org/approvals/approvals_withheld.htm

¹⁷ <http://www.nbaindia.org/approvals/patent.htm>

Government claim that biopiracy in India is rampant, and “that plant and soil samples are being regularly flown out of India under the pretext of joint research collaboration.”¹⁸ Despite the lack of documentation, activists further demonize industry, baldly asserting that “the herbal drug industry in India is mostly a flourishing biopiracy business. Companies collecting medicinal plants from forests and using the knowledge of communities to make products worth millions of dollars are accused of not paying anything to the communities from whom they got that knowledge,” and Devendra Sharma of the Forum for Biotechnology and Food Security in New Delhi accuses the Government of India of selling India’s “green gold for peanuts.”¹⁹

3. The Track Record: Conclusions

As Tomme Young (then-Senior Legal Officer, IUCN) pointed out at the ABIA Side-event in Curitiba, Brazil, mandatory disclosure regimes provide only perverse, negative incentives that do not lead to the generation or sharing of social benefits.²⁰ Among the adverse factors are:

- a. Cumbersome and complex regulatory processes: The cost and time required to develop partnerships within complex and evolving regulatory frameworks are significant barriers to bio-prospecting, where delay equals foregone opportunities: “Countries like Brazil and India, for example, are regularly avoided; it takes 1-3 years to get a permit, and researchers fear both the hostility they find to any research on genetic resources, and what one observer called the ‘national regulatory labyrinths’.”²¹
- b. Regimes that do not encourage the generation of benefits: Patent disclosure obligations have been ineffective as a mechanism to encourage the generation of benefits from genetic resource inventions. Without academic or commercial bio-prospecting, there can be no generation of benefits for either the country or its indigenous.
- c. A worsened climate for ABS discussions, despite the growing number of states that have implemented mandatory patent disclosure regimes and

¹⁸ http://www.atimes.com/atimes/South_Asia/FJ26Df02.html

¹⁹ Ibid.

²⁰ “Incentive and Motivation in the ABS Regime,” Tomme Rosanne Young, Senior Legal Officer, IUCN, PowerPoint Presentation, Curitiba, Brazil, accessed at <http://www.abialliance.com/html/news.html>

²¹ Laird and Wynberg, p. 37, also citing extensive delay and difficulty of natural products R&D in the Philippines.

other ABS obligations.²² Companies are tried and found guilty in the media, regardless of the merits of the situation, and are further alienated from participation in ABS regimes.²³

- d. Cutbacks in GR investment by multinational corporations. In addition to the scientific reasons given for the sharp fall-off in natural products development, the legal and public relations uncertainties associated with gaining access to genetic resources as a result of the Convention on Biological Diversity have also been cited. Companies that have reduced or eliminated natural products development include Lilly, Merck and Pfizer.²⁴

In December 2005, long-time ABS experts drew the following negative conclusions as to the efficacy of mandatory patent disclosure and other related ABS regulations:

In 1999, ten Kate and Laird reported that over the course of the previous two years of their study many of the companies they interviewed had come to believe that implementation of the CBD had gone badly wrong. They cited lack of clarity in the regulatory framework; bureaucracy and delays in receiving permits; lack of understanding of business; confusion about national focal points; unrealistic expectations and transaction costs; restriction of scientific traditions of collaboration and exchange; and the pressures these new regulatory frameworks place on already taxed natural product research programs (ten Kate and Laird, 1999, p296). These concerns continue today, but are also increasingly accompanied by an underlying unease with what are characterized as “dangerous” and “political” minefields of fickle regulatory processes, and an absence of goodwill.²⁵

Unintended Consequences: Right Holder Perceptions of Mandatory Patent Disclosure

During the September ABIA/SIPO meeting, ABIA members explained that, while the Chinese Government may view mandatory patent disclosure as increasing certainty, such disclosure actually reduces the certainty needed to cross the already high threshold associated with the development of biotech inventions in China. Among the factors

²² The CBD “has done little to quell poor nation’s fears of exploitation,” Dalton, Rex. “Bioprospects less than golden.” *Nature* V. 429 (2004): 598-600, and instead has actively precluded “the anticipated bioprospecting bonanza.”

²³ *Ibid.*

²⁴ Rouhi, A. Maureen. “Betting on Natural Products for Cures.” *CENEAR* 81 41 (2003): 93-103. See <http://pubs.acs.org/cen/coverstory/8141/8141pharmaceuticals3.html> See also Laird and Wynberg, p. 9.

²⁵ *Ibid.*, Laird and Wynberg. p. 30.

adding to uncertainty are increased litigation or fear of litigation; reduced access to foreign venture capital by indigenous Chinese biotech entrepreneurs; adverse consequences for the commercialization of China's own biotechnology sector; and a potential reduction in R&D on Chinese traditional herbal medicines.

1. Fear of litigation and related media and public relations exposure: This is a major and legitimate concern for industry. Although the Chinese Government believes that it is reducing uncertainty through the implementation of mandatory disclosure of source of genetic resources, the Government cannot predict nor control future actions by private parties. And, the risks of litigation are increased by the historical difficulty that U.S. companies have in defending their IP in foreign venues.²⁶ Even where Governments demonstrate the political will to provide certainty to investors, increased risks from private entities remain from NGOs, competing firms, and indigenous peoples.

Prominent international activists and Non-Government Organizations (NGOs) have historically opposed patenting of inventions relating to genetic resources and traditional knowledge. They have used litigation²⁷ and the media,²⁸ and have knowingly or unknowingly based challenges on incomplete or factually incorrect information.²⁹ NGOs include organizations that oppose all patenting of life forms like Friends of the Earth, the Edmonds Institute and Vandana Shiva who recently declared: "The promotion of piracy is not an aberration in the U.S. patent law. It is intrinsic to it,"³⁰) and those who oppose all industry engagement (Third World Network, Devendra Sharma).

²⁶ For example, in a highly publicized 1995 trade-mark case in the Supreme Court of the Philippines (Emerald Garment Manufacturing Corp. v. Court of Appeals), the U.S. producer of Lee Jeans lost the rights to use of its trademark in the Philippines in favor of a local jeans producer that had literally copied the product design and mark. http://www.lawphil.net/judjuris/juri1995/dec1995/gr_100098_1995.html For commentary on this and similar cases see <http://www.pcij.org/stories/1997/justice2.html>

²⁷ See <http://www.zmag.org/sustainers/content/2004-04/22shiva.cfm> (Vandana Shiva challenging Monsanto patents based on "bio-piracy of Indian wheat," and <http://www.edmonds-institute.org/yellowstone.html> (Edmonds Institute lawsuit to stop bio-prospecting in Yellowstone Park.)

²⁸ For recent media allegations by NGOs, see <http://www.abialliance.com/html/media.html> See also http://www.twinside.org.sg/access_7.htm

²⁹ The case of Pfizer, Phytopharm, the South African Council for Scientific and Industrial Research (CSIR), and the San people of South Africa concerning a molecule known as P57 derived from the Hoodia plant, is often cited, erroneously, as a case of inequitable benefit sharing with respect to biological material and traditional knowledge. A benefit-sharing program has now been worked out between the CSIR, which has patented P57 without acknowledgement of the San people, in which the San will receive a percentage of royalties Phytopharm receives on the commercial sales of products containing P57. <http://www.unl.edu/rhames/courses/current/hoodia.htm>

³⁰ The Progress Report: U.S. Monopolists Continue BioPiracy Against India, by Vandana Shiva, <http://www.progress.org/patent03.htm>

U.S. companies suffer enormous public relations damage from NGO allegations in the media, even in the absence of actual litigation, as in the case of unfounded claims of bio-piracy against Genencor for extremophiles collected in the late 1980's in Kenya prior to the date that the CBD came into force.³¹ Adoption of additional mandatory patent disclosure obligations opens the door to greatly expanded threats from anti-industry organizations, which are on record as opposing development of any ABS regime where industry would be a meaningful stakeholder and would gain certainty in intellectual property rights.

A second source of increased risk of litigation comes from other competing companies in the market. Implementation of mandatory disclosure of source for genetic resource inventions in China would create new incentives for competing companies to challenge validity of the disclosure as a way to defeat the patent. This may occur as a result of either an international or a local Chinese company that may be able to identify an alternative potential source for the genetic material, other than that cited by the patent holder. Whether this is done in good faith or with the intention of creating uncertainty for the right holder, the result is the same: it would increase uncertainty for investors in genetic resource inventions in China.

Local indigenous communities, encouraged by others or on their own, may also seek to challenge patents where they share genetic resources or traditional knowledge in common with other indigenous peoples. The commonality of genetic resources and traditional knowledge provides another very real source of uncertainty for industry, as competing communities may both claim similar genetic resources.³² In the case of Hoodia, for example, the plant is indigenous to several Southern African states, and the traditional knowledge relating to the appetite suppressant quality of the succulent resides in a number of indigenous tribes in South Africa alone.³³ This commonality of genetic heritage provides additional opportunities for patent challenge, and, with the imposition of mandatory patent disclosure of source as a condition of patentability, increases uncertainty for industry.

2. Negative impact In China: reduced access to foreign venture capital by indigenous Chinese biotech entrepreneurs: Established Western companies have choices in terms of where to invest for biotechnology. These companies will seek to reduce risk and to invest in countries that provide higher levels of certainty.

³¹ See http://www.captainhookawards.org/nominations/genencor_et_al

³² See <http://www.biodiversityhotspots.org/xp/Hotspots/ghats/>

³³ <http://www.plantzafrika.com/planthij/hoodia.htm>

For example, the shift from genetic resource research from Brazil to neighboring countries is well documented.

China's early success in gaining foreign direct investment at higher levels than India has been credited to China's earlier adoption of patent protection and other forms of intellectual property protection important to the biotech industry. "The Chinese government has also approached patenting in a way that benefits the biotechnology industry. The first Chinese patent laws for pharmaceuticals were adopted in 1992, and another set of patent law enforcement measures were enacted in 2001, in order to fulfill WTO requirements."³⁴ In contrast, India did not adopt patent protection until 2005, and the law still includes ambiguity and negative features like mandatory patent disclosure of origin for genetic resources and traditional knowledge. In comparison to China, India's regime appears to be harming both the indigenous and international commercialization of genetic resources. In the biotech sector, the overall value of China's biotech market was estimated in 2004 at approximately \$4.5 billion on the strength of strong FDI, having passed the billion dollar mark in 1997,³⁵ while India's biotech sector first broke the billion dollar mark in mid-2005, and remains second to China overall in FDI attractiveness.³⁶ It would be a shame if China's current strength in the biotechnology sector were to be dissipated by a weakening of its strong biotech patentability standards.

- Adverse consequences for the commercialization of China's indigenous biotechnology sector: By necessity, the establishment of new patent requirements would be worse for smaller indigenous Chinese biotechnology companies. Larger companies with well-resourced patent and other IP-departments will be more likely to be able to keep up-to-date with changing requirements for disclosure of source of genetic resources and ensure that they comply where necessary. However, it is more difficult for Small and Medium Enterprises (SMEs) to keep up with developments and, as a result, they may well have a higher risk of non-compliance. It would thus appear that a new disclosure of source obligation in China will have a greater adverse impact on small local biotech start-ups than on large multi-nationals.

Additional patent disclosure requirements would, by their nature, cast a cloud on patent validity, thereby making an already risky endeavor even

³⁴ "China's Biotechnology Bloom: Life Sciences in the World's Fastest Growing Economy," Nancy Chen, GeneWatch, Volume 17, No. 1

³⁵See "China's Biotechnology Bloom: Life Sciences in the World's Fastest Growing Economy," Nancy Chen, GeneWatch, Volume 17, No. 1,

³⁶ <http://www.sunmediaonline.com/indiachronicleapril/investmentupdate.html>

more uncertain. China's own indigenous bio-entrepreneurs and biotech companies at early stages of development are no different than other entrepreneurs anywhere else in the world: they need, above all else, certainty, especially with respect to their intellectual property. Often, the only asset that biotech start-ups have is their intellectual property—the patents that they hold on basic biotechnology processes that enable them to gain funding from investors. And, as often, the only variable on which venture capitalists can judge the potential of their investments in such high-risk ventures is the intellectual property offered by the start-up..

It would be extremely damaging to Chinese biotech entrepreneurs if SIPO were to dilute biotech patentability standards at this juncture. The Chinese Government has made a substantial investment both in brain-gain incentives to attract highly qualified Chinese biotechnology scientists to return to China, and in developing a “major biotechnology infrastructure,” including seventy-four national centers of molecular biology to accommodate returning scientists from abroad.³⁷

- Potential reduction in R&D on traditional Chinese medicines (TCM): China has also invested a great deal in the systematic study of traditional medicines from Chinese herbs and plant extracts for commercial development, both through China's traditional knowledge database and in government support for clinical research relating to TCM. This work has been ongoing since 1996, pursued in part by China's Institute of Medicinal Plant Development (IMPLAD).³⁸ IMPLAD activities include ethnography to rescue plants from the threat of extinction, cultivation of medicinal plants to establish germplasm- and gene-pool for development of medicines, R&D, patenting, and commercial development and production of drugs along the Western model. IMPLAD's accomplishments to date include joint ventures with three commercial companies in China, three branch institutes in sub-tropical southern China, and more than 1,000 papers and 30 monographs.³⁹

The commercialization of Chinese medicinal herbs could provide significantly more meaningful incentives for the conservation and sustainable use of genetic resources than the imposition of additional patent disclosure obligations relating to the source of genetic resources or

³⁷ Ibid.

³⁸ “Ancient and Modern Medicinal Herbs: China,” Shiling Yang, Institute of Medicinal Plant Development (IMPLAD), Beijing China, http://tcdc.undp.org/sie/experiences/vol7/Ancient%20and%20Modern%20Medicinal_China.pdf

³⁹ Ibid.

to the conditions of acquisition or exploitation of genetic resources. IMPLAD has enjoyed increasing success and funding, and looks to establish international collaboration and R&D. In July 2006, China's Ministry of Science and Technology pledged an additional 100 million yuan (12.5 million USD) for China's first international initiative to develop cancer and HIV/AIDS therapies from traditional herbal medicines.⁴⁰ In addition to Chinese and foreign government investment in TCM, major multinational biopharmaceutical companies like Novartis are also investing in clinical research in China on TCM, and investors remain very concerned about patent protection.⁴¹ All of this progress would be threatened by the adoption of mandatory disclosure of source as a condition of patentability.

Conclusion

China has benefited as an early mover in protecting the IP that is critical to the generation of commercial benefits to biotech firms. Its regime is currently superior to that of other developing countries at similar stages of development, including Brazil and India. It is not clear why China would seek to emulate failed ABS policies that may endanger China's biotechnology FDI and the commercialization of its own genetic heritage through research and development relating to TCM.

A patent source disclosure requirement in China may well duplicate the experience in Brazil and now India, where investment in natural products development fell precipitously. Where a potential patent holder is unsure about the possible negative impact of a disclosure obligation, whether due to the risk of increased litigation or adverse public relations exposure, it will be much less likely to try to develop new products out of genetic resources, whether or not it is certain of the source of the materials. Introducing such a requirement would delay or hinder Chinese biotechnology development and deter use of the patent system, to the detriment of overall Chinese society.

⁴⁰ <http://www.bgci.org/worldwide/news/0252/>

⁴¹ http://www.atimes.com/atimes/China_Business/HC11Cb05.html