Remedying the Misappropriation of Genetic Resources

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Abstract

In the absence of an effective international legal regime to regulate biopiracy, a second-best solution is for source countries to regulate access to their genetic resources. Among the pioneering legislation in this regard is the Indian Biodiversity Act of 2002. This legislation seems to accord with world's best practice of nesting bioprospecting within the broader environmental legal framework which will allow a greater degree of certainty. Similarly South Africa has enacted its National Environmental Management: Biodiversity Act, 2004, which regulates bioprospecting, within the framework of the National Environmental Management Act, 1998. The slow evolution of an international legal regime to deal with the biopiracy of genetic resources is now threatened with obsolescence as it now becomes possible to assemble DNA sequences in a laboratory. Those genes can be accessed in public databases without the necessity to access biological material from source countries. In 2016 the Conference of Parties of the Convention on Biological Diversity (CBD CoP) has begun meeting to consider how the Nagoya Protocol might be modified to deal with biopiracy and synthetic biology.

Keywords

Biopiracy · Traditional knowledge · WIPO · Genetic resources · Convention on biodiversity

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9.1 Biopiracy

Areas of biodiversity are valuable reservoirs of genetic material which can be used for both agricultural and medical innovations. For example, it is estimated that about 6.5% of all genetic research undertaken in agriculture is focussed upon germplasm derived from wild species and landraces (McNeely and Sherr 2002), and according to the World Health Organization's estimate, approximately 85% of the world's population depend upon plants for their primary health care (McGonigle 2016). Seventeen countries, including India, have been identified as "megadiverse" countries with significant proportions of the world's flora and fauna species (Mittermeier et al. 1989). Most of these countries are located in tropical and subtropical areas, and most of them, from an economic perspective, are developing or least developed countries (LDCs). In other words, their richness of genetic resources has not been translated into economic wealth. One of the reasons for this is the absence of a binding global legal regime which obliges the exploiters of genetic resources to seek the consent of source countries for access to those resources and to share the benefits resulting from their exploitation. The 1992 Convention on Biological Diversity (CBD) was an attempt to establish a global access and benefit-sharing (ABS) regime, but it failed to obtain the support of a number of exploiting countries, including the USA, which are located outside the areas of greatest biological diversity (Fowler and Hodgkin 2004).

This absence of a global legally binding ABS regime has permitted the unauthorised appropriation of a country's genetic resources. The typical method of appropriation is the securing of patent or plant variety rights over those resources in another country. This allows the proprietors of those intellectual property rights to prevent the utilisation in those other countries of the protected genetic resources. Thus, for example, the patenting of a gene in the USA of biological material obtained from an African country will have the effect of preventing that African country from exporting crops containing that gene to the USA. The privatisation of genetic material through intellectual property protection is of critical importance for food security as all countries are interdependent in their reliance upon genetic material from other countries. For example it is estimated that Bangladeshi rice contains 4 varieties from its own landraces and 229 borrowed landraces and USA rice comprises 219 native landraces and 106 borrowed landraces.

"Biopiracy" is the name given by some to the unauthorised appropriation of a country's biological resources (Blakeney 2004; Robinson 2010; Singh et al. 2016). An alternative characterisation of this practice is "bioprospecting", which was defined by the Secretariat of the CBD as "the exploration of biodiversity for commercially valuable genetic and biochemical resources" (UNEP 2000). Until there is a global legal regime which obliges all persons and enterprises to obtain permission for the exploitation of the biological resources of source countries, then bioprospecting can be undertaken with impunity.

The first notorious example of biopiracy concerned patents granted in 1994 by the US Patent and Trademarks Office (USPTO) and the European Patent Office (EPO) over Neem (*Azadirachta indica*) extracts by the US corporation W.R. Grace

& Company and the US Department of Agriculture. This patent concerned a method for extracting azadirachtin from neem tree seeds to be used as an insecticide.[1] A coalition of environmental NGOs challenged the patent on grounds that the patent lacked novelty and an inventive step because the fungicidal effect of hydrophobic extracts of neem seeds was known and used for centuries in India, both in Ayurvedic medicine to cure dermatological diseases and in traditional Indian agricultural practice to protect crops from being destroyed by fungal infections (Shiva and Holla-Bhar 1996). These arguments were accepted both by the US Patent and Trademarks Office (USPTO) and by the European Patent Office (EPO) in revoking the patent. This case generated a substantial campaign in India and other countries against perceived threats to the sovereignty of countries over their biological resources, and despite the revocation of the patent, it has come to be regarded as the quintessential example of biopiracy (Shiva 2013).

A second example of biopiracy involving the biological resources of India concerned a patent granted by the USPTO in September 1997 to RiceTec, an American company based in Texas, for "Basmati rice lines and grains".[2] Basmati rice has been cultivated in northern India, as well as in Pakistan for centuries. It is estimated that Basmati rice is India's primary rice export, being cultivated on between 10% and 15% of the total land area under rice cultivation (Shiva 2000). In April, 2000 the Indian Government challenged a number of the claims in this patent on the basis that the invention lacked novelty (Subbiah 2004). The USPTO ruled that most of the patent claims were invalid, but it upheld the patent in relation to three hybrid lines which RiceTec had developed from Basmati.[3] A separate complaint had been made to the US Federal Trade Commission (FTC) about RiceTec's description of its rice as "basmati", but the FTC took the view that this was a generic term and that consumers would not be deceived by the description "American basmati" (Subbiah 2004; Lightbourne 2003).

It should be noted that the acquisition of biological resources from one part of the world to establish valuable agricultural industries in other parts of the world has a long history, for example, the acquisition of tea and silk from China; potatoes, tomatoes and natural rubber from South America; oil palm from West Africa; and coffee from Ethiopia (Fowler and Mooney 1990).

Compounding the concerns about biopiratical exploitation of developing countries and LDCs is the perception that many instances of the appropriation of a country's biological resources is facilitated by reliance upon the traditional wisdom of indigenous and traditional peoples in identifying those resources. In almost all of the reported cases, those peoples did not share in the commercial benefits which resulted from the exploitation of those resources.

[1] US patent US5411736 A.

[2] US patent 5,663,484.

[3] US patent No. 5,663,484, Re-examination Certificate C1 (4525th) (reissued 29 January 2002).

9.2 Biological and Genetic Resources

"Biological resources" are defined in Article 2 of the Convention on Biological Diversity (CBD), 1992, as including "genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity". "Genetic resources" are defined as "genetic material of actual or potential value", and "genetic material" is defined as "any material of plant, animal, microbial or other origin containing functional units of heredity". Genetic resources are thus a subset of biological resources. It has been suggested that a resource is used as a biological resource if it is used in a way that its genetic characteristics are not central to its suitability for the respective use, such as "firewood, construction material, decoration, or for ecosystem services" (Rojahn 2010). On the other a biological resource whose specific utility is based on its heritable characteristics is a genetic resource. The following examples are given in a 2008 report commissioned for the CBD:

- Breeding new varieties and other genetic modification
- Further propagation and cultivation
- Identifying and extracting certain (novel) chemical compounds
- Taxonomic research and conservation
- Technical innovations based on that material (CBD 2008)

9.2.1 Sources of Genetic Resources

The CBD in Article 2 distinguishes between the country of origin of a genetic resource, such as a country which possesses this genetic resource in in situ conditions and a country providing a genetic resource from within its borders. Both countries may provide such resources from ex situ collections. Probably, the best-known ex situ collections are those administered by the Consultative Group for International Agricultural Research (CGIAR), which supports a collection of germplasm, which currently comprises over 710,000 accessions of cereals, legumes, roots and tubers, and trees and other essential staple crops are held at a number of international agricultural research centres, each focussing on crops and materials of interest to developing countries.[4] These centres include Africa Rice Center, International Center for Tropical Agriculture (Centro Internacional de Agricultura Tropical) (CIAT), International Maize and Wheat Improvement Centre (Centro Internacional de Mejoramiento de Maiz y Trigo) (CIMMYT), International Potato Centre (Centro Internacional de la Papa (CIP), International Center for Agricultural Research in the Dry Areas (ICARDA), International Crop Research Institute for the Semi-Arid Tropics (ICRISAT) and the International Rice Research Institute (IRRI).

[4] See http://www.cgiar.org/consortium-news/genebanks-investing-in-biodiversity-for-future-generations/, accessed 2 May 2017.

These CGIAR collections were established from the mid-1960s from deposits by source countries and by the collecting activities of CGIAR centre researchers, who were welcomed into source countries which were comfortable with the mission of the CGIAR to provide improved seed to farmers in developing countries (Blakeney 1998). With the development of recombinant DNA technology in the mid-1970s, it became possible for persons to identify and commodify, through patenting, the useful genes in germplasm in both in situ and ex situ collections.

An example of patenting from an ex situ collection maintained by a CGIAR institute involved the patenting of a gene from a strain of rice (*Oryza longistaminata*), originally from Mali. In the late 1970s, *O. longistaminata* was identified by a researcher working in Cuttack North India, as being resistant to bacterial blight. In 1978, this resistant sample was taken to IRRI in Los Baños, Philippines, for further investigation. Over a 15-year period, through conventional breeding, IRRI researchers developed a high-yielding, blight-resistant strain of rice. A postdoctoral research fellow from the University of California at Davis, working at IRRI, was permitted with co-workers at Stanford University to map, sequence and clone the gene Xa21, which was identified as the genetic locus which contributed the resistance to blight. On 7 June 1995, the Regents of the University of California filed a patent application for "Nucleic acids, from *Oryza sativa*, which encode leucine-rich repeat polypeptides and enhance *Xanthomonas* resistance in plants". The patent was granted by the US Patents and Trademark Office on 12 January 1999.[5] This patent generated some controversy because it was perceived to compromise IRRI's research efforts and those of its clients in the rice-producing regions of Asia. Bacterial blight is not a particular problem for US rice producers, and a primary effect of the patent was to prevent the export of bacterial blight-resistant rice, utilising the patent to the USA. This patent also raised the question of equitable compensation, at least for the traditional farmers of Mali who had conserved *O. longistaminata* (WIPO/UNEP, 2001).

Examples of the patenting of the genetic components of an in situ resource are the various patents obtained in relation to *Kava-kava* (*Piper methysticum* Forst. Piperaceae), which is native to a number of countries in the South Pacific. From this plant an intoxicating beverage had been made from its crushed roots to be used in ceremonies since ancient times. Patents have been obtained in the USA of genetic material from *Kava-kava* as an analgesic and anaesthetic and as a phytotranquiliser[6] and for the treatment of bladder and urinary tract cancers.[7] This patenting has been criticised as it has been undertaken without the informed consent of the source country and without any sharing of the benefits resulting from the patents (Forsyth 2003; Lindstrom 2009; Ji 2014).

Another example of "biopiracy" from in situ resources is the patenting of a gene isolated from *Streptomyces viridochromogenes* a micro-organism isolated from

[5] US patent 5,859,339.

[6] US patent 6,537,592, 25 March 2003; US Patent 7,105,185, 12 September 2006.

[7] US patent 7,326,734, 5 February 2008.

Cameroonian soil, which is responsible for the tolerance to glufosinate herbicides.[8] Despite the successful commercialisation of this chemical, no benefits have been shared with Cameroon (Mahop 2006).

9.2.2 The Role of Traditional Knowledge (TK) in Identifying Genetic Resources

In a number of cases involving appropriation of genetic resources conserved in situ, those resources have been identified with the assistance of traditional peoples. For example, in 1995, the South African Council for Scientific and Industrial Research (CSIR) obtained a patent on a compound found in the Hoodia cactus, used by the San People of the Kalahari Desert who had traditionally eaten the cactus to stave off hunger and thirst on long hunting trips. In 1997, it licensed this patent to the UK biotech company, Phytopharm, which in 1998, allocated its rights to the US pharmaceutical company Pfizer which marketed a Hoodia extract as a potential slimming drug and cure for obesity. Concern was expressed that the San, whose traditional knowledge (TK) had identified the utility of Hoodia, should have been consulted about the exploitation of their TK (Marcellin 2005) and their entitlement to a share of the benefits from its exploitation, estimated to be worth over US$3 billion per annum in the USA alone (Wynberg 2004).

An Australian example of the biopiracy of genetic resources identified with the use of traditional knowledge concerns the Kakadu plum (*Terminalia ferdinandiana*), a traditional food and medicine source for aboriginal Australian peoples in Northern Australia (Gorman et al. 2006). It is rich in vitamin C and contains gallic acids, which have antibacterial, antiviral and antifungal, anti-inflammatory, antitumour, anti-mutagenic and anti-bronchodilatory applications. US patents were granted in relation to the use of Kakadu plum in relation to skin care preparations and dietary supplements and for a food composition containing Kakadu plum[9] and

[8] US patent No. 5,276,268.

[9] Australian patent application 2007205838 by MARY KAY, INC. relates to a skin care product comprising Kakadu plum extract or acai berry extract. (Claim 1); Australian patent application 2004268233 by MANNATECH, INC. relates to a dietary supplement which may contain Australian bush plum (Claims 33–41); Australian patent application 2005328670 by MANNATECH, INC. relates to a modified release dietary supplement comprises polysaccharides which is compressed at a pressure of greater than 100 psi. (Claim 1); Australian patent application 2006237559 by MANNATECH INC. relates to a modified release dietary supplement which comprises polysaccharides which is compressed at a pressure of greater than 100 psi. (Claim 1); Australian patent application 2004203276 by CORADJI Pty Ltd relates to a method of removing the seed from the fruit of the *Terminalia ferdinandiana* (i.e. bush plum) (Claim 1); Australian patent application 2007231781 by EXIST MARKETING PTY LTD. to a method and compositions of treating bursitis which may contain Kakadu plum (page 14); Australian patent application 2007249801 by INTERLEUKIN GENETICS, INC. is to a food composition comprising rose hips and optionally Kakadu concentrate, from the Kakadu plum. (Claim 1); Australian innovation patent application 2008100919 by GREENTASTE Pty Ltd. is to a herbal composition which optionally may contain Kakadu plum (page 26).

a US patent granted for a method for preparing dried powder from the Kakadu plum and for anti-allergy compositions.[10] These US patents formed the basis of applications under the Patent Cooperation Treaty (PCT) designating more than 100 countries in which the patent would apply. When the skin care patent entered the national phase in Australia, a submission was made under section 27 of the Patents Act 1990 regarding the lack of novelty of many of the claims made in this application.[11] It was pointed out that the Kakadu plum had been used as a medicament by Aboriginal Peoples in Australia for over 40,000 years. This objection was communicated to the US applicant, which withdrew its Australian application (Robinson 2010), but the patent remains on foot in the other countries designated in the PCT application.

In 1995 and 2000, it was reported that University of Wisconsin scientists had patented and were exploiting patents[12] on "brazzein" a protein extracted from the berries of *Pentadiplandra brazzeana* from Gabon. This protein is apparently 2000 times sweeter than sugar, which makes it highly desirable as a natural, low calorie sweetener. Natur Research Ingredients, Inc., a US corporation, was reported in late 2008 to have acquired the sole rights to manufacture and distribute brazzein from the University of Wisconsin at Madison (Adams 2009). This exploitation of brazzein was reported as an early example of biopiracy in that there appeared to be no arrangements for the sharing of benefits with Gabon (RAFI 1995). It was cited as an instance of biopiracy to the UK Parliament's Select Committee on Environmental Audit in 1999 (UK Parliament 1999) and is referred to as the classic exemplar of biopiracy in analysing the concept of "justice" (Brody 2010).

In 2003, the Peruvian government identified several patents[13] and patent applications relating to "maca" (*Lepidium meyenii*), which had traditionally been cultivated in the Andes, including claims concerning therapeutic methods and uses of the plant (WIPO IGC 2003; NRC 1989). The Peruvian government expressed its concerns about the extent to which the patents and pending applications in the USA could prevent exports of maca extracts from Peru. Similarly, from 2001 the Japanese company Asahi Foods Co., Ltd., and an associated US company "Cupuacu International

[10] US patent 7175862 assigned to ACCESS BUSINESS GROUP INTERNATIONAL LLC is to a method of preparing dried powder from the Kakadu plum. US Patent 7384654 assigned to ACCESS BUSINESS GROUP INTERNATIONAL LLC is to an anti-allergy composition which may contain Kakadu concentrate. US patent 7384656 assigned to ACCESS BUSINESS GROUP INTERNATIONAL LLC is to a method of inhibiting an allergic response by administering a composition which may contain Kakadu concentrate.

[11] See D. F. Robinson: "The Biological Patent Predicament Traditional Knowledge and Biological Product Derivative Patents: Benefit-Sharing and Patent Issues Relating to Camu Camu, Kakadu Plum and Açaí Plant Extracts" Guest Article, United Nations University, Institute of Advanced studies, Traditional Knowledge Initiative, Published online 30 April 2010, accessed at http://www.unutki.org/news.php?doc_id=174.

[12] US patent No. 5,741,537, 21 April 1998; US Patent No. 5,527,555, 18 June 1996; US Patent No. 5,346,998, 13 September 1994.

[13] Granted patents include US 6552206 "Compositions and methods for preparation from Lepidium"; US 6428824 "Treatment of sexual dysfunction with an extract of *Lepidium meyenii* roots"; US 6267995 "Extract of *Lepidium meyenii* roots for pharmaceutical applications"; US 6878731 "Imidazole alkaloids from *Lepidium meyenii* and method of usage".

Inc." had obtained a number of patents on the extraction of lipids from the cupuaçu seeds.[14] The pulp of cupuaçu (*Theobroma grandiflorum*), which grows in the rainforests of Brazil, is used by traditional peoples to make fresh juice or as a sweetener for confectionary and as a medicament.

A final example of the patenting of genetic resources identified with the assistance of traditional peoples concerns camu camu (*Myrciaria dubia*), a plant with very high levels of ascorbic acid (vitamin C), used by traditional peoples in the Peruvian Amazon. In October 2005 Peru notified the World Trade Organization of "potential biopiracy" arising from a series of international patents and patent applications, principally published under the Patent Cooperation Treaty (PCT) and by Japanese Patent Office for skin preparations, cosmetics and food additives utilising camu camu (Peru 2005). This notification was also communicated to the World Intellectual Property Organization (Peru 2006).

In these various examples, the knowledge of traditional peoples is utilised to identify the biological resources which they use. In all of these patents were secured over genetic material which had different uses of that material to those of the traditional peoples. However, the important contribution of traditional peoples was in identifying those biological materials which might have promising active ingredients. The utilisation of this knowledge in identifying biologically active substances has saved bioprospectors the considerable amounts of money they would otherwise have expended in screening substances at random (Keswani et al. 2017). Discussed below are proposals for securing the consent of traditional peoples both to their knowledge and to the biological resources which they have identified as useful and the equitable sharing of commercial benefits with those peoples.

9.3 Remedying the Misappropriation of Biological Resources

9.3.1 Convention on Biological Diversity (CBD)

The Rio Earth Summit, which was convened in June 1992, promulgated the CBD which represented an attempt to establish an international programme for the conservation and utilisation of the world's biological resources (McConnell 1996). "The single most divisive issue in the negotiations was the relationship between intellectual property rights and access to genetic resources" (Chandler 1993), in particular the conditions for access and benefit sharing. Article 1 of the CBD declared the objectives of the Convention to be "the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources". The Convention noted in Article 3 the sovereign right of nations "to exploit their own resources pursuant to their own environmental policies", but in Article 15 required contracting

[14] JP 2001299278, 30 October 2001, JP2001348593, 18 December 2001, EP 1219698A1, 03 July 2002, WO0125377, 03 July 2002, WO02081606, 17October 2002.

parties to "endeavour to create conditions to facilitate access to genetic resources for environmentally sound purposes" by other contracting parties on mutually agreed terms and conditions on the basis of "prior informed consent". Access to biological resources is required by Article 16 to be "provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights". Article 19.2 provided for the grant of access on a fair and equitable basis and on mutually agreed terms, to contracting parties, "particularly developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those contracting parties".

Article 8(j) of the CBD had provided that TK holders should participate in the "the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices".

The CBD did not set out how ABS would be implemented. At the conference of the parties (COP) of the CBD in October 2001, an ad hoc open-ended working group on ABS was established, and at its first meeting in Bonn, it developed the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Benefit Sharing which was adopted by the seventh COP on a non-binding, voluntary basis.[15] The contribution of traditional peoples referred to in Article 8(j) of the CBD was decision taken into account by further sessions of the working group, and in 2010 the COP adopted the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity.[16] Article 6 of the Protocol reiterated the CBD's recognition of country's sovereign rights over natural resources and that access to genetic resources be subject to the prior informed consent (PIC) and on mutually agreed terms (MAT). Article 5 of the Protocol provided that the benefits arising from the utilisation of genetic resources "as well as subsequent applications and commercialisation" are to be shared with the provider of those resources in a fair and equitable way. Article 12 of the Protocol requires that signatories consider the customary laws, community protocols and procedures of indigenous and local communities (ILCs) with respect to traditional knowledge associated with genetic resources. The CBD and its Protocol are yet to secure acceptance or implementation by the principal bioprospecting nations.

9.3.2 International Treaty on Plant Genetic Resources for Food and Agriculture

The specific issue of the biopiracy of genetic resources from the international agricultural research centres of the CGIAR was sought to be dealt with by the 2001 International Treaty on Plant Genetic Resources for Food and Agriculture. Article

[15] 'Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization' in Report of the Sixth Meeting of the Conference of the Parties to the Convention on Biological Diversity, UN Doc. UNEP/CBD/COP/6/20 (2002).

[16] UNEP/CBD/COP/10/L.43/Rev.129 October 2010.

10.2 contains the agreement of the Contracting Parties to "establish a multilateral system, which is efficient, effective and transparent, both to facilitate access to Plant Genetic Resources for Food and Agriculture (PGRFA) and to share, in a fair and equitable way, the benefits arising from the utilisation of these resources, on a complementary and mutually reinforcing basis". The PGRFA to which the multilateral system applies are some 35 crops and 29 forages which are listed in Annexure I and other contributions by resource holders (Article 11(2)). The collections of the CGIAR are expressly included in the multilateral system (Article 11(5)). Access to PGRFA of such crops and forages is to be provided free or at a minimal cost. The treaty attempts to create an international genetic resources commons by seeking to limit the propertisation of the categories of crops and forages to which it applies (Halewood and Nnadozie 2008).

The International Treaty in Article 12.3 provides that facilitated access to PGFRA is to be provided under material transfer agreement on condition (d) that the recipients "shall not claim any intellectual property or other rights that limit the facilitated access" to PGFRA, or their "genetic parts or components", in the form received from the multilateral system. This, of course, does not prevent intellectual property rights being claimed in relation to germplasm which is modified by the recipient. A problematic issue is the extent of modification which must occur before it can be said that the form in which the germplasm was received has changed.

A standard material transfer agreement (SMTA) to be used for accessions of material falling within the International Treaty was finalised in 2006 (FAO 2006). The parties to the SMTA agree in Article 4.3 that the Governing Body of the Treaty and its Multilateral System (i.e. the Food and Agricultural Organization of the United Nations (FAO)) is identified as the third party beneficiary under the SMTA, including the FAO as the third party beneficiary puts it in a position to enforce the SMTA. The limited financial resources for legal enforcement actions of many of the institutes which will be supplying genetic resources under SMTAs means set up the FAO as a more likely litigant. However, Article 4.5 preserves the rights of the provider and the recipient from exercising their rights under the SMTA. Although the SMTA seeks to construct a legal basis for the enforcement of rights in relation to germplasm and other materials supplied under its terms, the greater likelihood is that the SMTA will be enforced as a moral obligation. Also recipients who do not abide by the terms of a SMTA are likely to be excluded from the receipt of any further material under the multilateral system.

Article 5 of the SMTA provides that in the case of transfers from CGIAR Centres, these will be subject to the Agreement between the FAO and the Centres under which trusteeship of their collections is conferred on the FAO. Article 5 (d) provides that access to PGRFA protected by intellectual and other property rights shall be consistent with relevant international agreements, and with relevant national laws, but under Article 6.2 the recipient agrees not to claim any intellectual property or other rights that limit the facilitated access to the material provided under the SMTA or its genetic parts or components, in the form received from the multilateral system. This terminology leaves it open for recipients to obtain intellectual property rights in modified derivatives.

Where a recipient obtains intellectual property rights on any products developed from the material supplied under a SMTA, or its components and assigns such intellectual property rights to a third party, Article 6.10 requires that the recipient shall transfer the benefit-sharing obligations of the SMTA, set out in Article 6.7 to that third party. Under Article 6.1 of the SMTA, the recipient undertakes that the material shall be used or conserved only for the purposes of research, breeding and training for food and agriculture. Such purposes shall not include chemical, pharmaceutical and/or other non-food/feed industrial uses.

Article 13.1 of the International Treaty recognises that benefits accruing from facilitated access to PGFRA shall be shared fairly and equitably under this Article. Article 13.2 envisages that this sharing of benefits include the exchange of technical information, access to technology, capacity building and the sharing of monetary benefits from commercialisation.

Article 7 of the SMTA provides that it shall be governed by "General Principles of Law", including the UNIDROIT Principles of International Commercial Contracts 2004, the objectives and the relevant provisions of the treaty and, when necessary for interpretation, the decisions of the Governing Body. Article 8 provides that disputes arising from the SMTA shall be by negotiation or third party mediation or where these are unsuccessful, "by arbitration under the Arbitration Rules of an international body as agreed by the parties to the dispute". Failing such agreement, the dispute shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce. The result of such arbitration shall be binding.

9.3.3 World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

Facilitating the biopiracy of genetic resources has been the establishment of a global patents regime pursuant to the TRIPS Agreement. Article 27 of TRIPS requires that patents be available in all fields of technology. This will include biotechnology and is obviously in tension with the objectives of the CBD and the International Treaty. It has been suggested that the TRIPS Agreement should be amended so as to require, or to enable, WTO members to require that patent applicants disclose, as a condition to patentability: (a) the source of any genetic material used in a claimed invention, (b) any related traditional knowledge used in the invention, (c) evidence of prior informed consent from the competent authority in the country of origin of the genetic material, and (d) evidence of fair and equitable benefit sharing[37] and that such provisions could be incorporated into the TRIPS Agreement by amendment.[17]

[17] WTO Doc. IP/C/W/228, IP/C/M/32, para. 128, IP/C/M/33, para. 121 (Brazil).

9.3.3.1 World Intellectual Property Organization (WIPO) and Genetic Resources

In September 1999, the delegation of Colombia proposed the introduction into the Patent Law Treaty, then under negotiation, that an article be inserted which provided that:

1. All industrial protection shall guarantee the protection of the country's biological and genetic heritage. Consequently, the grant of patents or registrations that relate to elements of that heritage shall be subject to their having been acquired made legally.
2. Every document shall specify the registration number of the contract affording access to genetic resources and a copy thereof whereby the products or processes for which protection is sought have been manufactured or developed from genetic resources, or products thereof, of which one of the member countries is the country of origin.

The Diplomatic Conference, which commenced on 11 May 2000, became bogged down on the question of obliging the identification of source countries in biotechnological patent applications. To facilitate progress on the procedural aspects, the source country question was referred to an expert group for further consideration. At the WIPO General Assembly in 2000, the member states agreed the establishment of an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). Three interrelated themes were identified to inform the deliberations of the Committee: intellectual property issues that arise in the context of (i) access to genetic resources and benefit sharing; (ii) protection of traditional knowledge, whether or not associated with those resources; and (iii) the protection of expressions of folklore (WIPO 2000).

The early sessions of the IGC were concerned with the formulation of model guidelines and intellectual property clauses for contractual agreements on access to genetic resources and benefit-sharing (e.g. WIPO, IGC 2001). At the same time the IGC has concerned itself with formulating treaties for the protection of traditional knowledge and traditional cultural expressions. This has been a long drawn-out process, largely attributable to conflicts between bioprospecting and source countries, as well as to tensions between traditional and dominant communities (Blakeney 2016). The draft text on the protection of genetic resources aims to prevent the misappropriation and patenting of these resources and of related traditional knowledge unauthorised third parties. This is sought to be achieved by requiring that a patent applicant disclose the country or source of origin of the subject matter (WIPO, IGC 2017). The negotiations have not yet settled an agreed definition of biotechnology, or whether the instrument will apply to derivatives. In any event, for a global regime based upon this text to be effective, national legislation will have to sanction the use of genetic resources obtained without informed consent or without benefit-sharing arrangements.

9.4 Conclusion

In the absence of an effective international legal regime to regulate biopiracy, a second-best solution is for source countries to regulate access to their genetic resources. Among the pioneering legislation in this regard is the Indian Biodiversity Act of 2002 which provides that "no person shall apply for any intellectual property right … in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority before making such application, provided that if a person applies for a patent, permission of the National Biodiversity Authority may be obtained after the acceptance of the patent but before the sealing of the patent by the patent authority concerned".[18]

This legislation seems to accord with world's best practice of nesting bioprospecting within the broader environmental legal framework which will allow a greater degree of certainty "in the relationship between overlapping laws and policies" (Cabrera et al. 2012). Similarly South Africa has enacted its National Environmental Management: Biodiversity Act, 2004, which regulates bioprospecting, within the framework of the National Environmental Management Act, 1998.

The slow evolution of an international legal regime to deal with the biopiracy of genetic resources is now threatened with obsolescence as it now becomes possible to assemble DNA sequences in a laboratory. Those genes can be accessed in public databases without the necessity to access biological material from source countries. At a meeting next month in Cancun, Mexico, parties to an International Treaty governing the use of genetic resources, from medicinal plants to pest-killing microbes, plan to discuss whether and how the agreement should apply to digital DNA sequences. In late 2016 the CBD CoP has begun meeting to consider how the Nagoya Protocol might be modified to deal with biopiracy and synthetic biology (Manheim 2016).

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