Chapter 3
Access to Plant Genetic Resources for Food and Agriculture

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Abstract This chapter looks at the contribution of plant genetic resources to agricultural innovation and concerns about the appropriation of those resources by unauthorized persons. It details 'biopiracy' episodes which have involved patents and plant variety rights. The chapter looks at the role of the traditional knowledge of indigenous peoples and farmers in identifying useful genetic resources. The international conventions regulating access to genetic resources are described, including the Convention on Biological Diversity, the Nagoya Protocol, the International Treaty on Plant Genetic Resources for Food and Agriculture and the World Trade Organization Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). The chapter concludes with an examination of the negotiations for a treaty on genetic resources at the World Intellectual Property Organization.

Keywords Genetic resources · Biopiracy · International conventions protecting genetic resources · WIPO international treaty on genetic resources

3.1 Biodiversity and Plant Genetic Resources

Seventeen countries, including Australia and India, have been identified as "megadiverse" countries with significant proportions of the world's flora and fauna species (Mittermeier et al., 1989). This biodiversity is a valuable repository of genetic material which can be used for agricultural innovations, particularly in a situation of climate change and population growth.

It has been repeatedly observed that crop wild relative species tend to contain greater genetic variation than and thus represent a reservoir of useful variation for

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M. Blakeney, K. H. M. Siddique (eds.), *Local Knowledge, Intellectual Property and Agricultural Innovation*, https://doi.org/10.1007/978-981-15-4611-2_3

crop improvement, especially because of their potential to contribute beneficial traits to crops, such as biotic and abiotic resistance, improved yield and climate adaptability (Hajjar & Hodgkin, 2007; Maxted et al., 2012; Prescott-Allen & Prescott Allen, 1988). By way of example, Dwivedi et al. observed that while many dominant genes for climate adaptation and trait enhancement have been lost during cereal crop domestication, they have been retained in the genome of the wild components of the *Triticeae* gene pools. De Pace, et al. noted that in its natural habitat, wild *Triticeae* species such as *Dasypyrum villosum* (*Dv*), whose genome was exposed to millions of years of climatic and environmental changes, "are now expressing increased heading earliness, density stands and plant biomass" (De Pace et al., 2011). They have suggested that deploying whole and dissected *Dv* nuclear genome in the homoeologous wheat genetic background through interspecific hybridization and introgression "could be a lower cost and effective option to help wheat breeders to merge and select the proper adapted gene pools to sustain the needed yearly grain yield increase" (De Pace et al.)

The agricultural value of plant genetic resources is considerable. It is estimated that genetic materials traceable to developing countries account for more than 95% of the output of the world's top twenty food crops (Chen, 2000, 176). It has been estimated that about 6.5% of all genetic research undertaken in agriculture is focussed upon germplasm derived from wild species and landraces (McNeely, 2001). Crop wild relatives, which are the source of potential crop improvements, exist mainly in situ. Maxted and Kell (2009) estimated that only 2–6% of global gene bank collections comprise crop wild relatives and that of the total number of species, only about 6% have been conserved in ex situ collections. There are around 1700 gene banks and germplasm collections around the world with some 7.4 million accessions of plant genetic resources (Dias, 2015, 7). The Consultative Group on International Agricultural Research (CGIAR), comprising eleven Centres hosting international crop and forage collections, holds about 0.7 million accessions of 3446 species from 612 genera. These centres include: Africa Rice Center, International Center for Tropical Agriculture (Centro Internacional de Agricultura Tropical) (CIAT). International Maize and Wheat Improvement Center (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). 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 and plant variety rights protection, the useful germplasm in both *in situ and ex situ* collections. This has circumscribed the availability of these genetic resources for crop improvement. These accessions have been characterised as "biopiracy" and have

generated efforts to create an international legal regime to proscribe unauthorised accessions and to regulate the access to plant genetic resources for food and agriculture, as well as encouraging the conservation of those resources. These developments are discussed below.

It should also be noted that "biopiracy" concerns have also been raised outside the agricultural context in relation to the acquisition of biological resources for the development of medicines. (Blakeney, 1997, 2019; Efferth, 2019; Sharma, Maurya, & Brahmacharimayum, 2018; Srivastava, 2011).

3.2 Biopiracy

The person credited with coining the term "Biopiracy" is Pat Mooney (Executive Director of ETC Group (Action Group on Erosion, Technology and Concentration), formerly RAFI (Rural Advancement Foundation International), who defined biopiracy as:

> the appropriation of the knowledge and genetic resources of farming and indigenous communities by individuals or institutions who seek exclusive monopoly control (patents or intellectual property) over these resources and knowledge (ETC, 2005).

in the context of the increasing assertion in the 1970s and 1980s of intellectual property rights over plant germplasm (see Blakeney, 2004; Kloppenburg & Kleinman, 1988; Robinson, 2010). Thus Vandana Shiva, the famous Indian environmental activist, explained that "biopiracy" referred "the use of intellectual property systems to legitimize the exclusive ownership and control over biological resources and biological products that have been used over centuries in non-industrialized cultures" (Shiva, 2001). A less pejorative characterization of this practice is "bioprospecting", defined as "the exploration of biodiversity for commercially valuable genetic and biochemical resources" (UNEP, 2000, para. 6). A vigorous scholarship has characterised bioprospecting as a valuable practice which benefits all farmers (Heald, 2003) and has even contested the existence of biopiracy as "rural legend" (Chen, 2005). This controversy had a North-South dimension as the principal sources of useful germplasm are the developing countries of the tropics, whereas the principal exploiters of that germplasm have tended to be the less biodiverse industrialized countries. On the one hand the bio-exploiters have insisted that genetic resources are the common heritage of mankind, whereas source countries and communities have asserted a right to prior informed consent and the sharing of benefits derived from the exploitation of those resources.

It has been observed that all countries are interdependent in their reliance upon germplasm from other countries. Thus, by way of example, it is estimated that Bangladeshi rice contains four varieties from its own landraces and 229 borrowed landraces and USA rice comprises 219 native landraces and 106 borrowed landraces (Fowler & Hodgkin, 2004). However, a number of high profile "biopiracy incidents" have generated demands for the establishment of an effective international

legal regime to mediate access to genetic resources. Those in the agriculture domain are mentioned below.

3.3 Patenting

The first notorious example of biopiracy concerned patents granted in 1994 by the United States 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 United States 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 & Holla-Bhar, 1996). These arguments were accepted both by the United States 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 (Eg see Shiva, 2013).

A second example of biopiracy, also 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 rich 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, 85). In April, 2000 the Indian Government challenged a number of the claims in this patent on the basis that the invention lacked novelty (see Subbiah, 2004, 552–53). 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" (see Lightbourne, 2003; Subbiah, 2004, 554).

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

[1] US Patent US5411736 A.

[2] US Patent 5,663,484.

[3] U.S. Patent No. 5,663,484, Reexamination Certificate C1 (4525th) (reissued Jan. 29, 2002).

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 Banos, Philippines for further investigation. Over a 15 year period, through conventional breeding IRRI researchers developed, a high-yielding, blight resistant strain of rice. A post-doctoral 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 7th 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 United States Patents and Trademark Office on 12 January 1999.[4] 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, 13).

In 1995 and 2000 it was reported that University of Wisconsin scientists had patented and were exploiting patents on "brazzein" a protein extracted from the berries of *Pentadiplandra brazzeana* from Gabon. 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 (Micalizzi, 2017). This exploitation of Brazzein 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 (Brody, 2010, 51).

Another illustration of biopiracy influencing the international intellectual property environment is the so-called Basmati affair. This commenced when RiceTec, an American company based in Alvin, Texas, was granted a patent by the USPTO in September 1997 for "Basmati rice lines and grains".[5] The "novel rice lines" were described in the patent as "lines whose plants are semi-dwarf in stature, substantially photoperiod insensitive and high yielding" and which "produce rice grains having characteristics similar or superior to those of good quality basmati rice". In March 1998 an Indian NGO, the Research Foundation for Science, Technology and Ecology, petitioned India's Supreme Court to direct the government to challenge the patent, or to commence an action with the Dispute Settlement Body of the WTO. The Indian Government commenced an action in the USPTO in April 2000, challenging three of the patent claims (15–17). In response, RiceTec withdrew a number of its claims.

[4] U.S. patent 5,859,339.

[5] Patent 5,663,484 (USPTO).

Probably the most notorious example of agricultural biopiracy concerned a patent granted by the US Patent and Trademarks Office of a patent on April 13, 1999 for an invention relating to "a new field bean variety that produces distinctly coloured yellow seed which remain relatively unchanged by season."[6] The applicant was the president of a Colorado-based seed company, Pod-ners, which was reported to have written to all US importers of Mexican beans requiring the payment of a royalty of six cents per pound (Rattray, 2002). Pod-ners was reported to have brought infringement actions against two companies that were selling the Mexican yellow beans in the US. In January 2000, the Mexican government announced that it would challenge the US patent and on 20 December 2000 CIAT filed a formal request for re-examination of the patent claiming that the patent "would establish a precedent threatening public access to plant germplasm… held in trust by CIAT and research centers worldwide" (CIAT, 2008) The basis of the re-examination was that the patent failed to meet the statutory requirements of novelty and non-obviousness (See Nottenburg, 2009). CIAT argued that of its 260 bean samples with yellow seeds, six of the accessions were "substantially identical" to claims made in the patent. CIAT's patent challenge also asserted that the yellow bean was "misappropriated" from Mexico, and that this was in breach of Mexico's sovereign rights over its genetic resources. By way of a cross-claim, Pod-ners filed a request for a reissue of the patent on the basis that certain prior art had not been considered in the original application. In the re-examination the Examiner rejected the patentee's claims as obvious, explaining that the Enola plant and seed appeared to be genetically identical to the yellow Azufrado Peruano 87 bean. The USPTO's Board of Patent Appeals and Interferences upheld the rejection, concluding that the Examiner had established a prima facie case of obviousness which Pod-ners had failed to rebut. In 2009 Pod-ners failed in an appeal to the Federal Circuit Court.

In 2003, the Peruvian government identified several patents 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). 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 Inc" had obtained a number of patents on the extraction of lipids from the cupuaçu seeds. 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 (See Matthews, 2011, 150–156).

Another example of "biopiracy" from *in situ* resources is the patenting of a gene isolated from *Streptomyces viridochromogenes* a micro-organism isolated from Cameroonian soil, which is responsible for the tolerance to glufosinate herbicides.[7]

[6] US Patent 5,894,079.

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

Despite the successful commercialisation of this chemical, no benefits had been shared with Cameroon (Mahop, 2006, 132).

A 2006 study by the Edmonds Institute, in cooperation with the African Centre for Biosafety, identified 36 instances of biopiracy, including the patenting of endophytes for improving fescues from North Africa Morocco and Tunisia and nematocidal fungi from Burkina Faso, as well as attributes of Ethiopian Teff (McGown, 2006).

3.4 Plant Variety Rights Protection

The 2006 African case studies by the Edmonds Institute included the utilization by American breeders of groundnut varieties from Malawi, Mozambique, Nigeria, Senegal and Sudan (McGown, 2006).

Concerns were raised in 1998 about plant breeder's rights (PBR) applications made in Australia by a number of agricultural research institutes in relation to a peavine and a lentil which had been bred from genetic stock obtained from ICARDA. A feature article in the *New Scientist* carried an accusation from a spokesperson from the South Asian Network on Food, Ecology and Culture which described the PBR applications as "blatant biopiracy" by "privatising seeds that belong to our farmers and selling them back to us". (Edwards & Anderson, 1998). CGIAR Chairman, Dr. Ismail Serageldin, called for a moratorium on the distribution of germplasm as "the strongest signal the CGIAR can send governments to ensure that … the materials in the CGIAR remain in the public domain" (CGIAR, 1998). To prevent a recurrence of this incident, the operating regulations of the Australian Plant Breeders Rights Office were amended to oblige applicants for PBRs in relation to varieties derived from germplasm obtained from CGIAR centres, to document that such applications were made with the permission of the relevant centre.

In November 1999, five traditional Peruvian varieties of yacon (Smallantus sonchifolius) an ancient Andean fruit held at the International Potato Center (CIP) in Peru, were distributed by the Peruvian Ministry of Agriculture to researchers in Japan. Yacon has a high fructose content with a high percentage of insulin and with antidiabetic properties. In 2000, Japanese researchers reported that the National Shikoku Agriculture Experiment Station had released the first commercial variety of yakon, "Sarada-Otome", on August 25, 2000 (Huaman, 2001). CIP's potato curator, Dr. Huaman expressed concern that Japanese researchers were not prepared to send germplasm of the new variety to be tested in Peruvian farmers' fields, thereby denying a source country of new derivatives of deposited germplasm (Huaman, 2001). CIP's Genetic Resources Policy Committee (GRPC), chaired by Dr. M. S. Swaminathan, concluded that CIP had no right to interfere in Peru's sovereign decision to send the germplasm to Japan and commended CIP for its proper management of its germplasm held "in-trust (Blakeney, 2001).

Responding to concerns about the impact of intellectual property rights upon the operation of the CGIAR, it commissioned a report on the use of proprietary

technologies by CGIAR Centres by the International Service for National Agriculture Research (ISNAR), which operated as its legal advisory body (Cohen, Falconi, Komen, & Blakeney, 1998). The report noted the burgeoning use of proprietary technologies by the centres and recommended that they undertake audits of their intellectual property management policies. These cases led to an intense discussion within the CGIAR of the approach to be taken within the organization to intellectual property rights. Some CGIAR Centres perceive that CGIAR-generated intellectual property might be used as a bargaining chip, to be traded for biological tools patented by the private sector. For example the Policy on Intellectual Property of the International Maize and Wheat Improvement Center (CIMMYT) envisages that intellectual property protection may be sought "to facilitate the negotiation and conclusion of agreements for access to proprietary technologies of use to CIMMYT's research and in furtherance of its mission.[8] This proprietisation of public sector agriculture research is questioned, particularly by those NGO's opposed to patenting in the life sciences (see Blakeney, 2000).

3.5 Traditional Knowledge and Identification of Useful Genetic Resources

The traditional knowledge of indigenous peoples and farmers has played an important role in identifying biological resources worthy of commercial exploitation. For example, the search for new pharmaceuticals from naturally occurring biological material has been guided by ethnobiological data (See McChesney, 1996; ten Kate & Laird, 2000) In a number of the "biopiracy" examples above, the knowledge of local communities, traditional and indigenous peoples was utilised to identify useful germplasm. The utilisation of this knowledge in identifying biologically active substances has saved bio-prospectors the considerable amounts of money they would otherwise have expended in screening substances plucked at random. Thus, "biopiracy" often involves both the unauthorised access to biological materials and the unauthorised exploitation of the knowledge used to identify those materials as useful. The close relationship between identifying useful genetic resources and traditional knowledge is emphasized by Sharma et al. (2018) who point out that about two-third of Indian population relies on indigenous knowledge of biological resources and that more than 7500 species of plants are utilized for the traditional purposes in India. They then list 17 specific cases of the unauthorized patenting of Indian biological resources used and conserved by traditional communities.

Examples of traditional knowledge with and agricultural application include: "mental inventories of local biological resources, animal breeds, and local plant, crop, and tree species" as well as plants which are indicators of soil salinity, seed

[8] CIMMYT, *Policy on Intellectual Property*, Article III.4.v, available at www.cimmyt.org/resources/obtaining/seed/ip_policy/htm/ip-policy.htm, accessed 18 October 2019.

treatment and storage methods and tools used for planting and harvesting (Hansen, 2007). A similarly significant contribution has been made by the knowledge of indigenous peoples and farmers in the development of new crop types and biodiversity conservation. These groups have been an important agency in the conservation of plant genetic resources and the transmission of these resources to seed companies, plant breeders and research institutions. They have not typically been paid for the value they have delivered, whereas breeders and seed companies have resorted to intellectual property rights to recover their development expenditures. The economic value of biological diversity conserved by traditional farmers for agriculture is difficult to quantify and it has been suggested that "the value of farmers' varieties is not directly dependent on their current use in conventional breeding, since the gene flow from landraces to privately marketed cultivars of major crops is very modest" because "conventional breeding increasingly focuses on crosses among elite materials from the breeders own collections and advanced lines developed in public institutions." (Wright, 1998). On the other hand, those collections and advanced breeding lines are often derived from germplasm contributed by traditional groups.

An 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 utilizing camu camu (Peru, 2005). This notification was also communicated to the World Intellectual Property Organization (Peru, 2006).

In 2006 Brazil in a submission expressed its concern to the WIPO Standing Committee on Trademarks, Industrial Designs, and Geographical Indications about a number of patents and trademarks on its plants (Brazil, 2006). One of these was a patent on Açai (*Euterpe oleracea*) a fruit that had been traditionally used in Brazil as a food and medicine obtained by a US Corporation, Mary Kay Inc. The same corporation had obtained a US patent[9] concerning the processing of the Kakadu plum (*Terminalia ferdinandiana*), a traditional food and medicine source for Aboriginal Peoples in Northern Australia (Gorman, Griffiths, & Whitehead, 2006). On January 19, 2007 Mary Kay Inc. applied under the Patent Cooperation Treaty to extend this patent to more than 100 countries.[10] The patent application entered the national phase in Australia on 22 July 2008.

The Examination Report issued by IP Australia, stated reported its finding that the "Aborigines have been using the Kakadu plum extract for around 40,000 years

[9] US Patent 7175862.

[10] WO/2007/084998.

as a food source and a healing agent."[11] On 12 October 2011 the Australian application was withdrawn, although the granted patents, as well as patent applications remain on foot in a number of countries (Robinson, 2010).

The bioprospecting issue which has been raised in relation to this case concerns the source of the Kakadu plum used by Mary Kay, Inc. It has been pointed out that if it was obtained by a commercial supplier, there would have been no obligation to share benefits with Indigenous communities under local or international legislation (Holcombe & Janke, 2012 at 309–11).

Discussed below are measures and proposed measures for securing consent to access traditional knowledge and the associated biological resources identified as useful and measures to secure the equitable sharing of commercial benefits with farmers and traditional communities.

3.6 Convention on Biological Diversity (CBD)

Most of the biodiverse countries are located in tropical and sub-tropical areas and most of them, from an economic perspective are developing or least developed countries (LDCs). In other words, their biological wealth 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.

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 utilization of the world's biological resources. "The single most divisive issue in the negotiations was the relationship between intellectual property rights and access to genetic resources" (Chandler, 1993, 161), in particular the conditions for access and benefit sharing. Article 1 of the CBD envisages "appropriate access to genetic resources" and "the fair and equitable sharing of benefits arising out of the utilization of genetic resources". "Genetic resources" are defined in Art.2 as meaning "genetic material of actual or potential value". The term "genetic material" is then defined in Art.2 to mean "any material of plant, animal, microbiological or other origin containing functional units of heredity". Thus, the CBD applies to seeds and cuttings and DNA extracted from a plant, such as a chromosome, gene, plasmid or any part of these such as the promoter part of a gene (See Glowka, 1998, 4).

Article 9 deals with "the conservation of components of biological diversity outside their natural habitats", for example, in germplasm and seed banks, botanical gardens, museums, laboratories and agricultural research institutions. This article calls for national legislation to provide for the acquisition, conservation, storage and

[11] The Examination Report is available at http://pericles.ipaustralia.gov.au/ols/auspat/applicationDetails.do?applicationNo=2007205838, accessed 18 October 2019.

management of these *ex situ* collections. Article 15(3) provides that the access and benefit-sharing provisions of the CBD do not apply to the genetic resources of a country which were collected prior to the entry of the CBD into force in that country. Thus, a country with a pre-existing collection of genetic material has the sovereign right to control access to that collection, but has no legal right to insist upon a share of any benefits derived from the use of that collection (Yusuf, 1994).

Article 15(1) of the CBD affirms "the sovereign rights of States over their natural resources" and provides that "the authority to determine access to genetic resources rests with the national governments and is subject to national legislation". Article 15(4) of the CBD envisages that where access is granted it will be subject to mutually agreed terms. Article 15(7) requires each Contracting Party to "take legislative, administrative or policy measures, as appropriate" and in accordance with a number of specified provisions of the Convention, "with the aim of sharing in a fair and equitable way, the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources".

Complementary to the equitable sharing of benefits, the CBD provides for the access of developing country signatories to technologies which may result from the utilisation of the genetic resources which they may provide. Article 16(1) recites the importance of access to biotechnologies to attain the objectives of the CBD and Art 16(2) provides for the access to technologies by developing countries on "fair and equitable terms, including on concessional and preferential terms". Article.19(1) requires parties to take appropriate measures to "provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research". Article 19(2) requires parties to "take all practicable measures to promote and advance priority access on a fair and equitable basis,…,especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contacting Parties" on mutually agreed terms.

The Rio Declaration in Principle 22 stated that "Indigenous peoples and their communities...have a vital role in environmental management and development because of their knowledge and traditional practices". The Preamble to the CBD recognised the

> …close and traditional dependence of many Indigenous and local communities embodying traditional lifestyles on biological resources, and the desirability of sharing equitably arising from the use of traditional knowledge, innovations and practices relevant to the conservation of biological diversity and sustainable use of its components.

Article 8(j) of the Convention required each signatory

> …subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.

The provisions of Art.8(j) require implementation through national legislation. It is expressed to be subject to national legislation, in order to preserve legislation on this subject which predates the CBD.

The discussion, in the context of the CBD, of the intellectual property rights of traditional and local communities has not tended to focus upon the rights of traditional farming communities. This subject has been taken up as an aspect of the International Treaty on Plant Genetic Resources for Food and Agriculture, which is discussed below.

3.7 The Nagoya Protocol

The CBD did not set out how access and benefit-sharing (ABS), envisaged in Arts 15, 16, 19(2) and 8j 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.[12] The contribution of traditional peoples referred to in Art. 8j 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.[13] 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 utilization 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 7 provides that "in accordance with domestic law, each Party shall take measures, as appropriate" with the aim of ensuring that TK associated with genetic resources that is held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these indigenous and local communities, on the basis of mutually agreed terms. Article 12.1 of the Protocol requires Parties in implementing their obligations "in accordance with domestic law" take into consideration indigenous and local communities' customary laws, community protocols and procedures, as applicable, to TK associated with genetic resources. The Nagoya Protocol entered into force on 12 October 2014, 90 days after the deposit of the fiftieth instrument of ratification.

[12] '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).

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

In June 2015 the African Union adopted the *African Union Practical Guidelines for the Coordinated Implementation of the Nagoya Protocol in Africa* which provide" a practical step by step guidance for the implementation of the Protocol and for an ABS system at national and regional levels." An important feature of the Guidelines is their stress on the importance of identifying and involve all stakeholders, ranging from private and communal traditional knowledge holders and/or land owners who have legal rights to provide access to genetic resources, local researchers and business people involved in bio-prospecting either as intermediaries or end users, and various government authorities tasked with regulating specific habitats (e.g. protected areas) or sets of resources (e.g. marine resources) or legal aspects.

3.8 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, which entered into force on 29 June, 2004. Article 10.2 of the Treaty 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 Annex I and other contributions by resource holders (Art 11(2)). The collections of the CGIAR are expressly included in the Multilateral System (Art. 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 & Nnadozie, 2008, 115).

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 (ie 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 sets 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 Art. 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, Art. 6.10 requires that the recipient shall transfer the benefit-sharing obligations of the SMTA, set out in Art. 6.7 to that third party. Under Art. 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 includes the exchange of technical information, access to technology, capacity building and the sharing of monetary benefits from commercialisation.

3.9 Farmer's Rights Under the International Treaty on PGRFA.

The concept of Farmers' Rights was developed as "a counterbalance to intellectual property rights (FAO, 1994)." Farmers' rights were intended to promote a more equitable relation between the providers and users of germplasm by creating a basis for farmers to share in the benefits derived from the germplasm which they had

developed and conserved over time (see Glowka, 1998, 20). Under Art. 5.1(c) of the International Treaty the Contracting Parties agreed, subject to national legislation, to promote or support, as appropriate, farmers and local communities' efforts to manage and conserve on-farm their plant genetic resources for food and agriculture and in Art. 5.1(d) to promote *in situ* conservation of wild crop relatives and wild plants for food production, by supporting, *inter alia*, the efforts of indigenous and local communities.

Article 9.2 of the International Treaty envisaged that "the responsibility for realizing Farmers' Rights…rests with national governments" and that national legislation should include measures relating to:

(a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture;
(b) the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture;
(c) the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture.

An assumption of Art.9 was that the landraces used by traditional farmers are a dynamic genetic reservoir for the development of new varieties and for the transmission of desirable genetic traits. The traditional knowledge of local and indigenous communities which permits the identification of useful plants is similarly perceived. The diversity of landraces and the associated information on their specific qualities contribute invaluable information to formal breeding processes.

At the periodic meetings of the Governing Body of the International Treaty member states have differed on the way in which farmers' rights might be implemented. On the one hand the industrialised agricultural states such as Australia, Canada and the USA have argued that the implementation of farmers' tights is a matter for national legislation.[14] On the other hand, calls have been made by developing countries, such as the Africa group that the Governing Body of take measures to support the Contracting Parties technically and financially in:

(a) building farmers' capacity to participate in decision-making regarding their rights to save, use, exchange and sell farm-saved seed and propagating material;
(b) facilitating access to relevant information regarding the laws and policies pertaining to farmers' rights to save, use, exchange and sell farm-saved seed;
(c) ensuring effective participation of farmers in such decision-making;
(d) raising awareness among farmers, policy-makers and other relevant groups;
(e) establishing legal support for informal seed systems;
(f) mainstreaming Farmers' Rights to save, use, exchange and sell farm-saved seed in legal and policy frameworks;

[14] Eg Seventh session of the Governing Bodies held in Kigali, 30 October to 3 November 2017, International Treaty Doc., IT/GB-7/17/L12 Rev.1

(g) up-scaling and institutionalizing successful local activities aimed at strengthening informal seed systems, including NGO-led activities, to the national level;
(h) harmonizing seed regulation in the region to protect Farmers' Rights.[15]

In relation to the realization of measures to protect traditional knowledge the Governing Body was requested by the Africa Group to support the Contracting Parties in:

(a) establishing measures to recognize traditional knowledge and facilitate its use;
(b) establishing measures to ensure that traditional knowledge, as well as the systems that generate such knowledge, are respected and promoted;
(c) facilitating documentation of traditional knowledge;
(d) making use of media to ensure publicity for traditional knowledge;
(e) building capacity for documenting and using traditional knowledge;
(f) establishing measures for scaling up documentation and use of traditional knowledge;
(g) developing and implementing legal provisions on traditional knowledge;
(h) supporting on-farm conservation activities by farmers.[16]

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 patent regime pursuant to the TRIPS Agreement. Art. 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 and that such provisions could be incorporated into the TRIPS Agreement by amendment.[17]

3.10 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:

[15] Global Consultation Conference on Farmers' Rights held in Addis Ababa in November 2010, reproduced in IT/GB-4/11/Circ.1, Annex 1, para.11.

[16] Ibid., para 12.

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

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 (eg 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).

There is not yet a draft treaty text on the protection of genetic resources, but a "Consolidated Document Relating to Intellectual Property and Genetic Resources" (WIPO, IGC, 2019). The negotiations are very far from conclusion. There is not yet even an agreed preamble, nor agreed definitions of terms. 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.

The mandate of the IGC for 2020/2021 is to:

> …continue to expedite its work, with the objective of finalizing an agreement on an international legal instrument(s), without prejudging the nature of outcome(s), relating to intellectual property which will ensure the balanced and effective protection of genetic resources (GRs), traditional knowledge (TK) and traditional cultural expressions (TCEs).[18]

[18] https://www.wipo.int/export/sites/www/tk/en/igc/pdf/igc_mandate_2020-2021.pdf, accessed 22 October 2019.

3.11 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".[19]

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. 18). 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.

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[19] Section 6(1), Indian Biodiversity Act of 2002.

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