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WIPO Treaty on Rights to Genetic Resources

India's Welcome Reflects Newfound Pragmatism

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India's welcome to the WIPO accord on recognition of indigenous knowledge reflects a new pragmatism. India's strict rules on accessing genetic material might be hindering research. So there is a case for a review to find a balance between protecting indigenous knowledge and supporting research.

The Government of India announced on 26 May that it had scored a big victory for the country and the global South when member states of the World Intellectual Property Organisation (WIPO) agreed to adopt a new international legal instrument imposing a specific disclosure requirement under patent law. The disclosure requirement requires patent applicants to reveal the geographical origins of any genetic material or traditional knowledge associated with genetic material that has contributed to the invention for which a patent is sought.

By way of illustration, if a company were to discover that a plant in India had medicinal properties to treat a disease and if it were to then file a patent application for active ingredients isolated from the plant, it would have to disclose to all patent offices, all across the world, that the plant in question was sourced from India. In addition, if the company's discovery of the medicinal properties of the plant was due to an indigenous community sharing its traditional knowledge with it, this too will have to be disclosed to patent offices.

Contrary to the government's claim that this treaty is a victory, the fact of the matter is that the disclosure requirement is tame to the point of being ineffective. To begin with, it requires countries to provide an opportunity to "rectify" the failure to make the required disclosure. Further, it prohibits signatory countries from revoking patents on the grounds of non-disclosure. It allows for other sanctions or remedies to be imposed on patentees in case of non-disclosure, but only if there has been "fraudulent conduct or intent". This is a very lenient approach to defaulters when contrasted to the standards prescribed in Indian law.

So, why then did the government not push for higher standards in the treaty instead of agreeing to a standard that will require it to amend its own domestic law?

Section 64 of India's Patent Act is less forgiving and penalises such non-disclosure by mandating the revocation of the patent without providing the patentee any opportunity to "rectify" non-disclosures. It also does not impose, on the person challenging the patent, the difficult burden of establishing fraudulent conduct or intent by the patentee. The standard in Section 64 is the only way to force disclosures that patentees are reluctant to make to the patent office.

As it stands now, India will have to dilute Section 64 to comply with the treaty. So, why then did the government not push for higher standards in the treaty instead of agreeing to a standard that will require it to amend its own domestic law?

The likely answer lies in that the WIPO treaty is not an end in itself but instead provides the means to ensure compliance with national laws, like the Biological Diversity Act (BDA), 2002, which regulates access to genetic material in India for the purposes of research or commercialisation. India's attempt to regulate access to biological material under the BDA has largely backfired. The serious difficulties faced in implementing the BDA may help explain the Indian climb-down on the standard of disclosure required in the WIPO Treaty.

A bit of history may help explain the issue.

Accessing Biological Material

The debate on regulating access to biological material began with the enactment of intellectual property (IP) laws in the developed countries after World War II to provide monopoly rights for the creation of new plant varieties. This was problematic because plant genetic material used to make new plant varieties was freely shared across national borders. For example, high-yielding varieties of wheat, like Sonora 64 and Rojo 64, which increased yields during the green revolution in India, were a cross of Japanese and Mexican rice varieties. Similarly, IR8, the high-yielding rice variety that boosted rice production in India was a cross of various rice varieties

from across Asia, ranging from Taiwan to Indonesia.

The creation of an intellectual property regime for private players to claim monopoly rights over new plant varieties [raised concerns in developing countries](#) because they had been freely sharing plant genetic material with universities and research centres in the West. They now faced the prospect of Western seed companies claiming proprietary rights over novel plant varieties sourced from the developing world and possibly blocking agricultural exports from the developing world. Alternatively, they could use the plant genetic material shared with them to develop improved varieties, which could be patented to compete with exports from the developing world.

For example, in the 1990s, in the [famous Basmati case](#), an American company had used samples of Basmati seeds in an American university to make a new variety of Basmati that could grow in Texas. Apart from opening the door to competing with Basmati exports from South Asia, the American company's patent on its new variety created the possibility of South Asian exporters being sued for patent infringement.

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These concerns over Western companies claiming propriety rights over plant varieties and other biological material escalated in the 1980s for two reasons. The first was the biotechnology revolution. After the Cohen-Boyer [invention of gene-splicing technology](#) in 1972, it was possible to exploit genetic material to create a whole range of biotech products that ranged from genetically modified plants to new medicines.

The second was the determined push by the United States to force the world to adopt the [Agreement on Trade Related Intellectual Property \(TRIPS\)](#) as part of the agreement to create the World Trade Organisation (WTO). By forcing developing countries to enact patent laws, TRIPS ensured that multinationals could claim monopoly protections over novel plant varieties and other biotech inventions in these countries. These patent monopolies would increase the price of commodities for consumers in these developing countries.

The negotiations towards adoption of the WTO Agreement were countered by a [vocal anti-globalisation movement](#), which questioned the logic and fairness of the developing world freely sharing genetic material with the developed world if the resulting inventions could be protected as patent monopolies in the global South due to TRIPS. This movement was particularly effective in conjuring images of indigenous people with knowledge of plants being exploited by rapacious Western seed and pharmaceutical corporations. The [“neem case”](#), which involved an American company patenting the active ingredient of the neem plant for use as a bio-pesticide, provided the perfect backdrop for activists who labelled the case as an instance of “biopiracy” by the West. The phrase “biopiracy” was a play off the phrases “software piracy” and “music piracy” used by the intellectual property industry to describe copyright infringement.

Convention on Biological Diversity

The pushback from the developing world manifested itself in the form of the [Convention for Biological Diversity \(CBD\)](#), which was adopted in 1992. The US was the only major economy which declined to become a signatory.

The CBD recognised national sovereignty over biological material and promoted equitable sharing of benefits that arose from the use of genetic material. This meant that countries could control the manner in which genetic material was accessed and utilised for the purposes of research and commercialisation—within their borders. In effect, the CBD reversed the principle that genetic material, especially in plants, was the [“common heritage of mankind”](#).

Ensuring whether the required permissions have been taken under national laws enacted pursuant to the CBD was never going to be easy, especially in a globalised economy where a plant from one part of the world can fuel innovation in a different corner of the world. It is in this context that the WIPO treaty promised to offer a solution by imposing obligations on all patent applicants to make necessary disclosures on the source of biological material and any traditional knowledge used in inventions for which they are seeking patents.

Biological Diversity Law

In countries like India the obligations under the CBD were translated into national law by legislation like the BDA in 2002. This legislation imposed obligations on scientists and companies to apply for permission before accessing any kind of genetic material in India or filing any patent applications anywhere in the world for protecting inventions arising out of genetic material accessed under the

BDA. These permissions are granted by the [National Biodiversity Authority](#) (NBA).

The NBA requires researchers or their institutes to sign access agreements as a precondition to accessing biological material. These agreements typically mandate the sharing of IP rights and royalty with the NBA. The NBA is supposed to use the royalties to preserve biodiversity in India and also share the royalties with communities whose traditional knowledge contributed to the invention.

In practice, however, the BDA appears to be an instance of India “cutting its nose to spite its face” because it has ended up hurting domestic stakeholders without really benefiting anybody. Since it came into being, the BDA has had three main opponents.

The first were Indian scientists, like entomologists Divakaran Prathapan, a scientist at Kerala Agricultural University, and Priyadarsanan Dharma Rajan, who have written extensively about how the BDA has adversely affected scientific research in India because of the red-tape involved in accessing genetic material. They have argued that the costs imposed by the BDA have far outweighed any benefits and that much of the discussion leading to the CBD was fuelled by activists and politicians, with scientists being largely excluded. They have [argued for reverting](#) to treating plant genetic resources as the common heritage of mankind.

Similarly, the international scientific community involved in research on plant varieties recognised the potential of the CBD to disrupt the well-established practice of sharing of seeds and other plant material across international borders. They responded to the CBD by pushing for the adoption of the [International Treaty on Plant Genetic Resources for Food and Agriculture \(ITPGRFA\)](#) in 2004, which effectively excluded 64 food crops from the CBD. India, which is a signatory to this treaty, has started the process of exempting these 64 food crops from the purview of the BDA. The key beneficiaries of this exemption, apart from agricultural scientists in the public sector, are private seed companies, many of them Indian.

Given the gradual hollowing out of the Biodiversity Agreement in response to the difficulties thrown up in its implementation, it was perhaps prudent for India to not take a hardline during the negotiation of the WIPO treaty.

A third powerful lobby that felt the brunt of the BDA was the Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homoeopathy (Ayush) industry, which sources key ingredients from plants that are often cultivated for this very purpose. As originally envisaged by the BDA, domestic companies were not subject to the same obligations as foreign companies. This changed with a [judgment of the Uttarakhand High Court](#) in December 2018, which required domestic companies to apply for the same permissions under the BDA as foreign companies. This judgment also opened the door for vexatious raids of the Ayush industry by bureaucrats over compliance issues with the BDA. This, in turn, led to the Ayush industry successfully lobbying for [sweeping amendments to the BDA](#), which included the decriminalisation of many penal provisions.

Rethink the BDA

Cumulatively, the above events bring us back to the question of the WIPO treaty and the probable reason for India agreeing to a diminished disclosure requirement in patent applications. Given the gradual hollowing out of the BDA over the years in response to the difficulties thrown up in its implementation, it was perhaps prudent for India to not take a hardline during the negotiation of the WIPO treaty.

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Activists working on rights of indigenous communities in India will disagree. They will likely argue that the diluted disclosure requirements will make it harder to track compliance under laws like the BDA. But the only relevant question to ask in response is whether any of these communities have been rewarded for the fruits of their traditional knowledge under the present BDA.

I suspect the answer is zero, and if that is the case, it may be time to rethink the manner of regulating access to genetic material, especially if the scientific community in India is being hindered by the red tape that still exists under the BDA. Prudent policymaking must be pragmatic and consider the cost and benefit of a trade-off. The government must conduct a survey of the scientific community on the challenges it faces under the BDA and address its difficulties. India has to find a better way to balance the researcher’s need for access to biological material and the right of indigenous communities to be rewarded for providing access to their traditional knowledge.

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