



July 29, 2011

James Nation
First Secretary (Trade)
Australian Embassy
1601 Massachusetts Avenue NW
Washington DC 20036 – 2273

Re: Questions from Australia relating to future developments affecting intellectual property, innovation, trade, and genetic resources

Dear Mr. Nation:

Intellectual Property Owners Association (IPO) welcomes the opportunity to provide the enclosed response to your request for comments on future developments affecting intellectual property, innovation, trade, and genetic resources.

IPO is a trade association representing companies and individuals in all industries and fields of technology who own or are interested in intellectual property rights. IPO's membership includes more than 200 companies and more than 12,000 individuals who are involved in the association either through their companies or as inventor, author, law firm, or attorney members.

We understand that the Government of Australia has sought views from the United States of America and a range of other countries, as well as several non-governmental organizations (NGOs). We also understand that your forthcoming strategy paper does not represent any intention to change Australia's negotiating positions on intellectual property or genetic resources in the Convention on Biological Diversity, World Intellectual Property Organization, World Trade Organization or other institutions or processes, but is strictly a research project. With these understandings in mind, IPO is pleased to provide the enclosed comments. IPO recognizes the importance of these issues and has sought to participate in these and similar discussions relating to genetic resources in a productive manner.

Please feel free to contact IPO should you have any questions.

Sincerely,

Douglas K. Norman (handwritten signature)

Douglas K. Norman
President

Enclosures

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Comments by Intellectual Property Owners Association (IPO) on questions from Australia relating to future developments affecting intellectual property, innovation, trade, and genetic resources

1. What trends are you seeing in the number of patent applications utilising genetic resources?

- IPO has not conducted any analyses concerning numbers of patent applications “utilising genetic resources” and therefore cannot comment on any trends in patent filings.
- Studies in the Convention on Biological Diversity (CBD) context indicate that biopharmaceutical research and development companies have reduced natural products research.¹ This is partly due to what is seen as overly restrictive access and benefit-sharing (ABS) regulations, particularly in countries like Brazil and India, which are “regularly avoided.”²
- This question also highlights a fundamental issue at the international level, which makes it difficult to answer. Despite the recent definition included in the Nagoya Protocol, there is little common understanding of the scope of the term “using” or “utilization” of genetic resources.
- For example, in a 2005 submission to the World Trade Organization,³ Peru disclosed several patent applications that it viewed to be “potential cases of biopiracy.” The initial findings were based merely on the inclusion of terms in patent documents contained in certain databases. While Peru acknowledged that this does not alone prove “biopiracy,” it nonetheless underscores the challenge of identifying subject matter that “utilises genetic resources.”
- Some have asserted that even use of genetic information without any access to a plant or genetic resource itself could be considered “use of a genetic resource.”
- This lack of common understanding underscores the concerns of intellectual property owners regarding collection of such data. The scope of these terms should be precisely defined. Otherwise, the data collected, where it is possible to do so, may be faulty and lead to improper conclusions.

¹ Laird & Wynberg. Access and Benefit-sharing in Practice: Trends in Partnerships Across Sectors, CBD Technical Series No. 38 (2008), at p. 102.

² Id. at 127.

³ See Peruvian submission, WTO Document No. IP/C/W/441

2. *Do you have a sense of the value of these patents and the implications for the local economy?*

- As a general matter it is difficult to assess patent value because patenting occurs well before commercialization. Furthermore, most patented products are not successfully commercialized. However, the small number of products that are commercialized may carry very significant value.
- In an effort to analyze the patent applications named by Peru to be “potential cases of biopiracy,” referenced above, the Biotechnology Industry Organization (BIO) analyzed 144 patent applications cited in the Peru submission.⁴ For the vast majority of the cited patents, the invention cited related to the plant itself or an uncharacterized extract from the plant. None of the patents involved bioengineered products. In addition, only 4 related to either a “pharmaceutical” or “biotechnological” invention – the remainder related to cosmetics, herbal remedies, “nutraceuticals,” or food products.
- The distribution among various industries may have a general correlation to “value,” but this was not assessed by the study.
- However, due to the uncertainties mentioned previously, it is clear that valuable patents could be subject to claims of impropriety and targeted for potential sanctions under over-reaching ABS laws, even where patent owners were in good faith and had not acted in an illicit or improper manner concerning use or collection of genetic resources.

3. *Can you provide an assessment of the likely future trends of such patent applications?*

- As noted, IPO has not done any study of patent applications. Thus, we cannot speculate on “likely future trends” in patent applications.
- As a general comment, however, we do expect that implementation of onerous conditions in ABS laws, or new requirements in intellectual property laws (e.g., disclosure of origin) would undermine innovation and the development of new technologies based on genetic resources. This reduction in innovation may translate to reduced patent filings – at least in regard to those technologies requiring greater up-front investment.

⁴ BIO presented its findings during a side event at the Fourth Ad-Hoc Open-Ended Working Group on Access and Benefit-Sharing of the CBD on January 31, 2006. See <http://www.cbd.int/register/side-events/list.aspx?mtg=ABSWG-04>.

4. *How significant do you assess genetic resources will be for innovation, new technologies and as a source of economic growth, including for the United States over the next 5-10 years?*

- As noted above, we have not conducted any empirical analyses related to this question. However, in light of the studies about industry trends, we do not expect use of genetic resources to significantly impact economic growth in the United States over the next 5-10 years.
- For example, the highly touted International Cooperative Biodiversity Groups (ICBG) program, managed since 1992 by the Fogarty Center in the National Institutes of Health, has reportedly analyzed thousands of samples of genetic resources with the goal of guiding natural products drug discovery, crop protection science, bioenergy and other research toward international collaborative models involving benefit-sharing consistent with the CBD model. Yet, there have been only a handful of discoveries resulting in active granted patents, and no products based on this research have reached the market.⁵
- Thus, while overzealous ABS rules and new requirements in patent laws will likely undermine innovation and development of new technologies, the positive value of genetic resources and natural products has not been concretely demonstrated.

5. *How do you think regulations over the use of genetic resources are likely to develop in the United States? Do you see a trend towards promoting or restricting the use of genetic resources in research and development?*

- These questions would be better directed to the United States Government, which would be responsible for formulating any such regulations.
- Nonetheless, it should be noted that the United States already has regulations concerning the use of genetic resources that are accessed or acquired from United States National Parks⁶.
- We do not anticipate any changes to current regulations in the United States, and therefore do not envision a trend either promoting or restricting the use of genetic resources in research and development as a result.

⁵ See Fogarty International Center website at <http://www.fic.nih.gov/Programs/Pages/biodiversity.aspx>.

⁶ See *Access to Genetic Resources Regime of United States National Parks*, WIPO Doc. No. WIPO/GRTKF/IC/4/13 (Dec. 6, 2002).

6. *What impact is this likely to have on the ways companies and other researchers access or use genetic resources?*

- As noted, we do not anticipate any changes to current regulations. Consequently, we see no change in the manner that companies or other researchers access or use genetic resources.
- Implementation of onerous laws in jurisdictions outside the United States may provide a disincentive for companies or researchers to perform research or to invest in technologies that may relate to genetic resources – to the extent an individual researcher or company may be interested in accessing resources or commercializing products in such jurisdiction.

7. *If the Nagoya Protocol on Biological Diversity were to be ratified and enter into effect, how would you see the implementation of access and benefit-sharing arrangements under the protocol affecting trade in and research and development based on genetic resources?*

- Because the United States is not a party to the CBD, we do not expect the United States to ratify the Nagoya Protocol.
- As a general matter, parties to the Nagoya Protocol should implement its provisions in a sensible manner that ensures respect for mutually agreed terms, does not attempt to “retroactively” or otherwise apply the Protocol to genetic resources outside the scope of the Protocol, and avoids onerous requirements or interference with intellectual property or other regulatory systems.
- If this is done appropriately, we do not believe that implementation of the Protocol will undermine trade in and research and development based on genetic resources.

8. *What do you see as the possible implications of developments in IPRs covering genetic resources for the global trading system and related areas of international cooperation (such as the environment and development)?*

- The implications of developments in IPRs that may relate to genetic resources for the global trading system are similar to those in other technologies. IPR is an incentive for research and development and for bringing new products to market.
- The Nagoya Protocol is consistent with the notion that IPRs are not relevant to the enforcement of access and benefit-sharing laws or to compliance with ABS agreements. To the contrary, IPR is mentioned in the Nagoya Protocol solely in connection in the context of mutually agreed upon terms.
- This is important because the main role of intellectual property rights is to provide incentives for innovation – thus, the rewards from such incentives (e.g., royalties

deriving from strong patent rights) may be distributed through mutual consent in ABS agreements (or licensing or other agreements).

- However, to the extent that certain parties continue to seek to insert new requirements (e.g., disclosure of origin) in patent laws, this will cause greater uncertainty over rights and, consequently, inhibit research and development in genetic resources. This will reduce generation of monetary and other benefits necessary to incentivize conservation and sustainable use of genetic resources, but will also inhibit R&D in genetic resources that may be of great importance to meet future needs, including in environmental challenges such as global climate change.