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SUI GENERIS PROTECTION FOR PLANT VARIETIES AND TRADITIONAL KNOWLEDGE IN BIODIVERSITY AND AGRICULTURE: THE INTERNATIONAL FRAMEWORK AND NATIONAL APPROACHES IN THE PHILIPPINES AND INDIA

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ABSTRACT

The so-called 'biotechnology clause' of Article 27.3(b) of the WTO-TRIPS Agreement requires from member states protection for plant varieties either via the patent system or via an 'effective sui generis system' or by a combination of the two. Many developing countries prefer forms of sui generis protection, which allow them to include exceptions and protection measures for traditional agricultural practices and the traditional knowledge of farmers and local communities. However, 'traditional knowledge' remains a vaguely defined term. Its extension to biodiversity has brought a diffusion of the previously clearer link between protected subject matter, intellectual property and potential beneficiaries. The Philippine legislation attempts a 'bottom-up' approach focusing on the holistic perceptions of indigenous communities, whereas national economic interests thus far receive priority in India's more centralist approach. Administrative decentralisation, recognition of customary rights, disclosure requirements, registers of landraces and geographical indications are discussed as additional measures, but their implementation is equally challenging. The article concludes that many of the concepts remain contested and that governments have to balance the new commercial incentives with the biodiversity considerations that led to their introduction, so that the system can be made sufficiently attractive for both knowledge holders and potential users of the knowledge.

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I

BACKGROUND

The legal protection of plant breeders in developed countries goes back to the 1920s and 1930s.¹ More recently, it has expanded dramatically with the various amendments of the UPOV Convention,² and also following the 'biotechnology revolution', which in turn led to a more liberal use of the principles of patent law for subject matter of a biological nature.³ However, while the debate has advanced rapidly in the industrialised world, it is still relatively new to developing countries, whose intellectual property systems are still focused on the more conventional and established forms of intellectual property rights such as trademarks and copyright. As in so many other fields of intellectual property, the WTO-TRIPS Agreement accelerated the process of introducing intellectual property rights for plant material to developing countries. The so-called 'biotechnology clause' of Article 27.3(b) allows WTO member states to exclude plants and animals and essentially biological processes for the production of plants or animals from patenting, but it requires the availability of patents for micro-organisms and non-biological and microbiological processes. In addition, it requires protection for plant varieties, which member states may provide either via the patent system or via an 'effective *sui generis*' system or by using a combination of the two systems.⁴

Because of its potential impact on food security, traditional farming methods and the livelihood of small-scale farmers in developing countries, the provision has been among the most controversial aspects of the TRIPS Agreement. As a consequence, a provision was made for a review of Article 27.3(b) four years after the WTO Agreement came into force. However, this review process, which should have taken place in 1999, has been marred by difficulties and even by disagreement over the meaning of the term 'review.' Some developing countries have brought forward far-reaching proposals to amend Article 27.3(b). The thrust of such proposals is to prohibit patenting of life forms and to strengthen the traditional rights of farmers to the use of saved seeds (farmers' rights), traditional knowledge about plants and farming methods and the preservation of biological

¹ See, e.g., the Plant Patent Act, 35 U.S.C. §§ 161-164 (1930).

² UPOV stands for the International Union for the Protection of New Varieties of Plants.

³ For details, see LIONEL BENTLY & BRAD SHERMAN, INTELLECTUAL PROPERTY LAW (2003).

⁴ For details, see Margaret Llewelyn, Which Rules in World Trade Law – Patents or Plant Variety Protection, in Intellectual Property: Trade, Competition and Sustainable Development 303-339 (Thomas Cottier & Petros C. Mavroidis eds., 2003).

diversity.⁵ Developed country members of the WTO, on the other hand, have argued that any review of Article 27.3(b) should only concern the implementation of the provision. For developed country members with advanced biotechnology industries such as the US, the aim is rather to eliminate the exclusion from patentability of plants and animals and to restrict the freedom for developing countries to develop their own *sui generis* systems for plant variety protection by relying as far as possible on the UPOV Convention in its 1991 version.

Possible elements of such *sui generis* protection systems and their relationship to forms of traditional knowledge are the subject of this article. In view of the concerns of developing countries regarding patents in this field, many countries so far show a preference for *sui generis* protection for plant varieties to the patenting option or a blending of the two systems.

The article will begin with an explanation and an update of the international framework of the debate and of the terminology used for various forms of traditional knowledge, which is essential for an understanding of the national efforts that are undertaken in this field. It will then analyse UPOV as the "ready-made" solution to implement plant variety protection and discuss alternative models and additional provisions that provide practical solutions. Finally, it will provide two case studies of national approaches, that of the Philippines and India. The examples show quite different policy approaches, a more decentralised approach focusing on indigenous peoples in the Philippines and a more centralised approach to the administration of farmers' rights and access to biodiversity in India. Some of these differences are less accentuated if one examines the actual implementation of the policies. In addition, with the recently released Protection, Conservation and Effective Management of Traditional Knowledge Relating to Biological Diversity Rules of 2009, India also attempts to move to more decentralised mechanisms for access to traditional knowledge and benefit sharing. The Philippine experience indicates, however, that too stringent conditions may scare off potential applicants and that for the system to operate successfully, it is important to find the right balance between the interests of knowledge holders and the expectations of users seeking access.

⁵ See United Nations Conference on Trade and Development (UNCTAD) & International Centre for Trade and Sustainable Development (ICTSD), Resource Book on TRIPS and Development 396-397 (2005) (submission to the WTO Council by the African Group of Countries in 2003).

II

THE INTERNATIONAL FRAMEWORK FOR TRADITIONAL KNOWLEDGE, ACCESS TO GENETIC RESOURCES AND PLANT VARIETY PROTECTION

While the use of intellectual property law related to life forms expanded, particularly in industrially advanced countries, there has been a tightening of access to the biological resources necessary for biotechnological research in the most bio diverse countries of the world, which are predominantly developing countries. Thus, while the non-binding International Undertaking on Plant Genetic Resources of 1984 still regarded plant genetic resources as "heritage of mankind" and as freely accessible and exchangeable, the 1992 Convention on Biological Diversity (CBD) gave nation states "the sovereign right to exploit their own resources pursuant to their own environmental policies" (Article 3, CBD) and provided that "the authority to determine access to genetic resources rests with the national governments and is subject to national legislation" (Article 15(1), CBD). The CBD discourages neither biotechnological research (Article 19, CBD) nor intellectual property rights (Article 16(2), CBD). However, intellectual property rights should be "supportive of and not run counter to" the objectives of the CBD (Article 16(5)). Resource-rich parties are required to "endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses" (Article 15(2), CBD), while technologically advanced users shall provide access to and transfer of technology relevant for or resulting from the sustainable use of genetic resources (Article 16, CBD) as well as participation in relevant research projects (Article 15(6), CBD). Access to such resources shall be on "mutually agreed terms" (Article 15(4), CBD) and with "prior informed consent" (Article 15(5), CBD) and shall lead to fair and equitable sharing of "the results of research and development and the benefits arising from the commercial and other utilization of genetic resources" (Article 15(6), CBD). Importantly, while the International Undertaking on Plant Genetic Resources and the subsequent Plant Genetic Resources Treaty are confined to plants for food and agriculture, the CBD extends also to plants for medicinal and pharmaceutical purposes. Indeed, desire by providing countries of genetic

⁶ Michael Blakeney, Intellectual Property Aspects of Traditional Agricultural Knowledge, in IP IN BIODIVERSITY AND AGRICULTURE 44 (Peter Drahos & Michael Blakeney eds., 2001); Carlos Correa, Access to Plant Genetic Resources and Intellectual Property Rights, in IP IN BIODIVERSITY AND AGRICULTURE 105 (Peter Drahos & Michael Blakeney eds., 2001).

⁷ The shift in the CBD was preceded by similar resolutions at the FAO conferences in 1989 and 1991 that added Annexes to the International Undertaking on Plant Genetic Resources. See Gregory Rose, International Law of Sustainable Agriculture in the 21st Century: Resources for Food and Agriculture, 15 GEO. INT'L ENVTL. L. REV. 583, 602 (2003).

resources to share in the profits made from pharmaceutical research was a substantial reason for the negotiation of Article 15.8

While the parties to the convention are of course nation states, the CBD foresees an important role for indigenous and local communities. According to Article 8(j) of the CBD, each party, subject to its national legislation, is required to "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." In other words, parties to the Convention are required to pass on the benefits of the Convention and to replicate benefit-sharing mechanisms at the local level.

The shift to national sovereignty over biological resources has been further reaffirmed in the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), negotiated under the auspices of the United Nations Food and Agriculture Organization (FAO). In creating a multilateral system of access and benefit sharing, the parties "recognize the sovereign rights of States over their own plant genetic resources for food and agriculture, including that the authority to determine access to those resources rests with national governments and is subject to national legislation" (Article 10, ITPGRFA). However, in contrast to the CBD, the ITPGRFA relates only to plant genetic resources for food and agriculture and the multilateral system covers essential food crops listed in Annex I of the Treaty. The Treaty promotes a standard material transfer agreement (MTA) with certain mandatory provisions,9 including the limitation of access to food and agriculture related purposes of utilisation and conservation for research, breeding and training (Article 12.3(a), ITPGRFA), a prohibition for the recipients to claim intellectual property rights or other rights limiting facilitated access (Article 12.3(d), ITPGRFA), the continuous process of making available conserved resources by the recipients (Article 12.3(g), ITPGRFA) and the payment of an equitable share of the benefits arising from the commercialisation of products incorporating accessed materials to a Trust Account established by the Governing Body of the Treaty (Article 13.2(d)(ii), ITPGRFA). The last mentioned article also provides that the Governing

⁸ Id. at 607.

⁹ The predecessors of these MTAs are to be found in the agreements between the FAO and the International Agricultural Research Centres (IARCs) within the Consultative Group on International Agricultural Research (CGIAR). See supra note 7, at 595.

Body may decide to establish different levels of payment for various categories of recipients and may decide to exempt small farmers from developing countries or countries with economies in transition from such payments.

In contrast to the bilateral mechanisms thus far available under the CBD, the access and benefit sharing mechanism promoted by the ITPGRFA is a multilateral system. Since payments to the envisaged trust fund are not mandatory for material "available without restriction", payments are mandatory mainly for plant patent holders, but not necessarily for holders of plant breeders' rights. ¹⁰ Under the circumstances and given the absence of the main patenting nations US and Japan from the ITPGRFA¹¹, the available funds under the system will remain very small and are unlikely to even cover the administrative costs of the treaty. ¹² And while the ITPGRFA still covers in its Annex approximately 80-90 per cent of the most vital crops, a number of vital crops were not included, because specific developing countries were not willing to add them to the list. ¹³

Similar to the CBD and the earlier International Undertaking on Plant Genetic Resources, the ITPGRFA recognises the traditional knowledge of local and indigenous communities and of farmers in Article 9 on 'Farmers' Rights.' In particular, it encourages national governments to realise farmers' rights by protecting and promoting traditional knowledge relevant to plant genetic resources for food and agriculture, the right to equitably participate in sharing benefits from the utilisation of plant genetic resources and the right to participate in decision making at the national level on the conservation and sustainable use of food and agriculture related plant genetic resources (Article 9.2, ITPGRFA). However, the treaty language is couched in the most qualified terms. Parties have to protect and promote farmers' rights "in accordance with their needs and priorities" and "as appropriate, and subject to national legislation." Article 9.3 of the treaty reserves the traditional farmers' privilege to "save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate."

¹⁰ See Charles R. McManis & Eul Soo Seo, The Interface of Open Source and Proprietary Agricultural Innovation: Facilitated Access and Benefit-Sharing under the New FAO Treaty, 30 WASH. U. J.L. & POL'Y 405, 452-453 (2009) (it is argued that UPOV-compliant plant variety protection as well as intellectual property rights with sufficiently broad 'experimental use' privileges will not 'limit facilitated access' under Article 12.3(d)).

¹¹ The United States signed the treaty in 2002, but did not move further to accession, approval, acceptance and ratification. *See* List of Contracting Parties, http://www.fao.org/Legal/treaties/033s-e.htm (last visited 6th July 2010).

¹² See supra note 10, at 460 (quoting a calculation by the NGO Berne Declaration that on the basis of an estimated seed market of \$30 billion in 2019, income from benefit-sharing will be as little as \$2.31 million per year.

¹³As for example with the inclusion of soybeans that was objected to by China. For this aspect of the debate and for further examples, *see supra* note 7, at 616. See also supra note 10, at 460 (provides further examples).

Of the various provisions of the treaty, the obligation not to claim "intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System" has been controversial. While the provision has been interpreted as not covering intellectual property rights to germplasm modified by the recipient, ¹⁴ the provision is regarded as one of the reasons for the absence from the treaty of both the US and Japan, the two main countries active in the patenting of life forms.

Since the Johannesburg World Summit on Sustainable Development in 2002, an international regime for access and benefit sharing is further being negotiated in the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing of the Convention on Biological Diversity. The latest meeting of the Working Group in Cali, Colombia, in March 2010 produced a revised Draft Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization. The Working Group hopes to finalise negotiations on the Draft Protocol in time for the next Conference of the Parties of the CBD in Nagoya, Japan, in October 2010. ¹⁵

Ш

THE RELATIONSHIP BETWEEN PROTECTED SUBJECT MATTER, TRADITIONAL KNOWLEDGE, INTELLECTUAL PROPERTY RIGHTS AND THE BENEFICIARIES OF ANY FORM OF PROTECTION

The term "traditional knowledge" is used in the international debate in various forms, with often widely diverging coverage of subject material, different elements of the intellectual property system and with different stakeholders and beneficiaries, the interests of whom do not always coincide. It is, therefore, necessary at the outset to gain some understanding of the meaning of the term for the purposes of this article. A widely used first working definition stemmed from a WIPO study of

¹⁴ Michael Blakeney, *Bioprospecting and Biopiracy*, *in* INTELLECTUAL PROPERTY AND BIOLOGICAL RESOURCES 393, 417 (Burton Ong ed., 2004). The interpretation hinges on the term 'in the form received' which was one of the most contentious issues during the treaty negotiations, *see supra* note 10, at 453.

¹⁵ Conference of the Parties to the CBD, Ad Hoc Open-ended Working Group on Access and Benefit-Sharing, Report of the First Part of the Ninth Meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing, U.N. Doc. UNEP/CBD/WG-ABS/9/3 (Apr. 26, 2010), available at http://www.cbd.int/doc/meetings/abs/abswg-09/official/abswg-09-03-en.pdf.

¹⁶ Whether at least 'broad, non-exhaustive and non-exclusive definitions' are necessary or whether a more loosely worded terminology is sufficient remains contested. As for traditional cultural expressions, see Christoph Antons, What is 'Traditional Cultural Expression?' – International Definitions and their Application in Developing Asia, 1 WIPO J. 103, 104 (2009) (the statements of the representatives of New Zealand and Singapore, on the one hand, and of Nigeria, on the other hand).

2001¹⁷ on the needs and expectations of traditional knowledge holders, which in turn was based on fact-finding missions to various parts of the world undertaken in 1998 and 1999. 'Traditional knowledge' according to this working definition comprised "tradition-based literary, artistic or scientific works; performances; inventions; scientific discoveries; designs; marks, names and symbols; undisclosed information; and all other tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields." This working definition was clearly influenced by a more holistic understanding of traditional knowledge as encompassing forms of art as well as knowledge about the healing effects of plants and about the environment. This understanding is particularly common among many indigenous societies, which are not using elaborate writing systems to transmit their knowledge. Here, art forms such as songs, stories, dances and paintings are frequently used to collectively memorise the knowledge and to transmit it to following generations. As a result, cultural expressions and objects and their included traditional knowledge acquire a secret and sacred status in some indigenous societies¹⁸ that makes it difficult to distinguish between artistic expressions and scientifically relevant knowledge in the way that intellectual property lawyers are familiar with.¹⁹

That the character of the holders of the knowledge and the culture and forms of life of the community are important in defining traditional knowledge follows from a further clarification from the WIPO report. Accordingly, "tradition-based refers to knowledge systems, creations, innovations and cultural expressions which: have generally been transmitted from generation to generation; are generally regarded as pertaining to a particular people or its territory; and are constantly evolving in response to a changing environment." Since the knowledge pertains to a particular people or its territory, there is, therefore, a crucial link between the knowledge and its particular holder(s) that is very different from the neutral forms of ownership in other areas of

¹⁷ World Intellectual Prop. Org. [WIPO], Intellectual Property Needs and Expectations of Traditional Knowledge Holders: WIPO Report on Fact-finding Missions on Intellectual Property and Traditional Knowledge (1998-1999) (April 2001), available at http://www.wipo.int/tk/en/tk/ffm/report/index.html (follow links 'Part 1' + 'Part 2' + 'Annex').

¹⁸ Jurg Wassmann, *The Politics of Religious Secrecy, in* EMPLACED MYTH: SPACE, NARRATIVE AND KNOWLEDGE IN ABORIGINAL AUSTRALIA AND PAPUA NEW GUINEA (Alan Rumsey & James F. Weiner eds., 2001); Eric Kline Silverman, *From Totemic Space to Cyberspace: Transformations in Sepik River and Aboriginal Australian Myth, Knowledge, and Art, in* EMPLACED MYTH: SPACE, NARRATIVE AND KNOWLEDGE IN ABORIGINAL AUSTRALIA AND PAPUA NEW GUINEA (Alan Rumsey & James F. Weiner eds., 2001).

¹⁹ Darell A. Posey, Can Cultural Rights Protect Traditional Cultural Knowledge and Biodiversity?, in CULTURAL RIGHTS AND WRONGS 43 (Halina Niec ed., 1998); Christoph Antons, Traditional Cultural Expressions and Their Significance for Development in a Digital Environment: Examples from Australia and Southeast Asia, in INTELLECTUAL PROPERTY AND TRADITIONAL CULTURAL EXPRESSIONS IN A DIGITAL ENVIRONMENT 288 (Christoph Beat Graber & Mira Burri-Nenova eds., 2008); Christoph Antons, Traditional Knowledge in Asia: Global Agendas and Local Subjects, in REGULATION IN ASIA: PUSHING BACK ON GLOBALIZATION 66 (John Gillespie & Randall Peerenboom eds., 2009).

intellectual property law. Identifying the holders of traditional knowledge becomes not just a practical necessity for the purposes of obtaining consent and for implementing forms of benefit sharing, but it also defines the "traditional" character of the subject matter. In other words, whether a certain form of knowledge is regarded as "traditional" will depend on the lifestyle, customary laws and forms of transmission used by its "owner" or "holder."²⁰

Prior to any discussion about traditional knowledge in the context of biological diversity, farming practices and knowledge about the environment, the area of concern was largely "folklore", i.e., the protection of traditional forms of art and cultural expressions. This discussion goes back to the 1960s, when developing countries began to realise that their folkloristic material, in particular in the form of music, was being popularised and commercially exploited by companies from the industrialised world.²¹ At the time, the discussion produced WIPO and UNESCO-sponsored model provisions for the protection of folklore and the Tunis Model Law for the Protection of Folklore of 1976. The first extension of the concept of traditional knowledge came with the emergence of the concept of farmers' rights in FAO Resolution 4/89. They were further defined in FAO Resolution 5/89 as "Rights arising from the past, present and future contribution of farmers in conserving, improving and making available Plant Genetic Resources, particularly those in the centres of origin/diversity. These rights are vested in the International Community, as trustees for present and future generations of farmers, for the purpose of ensuring full benefits of farmers and supporting the continuation of their contributions...". 22 With the arrival of the Convention on Biological Diversity, the concept of traditional knowledge was again further extended to include the "knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity."²³

The CBD promoted the now widely required forms of benefit-sharing and prior informed consent as ethically important pre-conditions for the use of traditional knowledge. Of equal importance was, however, the fact that the Convention broadened the perspective from folklore to traditional knowledge and its impact on biodiversity and the environment. As far as plant material was concerned, the focus was now no longer only on agricultural foodstuff and the relatively settled

²⁰ See also WIPO, INTELLECTUAL PROPERTY AND TRADITIONAL KNOWLEDGE (FREE INFORMATION PRODUCT – BOOKLET No. 2), available at http://www.wipo.int/freepublications/en/tk/920/wipo pub 920.pdf.

²¹ Michael Halewood, Indigenous and Local Knowledge in International Law: A Preface to Sui Generis Intellectual Property Protection, 44 MCGILL L.J. 953, 967-968 (1999).

²² See Carlos Correa, Options for the Implementation of Farmers' Rights at the National Level 4 (S. Ctr., T.R.A.D.E. Working Paper No. 8, 2000).

²³ Convention on Biological Diversity art. 8(j), June 5, 1992, 1760 U.N.T.S. 79.

communities of traditional farmers and plant breeders. Biodiversity meant broadening the focus of the protected subject matter to plants related to, for example, forestry or pharmaceutical use²⁴ and to the people involved in their conservation and development, often forest dwellers and nomadic people, in many countries termed 'indigenous' because of their longer relationship with the land in comparison to a mainstream population that had arrived in later waves of migration.

However, while such knowledge may be held by people identifiable as indigenous, this is by no means a necessity. Just as folkloristic material may be provided by indigenous communities as well as by local non-indigenous communities inhabiting particular parts of a country, traditional knowledge about plants or the environment can now be held by indigenous people or by traditional healers or by farmers using traditional methods of farming particularly well suited to the local environment. Plants used in traditional medicines, for example, are sourced from forests as well as from private herbal gardens and, with increasing commercialisation of such medicines, also from commercial farms.²⁵ Anthropologists have further pointed out that the previous distinction between lowland farmers and forest conserving tribal people in the uplands in countries such as Thailand can no longer been maintained. While farmers have long begun to supplement their income with additional swidden agriculture in areas formerly regarded as tribal domains, tribal people have equally become agricultural labourers on farms outside of their tribal territories.²⁶ Thus, with the widening of the scope of potential holders of traditional knowledge, the focus has to some extent moved away from locally confined living communities (which to some degree has always been a legal fiction as people, including 'indigenous' people, are of course mobile) to the nation state. Traditional knowledge about farming or healing (arguably both forms of 'sustainable use') may well be held throughout a particular country and may be incorporated into national culture. Examples include Chinese traditional medicine, Indian ayurvedic medicine or Thai traditional medicine.

Thus, the extension of traditional knowledge to biodiversity in the CBD has brought a diffusion of the previously clearer (although by no means easily to establish) link between protected subject matter, intellectual property involved and the potential beneficiaries. Protectable subject matter

²⁴ Supra note 10. As McManis and Seo point out, approximately half of the world's medicines are estimated to contain compounds of plant origin.

²⁵ Christoph Antons & Rosy Antons-Sutanto, *Traditional Medicine and Intellectual Property Rights: A Case Study of the Indonesian Jamu Industry, in* Traditional Knowledge, Traditional Cultural Expressions and Intellectual Property Law in the Asia-Pacific Region 363, 365 & 369 (Christoph Antons ed., 2009).

²⁶ Tim Forsyth & Andrew Walker, Forest Guardians, Forest Destroyers: The Politics of Environmental Knowledge in Northern Thailand 60-63 & 222 (2008).

comes in the form of knowledge and innovations relevant for the conservation and sustainable use of biological diversity. As outlined previously, this may be anything from the knowledge of forest dwellers or farmers about their environment or healing plants or local breeding conditions to nation-wide practised forms of traditional medicine using herbs and plants. The identification of potential right holders and beneficiaries has become equally difficult with their being defined now as "indigenous and local communities embodying traditional lifestyles." Finally, the focus on indigenous communities that often have no written tradition of transmitting their knowledge, has also meant that the previously clearer distinction between subject matter related to copyright (folklore) and other forms of traditional knowledge (agricultural plants and biodiversity) has become problematic in some countries. The use of artistic expressions for the transmission of knowledge by many of these people means that traditional knowledge from this perspective can now concern almost any form of intellectual property.

Folklore and farmers' rights have been widely accepted as concepts, although attempts at implementation have been uneven and often half-hearted and terms such as 'folk' art have occasionally been criticised as prejudicial, patronizing and outmoded.²⁷ However, the further extended form of traditional knowledge leading to some form of "intellectual property in biodiversity" is for many parties even more difficult to accept or to put into practice. It requires first of all the recognition that even plants grown in the wild are not really wild but have been modified by human impact, for example, through the deliberate use of fire for cultivation and regeneration purposes in rainforest areas and through slash and burn agricultural practices by indigenous and nomadic or semi-nomadic people. In other words, it requires a rehabilitation of the knowledge and practices of such forest dwellers, which thus far has been often blamed in official discourses for the destruction of forests.²⁸ It requires, secondly, the recognition of indigenous and local communities by the national government as groups that are able to hold rights separate from the mainstream population.

These requirements put many governments in developing countries into a difficult position. On the one hand, they appreciate the potential value of traditional knowledge, which can be used as a bargaining tool in negotiations with the industrialised countries. On the other hand, young nation states regard the promotion of a national identity as important. In countries that are still struggling

²⁷ Nelson H. H. Graburn, Arts of the Fourth World, in THE ANTHROPOLOGY OF ART: A READER 412, 413-414 (Howard Morphy & Morgan Perkins eds., 2006).

²⁸ For the historical background of such policies, see Nancy Lee Peluso & Peter Vandergeest, Genealogies of the Political Forest and Customary Rights in Indonesia, Malaysia and Thailand, 60 J. ASIAN STUD. 761 (2001).

to overcome thinking in tribal or community terms and focus instead on considerations at a national level, it is difficult to recognise the preferential interests of local or indigenous communities that the CBD requires. What's more, many national governments in fact blame 'backward' looking communities for the destruction of the rainforest and of biodiversity through slash and burn practices and shifting agriculture.²⁹ The difficulties in adopting an unequivocal position on traditional knowledge under these circumstances become visible from the examples in Asia presented at the end of this study. They are also becoming visible from the deliberations at WIPO regarding the creation of a voluntary fund to enable accredited and indigenous communities to participate in the debate of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. The governments of India and Indonesia in particular expressed concern about the use of the terms 'indigenous and local communities' and the exclusion of civil society at large that this implied. The Indonesian delegation expressed a preference for terms such as 'traditional society' or 'society or community bound by customary law.'30 Equally, while voting in favour of the UN Declaration on the Rights of Indigenous Peoples in 2007, the Indonesian representative proceeded on the basis of ILO Convention No. 107 of 1957 "according to which indigenous people were distinct from tribal people" and concluded that "the rights in the declaration accorded exclusively to indigenous people and did not apply in the context of Indonesia."31

Perhaps recognising the difficulties in adopting a too extended definition, WIPO has in recent years moved back to an approach that distinguishes folklore/cultural expressions and what is now termed "traditional knowledge in the strict sense." In more recent publications, WIPO still acknowledges the holistic understanding and interrelationship between folklore and traditional knowledge (TK), but it maintains that the protection of traditional cultural expressions (TCEs)/folklore "is in practice distinct from but related to" the protection of TK. It was, therefore, necessary, to produce a second publication focusing on "the complementary protection of TCEs"

²⁹ For a critical assessment of such government positions, see CIVILIZING THE MARGINS: SOUTHEAST ASIAN GOVERNMENT POLICIES FOR THE DEVELOPMENT OF MINORITIES (Christopher R. Duncan ed., 2004).

³⁰ WIPO Secretariat, Second Draft Report on Eighth Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, 26-27, WIPO/GRTKF/IC/8/15 Prov 2 (Oct. 5, 2005), available at http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_8/wipo_grtkf_ic_8_15_prov_2.pdf (for the Indian position, see 30, 40 & 48).

³¹ See Press Release, U.N. General Assembly, General Assembly Adopts Declaration on Rights of Indigenous Peoples; 'Major Step Forward' Towards Human Rights for All, Says President (Sept. 13, 2007), available at http://www.un.org/News/Press/docs/2007/ga10612.doc.htm (statement of the Indonesian representative in the United Nations General Assembly).

whereas the TK publication was to focus "on the protection of TK as such – that is to say, the content or substance of knowledge."³²

As a consequence, WIPO has produced separate draft model provisions for TCEs/folklore and for TK. In a reproduction of its document 'The Protection of Traditional Knowledge: Revised Objectives and Principles', WIPO defines the scope of the subject matter in Article 3(2) differently and in a manner that takes into account criticisms of earlier working definitions. Accordingly, traditional knowledge comprises:

The content or substance of knowledge resulting from intellectual activity in a traditional context, and includes the know-how, skills, innovations, practices and learning that form part of traditional knowledge systems, and knowledge embodying traditional lifestyles of indigenous and local communities, or contained in codified knowledge systems passed between generations. It is not limited to any technical field, and may include agricultural, environmental and medicinal knowledge, and knowledge associated with genetic resources.³³

While some countries have adopted the holistic approach expressed in the earlier WIPO working definition,³⁴ this article is predominantly concerned with the relationship between *sui generis* protection for plant varieties and traditional knowledge protection and therefore does not cover cultural expressions. The remaining forms of traditional knowledge protection and access legislation related to plant varieties are more difficult to separate, however, and only a few of the aims for various benefit-sharing mechanisms and encouragement of biodiversity protection can be realised via *sui generis* legislation for plant varieties. The following part of this article will begin by explaining the concept of farmers' rights. Agriculture is an area of traditional knowledge protection in which the identification of the traditional knowledge holders (and their reward or compensation) has been regarded as comparatively easier than in some of the other areas. In most developing countries, traditional knowledge holders are seen as largely identical with local farmers (indigenous or non-indigenous), as long as they are still practising some form of traditional

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³² Supra note 20.

³³ WIPO Secretariat, Reproduction of Document WIPO/GRTKF/IC/9/5 "The Protection of Traditional Knowledge: Revised Objectives and Principles", WIPO/GRTKF/IC/12/5(c) (Dec. 6, 2007), available at http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_12/wipo_grtkf_ic_12_5_c.pdf.

³⁴ See, e.g., in the Philippines, An Act to Recognize, Protect and Promote the Rights of Indigenous Cultural Communities/Indigenous People, Creating a National Commission of Indigenous People, Establishing Implementing Mechanisms, Appropriating Funds Therefore, and for Other Purposes, Rep. Act 8371 (1997) (Phil.); see also Rule 2 (v) of the Protection, Conservation and Effective Management of Traditional Knowledge Relating to Biological Diversity Rules, 2009 (rules drafted by the National Biodiversity Authority of India; the definition of 'traditional knowledge' includes in the concept a list of cultural expressions).

farming.³⁵ The matter may become more controversial again, however, where it concerns forms of swidden agriculture. As was explained above, governments tend to regard such forms of agriculture as harmful to the environment.

IV

THE CONCEPT OF FARMERS' RIGHTS

It has often been said that the concept of Farmers' Rights is based on equity considerations to compensate traditional farmers for their past contributions in improving and making available Plant Genetic Resources for Food and Agriculture (PGRFA). While the concept had already been introduced in FAO discussions in the early 1980s and is now well established, the debate has recently turned to the question of how to best implement farmers' rights. Here, a market based solution, that is treating Traditional Plant Genetic Resources for Food and Agriculture (TPGRFA) as private goods is often contrasted with a compensation solution, in which TPGRFA remain in the public domain, but the nation states where they occur are empowered to negotiate compensation for their traditional farming sectors. Because of the difficulties in assessing the value of landraces and other forms of TPGRFA, the focus in this field has been on compensation approaches based on equity considerations, so that the use of 'rights' in this context has been largely symbolic. This means also that the paradigm shift from 'heritage of mankind' to proprietary concepts has been incomplete. While resources are now under national control, this control has not yet been further devolved to local communities, cooperatives or individuals. Further, the Multilateral System of the ITPGRFA, designed to counter the emerging proprietary concepts in this field, has been described as "a hybrid approach to agricultural innovation, combining open source and proprietary elements."36

V

ESSENTIAL AND FACULTATIVE ELEMENTS OF A *SUI GENERIS* SYSTEM FOR PLANT VARIETIES

As the WTO-TRIPS Agreement does not make reference to the UPOV Convention, the UPOV Acts of both 1978 and 1991 are suitable models for a national *sui generis* system. However, if a country wants to join UPOV as such, it must adopt the 1991 version, as the deadline for UPOV

³⁵ See, e.g., Daniel Alker & Franz Heidhues, Farmers' Rights and Intellectual Property Rights – Reconciling Conflicting Concepts 14-15 (Inst. of Agric. Econ. and Soc. Sci. in the Tropics and Subtropics, Discussion Paper No. 2/2002, 2002), available at https://entwicklungspolitik.uni-hohenheim.de/uploads/media/DP_02_2002_Alker.pdf.

³⁶ Supra note 10, at 456.

members to join the 1978 Act was 24 April 1999.³⁷ Whether a country wants to join UPOV or adopt any of its Acts ultimately depends on its capacity and national ambition in the field of plant breeding. Both Acts promote commercial plant breeding. Because of the protection criteria of distinctness, uniformity and stability (commonly referred to as the DUS criteria) they have been criticised for furthering the genetic uniformity of crops and, thereby, being ultimately harmful to biodiversity. Both Acts are adequate for a country that has ambitions and realistic hopes for its plant breeding industry in the near future. The more ambitious and better positioned countries may want to join UPOV directly and thus have to adopt the 1991 version of the Act. The 1991 version extends the rights of breeders in comparison to the 1978 version. The acts which require authorisation under UPOV 1991 include according to Article 14: production or reproduction, conditioning for the purposes of propagation, offering for sale, selling or other marketing, exporting, importing and stocking for the aforementioned purposes. This compares to the still relatively simple list of rights in Article 5 of UPOV 1978, which is to authorise the production for purposes of commercial marketing, the offering for sale and the marketing of the reproductive or vegetative propagating material, as such, of the variety.³⁸

More importantly, under UPOV 1991, the rights of the breeder also extend to the harvested material obtained through the use of propagating material and of "essentially derived" varieties. This means, first of all, that the so-called 'farmers' privilege' of re-using harvested seed from protected varieties no longer applies automatically, but it must now be specifically implemented by a government concerned about traditional farming practices. It is, therefore, now regulated as an exemption to breeders' rights in Article 15 of the 1991 version. Secondly, commentators from developing countries³⁹ have expressed concern about the vague criterion of the "essentially derived variety", which they expect to be settled more often than not through agreement or litigation rather than examination, thereby favouring the stronger party. Even among those countries with ambitions to establish a commercial plant breeding sector, the choice between the two UPOV versions is, therefore, one of graduation and levelling out of the advantages and disadvantages. Countries with strong prospects for a commercial plant breeding sector may opt for direct

³⁷ TSHIMANGA KONGOLO, UNSETTLED INTERNATIONAL INTELLECTUAL PROPERTY ISSUES 64 (2008).

³⁸ For a comparison of the 1978 and 1991 versions of UPOV, see Graham Dutfield, Intellectual Property Rights, Trade and Biodiversity 26-29 (2000).

³⁹ See Biswajit Dhar & Sachin Chaturvedi, Introducing Plant Breeders' Rights in India – A Critical Evaluation of the Proposed Legislation, 1 J. WORLD INTELL. PROP. 245 (2005).

⁴⁰ Supra note 10, at 424. McManis and Seo argue that the requirement that an essentially derived variety must be 'predominantly derived' from a protected variety and the examples of how an essentially derived variety can be obtained makes the scope of protection narrower than the one that copyright provides for 'derivative works.'

accession to UPOV and adoption of the 1991 version.⁴¹ The majority of the developing countries in Asia will probably be fairly advanced in classical scientific breeding with a strong involvement of the public sector. Adoption of one of the UPOV versions seems a possibility here, perhaps in some cases modified along the lines of the various options outlined below.

For countries below that threshold, especially those with a mainly traditional farming sector and without any immediate prospects for a successful commercial plant breeding sector, modifications to the UPOV framework may be advisable. Leskien and Flitner have summarised options for such modifications in a report for the International Plant Genetic Resource Institute (IPGRI) of 1997.⁴² First, countries may define the subject matter of protection more widely in their own interest. A wider definition of 'plant varieties', for example, would create space for the recognition of 'traditional' or 'local varieties', which are not as uniform as varieties under the UPOV definition and could be distinguished from these commercial varieties. Moreover, there is nothing in the TRIPS Agreement preventing countries from extending the protection of a sui generis legislation to traditional knowledge and farmers' rights. 43 Second, TRIPS allows for variation of the so-called DUS requirements of UPOV (referring to the necessity for protection that a plant variety must be distinct, uniform and stable). While distinctness is a requirement also under TRIPS, the wording used should make it plain that more than merely 'cosmetic breeding' is required. But apart from distinctness, TRIPS merely requires that the variety is sufficiently identifiable to allow for registration and protection, so there is some scope for a re-interpretation of the uniformity and stability requirements or for the setting up of 'second registers' for traditional and landraces.⁴⁴ Third, the sui generis legislation may link the granting of rights to proof of prior informed consent by the providers of germplasm. 45 In 2003, such a disclosure requirement was proposed by a group of developing countries in the Council for TRIPS as an amendment of the TRIPS Agreement to

⁴¹ For an excellent summary of the pros and cons of adopting the different options for *sui generis* protection, *see* International Plant Genetic Resources Institute (IPGRI), Key Questions for Decision-Makers: Protection of Plant Varieties under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (1999), *available at*

 $http://www.bioversityinternational.org/fileadmin/bioversity/publications/pdfs/41_Key\%20 questions\%20 for \%20 decision-makers.pdf.$

⁴² Dan Leskien & Michael Flitner, Intellectual Property Rights and Plant Genetic Resources: Options for a Sui Generic System (IPGRI, Issues in Genetic Resources No. 6, 1997), available at

http://www.bioversityinternational.org/fileadmin/bioversity/publications/pdfs/497.pdf.

⁴³ *Id.* at 48-49.

⁴⁴ Supra note 42, at 53-54.

⁴⁵ Supra note 42, at 56.

harmonise the requirements under TRIPS with those under the CBD.⁴⁶ The proposal is since strongly debated in the various forums concerned with traditional knowledge. Industrialised countries have either opposed the proposal or adopted disclosure requirements that leave the remedies for failure to comply outside of the patent system and do not lead to revocation of patents.⁴⁷ Fourth, the scope of *sui generis* protection may range from rights via the 1991 and 1978 UPOV models to the use of PVP seals, depending on the needs and prospects for commercial plant breeding in a particular country.⁴⁸ Fifth, any *sui generis* legislation may be further supported by measures such as the establishment of community gene funds, registers and databases for forms of traditional knowledge and the creation of an office of public defender to mediate and intervene in conflicts between communities and national governments or between states and multinational corporations.⁴⁹ With a view to some of these options outside of UPOV, analysts have critically noted, however, that they will have to be assessed against the TRIPS requirement of Article 27.3(b) that an 'effective' *sui generis* system must be provided.⁵⁰

VI

OTHER SUPPLEMENTARY MECHANISMS FOR THE PROTECTION OF TRADITIONAL KNOWLEDGE

There are other supplementary mechanisms to protect forms of traditional knowledge related to plant varieties and biodiversity that cannot be discussed in detail within the limited scope of this article. Some of these will be referred to again in the context of the case studies from Asia below. For example, geographical indications may be employed to bring about protection of traditional knowledge via symbols akin to trade marks, where other more direct measures of traditional

⁴⁶ Supra note 5, at 398. For a more detailed discussion, see DISCLOSURE REQUIREMENTS: ENSURING MUTUAL SUPPORTIVENESS BETWEEN THE WTO TRIPS AGREEMENT AND THE CBD (Martha Chouchena-Rojas et al. eds., 2005). For a view opposing such disclosure requirements, see Jon P. Santamauro, Reducing the Rhetoric: Reconsidering the Relationship of the TRIPS Agreement, CBD and Proposed New Patent Disclosure Requirements Relating to Genetic Resources and Traditional Knowledge, 29 EUR. INTELL. PROP. REV. 91 (2007).

⁴⁷ Brendan Tobin, *The Role of Customary Law and Practice in the Protection of Traditional Knowledge Related to Biological Diversity, in* Traditional Knowledge, Traditional Cultural Expressions and Intellectual Property Law in the Asia-Pacific Region 127, 140 (Christoph Antons ed., 2009).

⁴⁸ Supra note 42, at 58-62.

⁴⁹ Supra note 42, at 64-65.

⁵⁰ Supra note 10, at 435; see also supra note 4, at 308 (Llewelyn nevertheless sees "scope for both imaginative interpretation and application."); see also Prabash Ranjan, Recent Developments in India's Plant Variety Protection, Seed Regulation and Linkages with UPOV's Proposed Membership, 12 J. WORLD INTELL. PROP. 219, 222-223 (2009) (suggesting that what is 'effective' should not be judged exclusively from the perspective of plant breeders, but also from the perspective of farmers).

knowledge protection fail.⁵¹ Furthermore, there is the discussion, already mentioned above, about disclosure requirements for intellectual property rights applications that make use of forms of traditional knowledge.⁵² Finally, there is an emerging debate about the importance of forms of customary law in the context of sustainable development in general⁵³ and in the context of traditional knowledge protection in particular.⁵⁴ It has been argued, among other things, that customary law could provide avenues to overcome the 'tragedy of the commons' theory that open access by self-interested individuals necessarily leads to over-exploitation of resources. Rather than moving to the opposite extreme of privatising resources, proponents of the role of customary law in sustainable development argue that many customary law systems operate with forms of limited common property, 55 where access to the resources is restricted, for example, to certain seasons or certain groups at certain times, thus avoiding overexploitation. The discussion about these issues in the context of traditional knowledge and intellectual property has only just begun and some reference to the use of customary law will be made in the case studies following. It is important to note, however, that customary law also faces many obstacles, such as limited recognition within the state systems of developing nations, the difficulties of creating representative bodies of customary law communities within the wider national and international setting, the concerns of human rights lawyers about some customary practices, the question of membership of local societies in an age of globalisation and extensive migration, and the general difficulties of adapting indigenous worldviews to the developmental agenda of an industrialising state. ⁵⁶ Critics have pointed out that, at first, colonial policies and subsequently internal migration in post-colonial nation states mean that boundaries of customary communities are now difficult to draw and customary law would have to be resurrected from a long period of decline.⁵⁷ We will return to some of these issues in the context of the following case studies and in the conclusion to this article.

⁵¹ See David R. Downes, How Intellectual Property Could Be a Tool to Protect Traditional Knowledge, in THE EARTHSCAN READER ON INTERNATIONAL AND SUSTAINABLE DEVELOPMENT (Kevin P. Gallagher & Jacob Werksman eds., 2002); Dwijen Rangnekar, The Socio-Economics of Geographical Indications: A Review of Empirical Evidence from Europe (UNCTAD-ICTSD, Project on IPRs and Sustainable Development Series – Issue Paper No. 8, 2004), available at http://ictsd.org/downloads/2008/07/a.pdf.

⁵² See supra note 47.

⁵³ PETER OREBECH ET AL., THE ROLE OF CUSTOMARY LAW IN SUSTAINABLE DEVELOPMENT (2005).

⁵⁴ See WIPO, Customary Law & the Intellectual Property System in the Protection of Traditional Cultural Expressions and Knowledge (WIPO, Issues Paper, 2006), available at

http://www.wipo.int/tk/en/consultations/customary_law/issues.pdf

⁵⁵ For a detailed discussion, see *supra* note 53, at 12.

⁵⁶ For a discussion in relation to some of these problems, see supra note 53, at 338.

⁵⁷ Martin Chanock, Branding Identity and Copyrighting Culture: Orientation Towards the Customary in Traditional Knowledge Discourse, in Traditional Knowledge, Traditional Cultural Expressions and Intellectual Property Law in the Asia-Pacific Region 177 (Christoph Antons ed., 2009). For different assessments of such problems based on

VII

EXAMPLES FROM ASIA

The following case studies from the Philippines and India represent two examples of the different approaches to traditional knowledge protection currently used in Asia. They range from traditional knowledge protection as part of a comprehensive protection of indigenous cultural rights, as in the Philippines, to the protection of specialised segments of traditional knowledge in the national interest, the approach adopted by the national government in India.

A. THE PHILIPPINES

1. The Intellectual Property Code and the Plant Variety Protection Act

Intellectual property legislation in the Philippines provides only limited recognition for forms of traditional knowledge. Section 22.4 of the Intellectual Property Code of the Philippines declares as non-patentable, plant varieties or animal breeds or essentially biological processes for the production of plants or animals other than micro-organisms and non-biological and microbiological processes. However, the provision explicitly leaves room for the enactment of sui generis protection for plant varieties and for a system of community intellectual rights protection. The sui generis option has meanwhile been exercised with the enactment of the Philippine Plant Variety Protection Act of 2002.58 The Act follows the 1991 UPOV model. In section 43 (d), it protects the traditional right of small farmers to save, use, exchange, share or sell their farm produce of a protected variety, except when a sale is for the purpose of reproduction under a commercial marketing agreement. The availability of this exception is to be determined by the National Plant Protection Board. The provision further allows exchange and sale of seeds among small farmers for reproduction and replanting on their own land. Farming Communities and bona fide farmers' organisations are further encouraged to build inventories of locally bred varieties to safeguard them against misappropriation and monopolisation. NGOs have assisted local farming communities to establish and upgrade such community registers of their local and traditional varieties.⁵⁹

fieldwork in Indonesia, see also Tania Murray Li, The Will To Improve: Governmentality, Development and the Practice of Politics (2007); Franz von Benda-Beckmann & Keebet von Benda-Beckmann, Between Global Forces and Local Politics: Reorganisation of Village Government in Indonesia, in Globalisation and Resistance: Law Reform In Asia Since the Crisis (Christoph Antons & Volkmar Gessner eds., 2007).

⁵⁸ An Act to Provide Protection to New Plant Varieties, Establishing a National Plant Protection Board and for Other Purposes, Rep. Act 9168 (2002) (Phil.).

⁵⁹ ALYWIN D. M. ARNEJO, THE COMMUNITY REGISTRY AS AN EXPRESSION OF FARMERS' RIGHTS: EXPERIENCES IN COLLECTIVE ACTION AGAINST THE PLANT VARIETY PROTECTION ACT OF THE PHILIPPINES, available at

2. Bioprospecting under Executive Order No. 247

The Philippines has seen a new emphasis on the environment and on biological resources since the early post-Marcos years. Following the People Power Revolution of 1986, new President Corazon Aquino restructured and reformed the former Natural Resources Ministry, transforming it into the Department of Environment and Natural Resources. Following the Earth Summit in Rio de Janeiro in 1992, Aquino's successor, Fidel Ramos, initiated the Philippine Commission on Sustainable Development (PCSD), which in turn translated the Earth Summit's Agenda 21 into the local Philippine version. Also in 1992, Ramos established via RA No. 7586 the National Integrated Protected Areas System (NIPAS), which designated ecologically sensitive areas such as sanctuaries, reserves and natural parks.

This was followed by Executive Order No. 247 "Prescribing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, their By-Products and Derivatives, for Scientific and Commercial Purposes, and for Other Purposes" of May 1995 (EO 247) and by the DENR implementing regulations for this order DAO 96-20. EO 247 was deliberately drafted in the form of Executive Order rather than as a legislative bill to take advantage of the supportive climate for such legislation under the Ramos administration. 62 EO 247 covered all types of biodiversity collection, except for traditional use, and it created the Inter-Agency Committee on Biological and Genetic Resources (IACBGR). Parties interested in bio prospecting in the Philippines had to enter into a research agreement with a relevant government department on recommendation of the IACBGR. EO 247 distinguished between commercial research agreements and academic research agreements. It foresaw certain minimum requirements for commercial research agreements, including provision for royalty payments, provision of information about discoveries with a commercial value, involvement of Philippine researchers in research conducted by foreigners and termination of the agreement after a maximum of three years. Only duly recognised Philippine universities, academic institutions, domestic and intergovernmental entities were allowed to apply for a renewable academic research agreement with a maximal duration of five years. Prior informed

http://www.capri.cgiar.org/pdf/GRarnejo.pdf (paper presented at the CAPRi-IPGRI International Workshop on Property Rights, Collective Action and Local Conservation of Genetic Resources, Rome (2003)).

⁶⁰ WALDEN BELLO ET AL., THE ANTI-DEVELOPMENT STATE: THE POLITICAL ECONOMY OF PERMANENT CRISIS IN THE PHILIPPINES 218 (2004). For a discussion on the policy shifts within DENR under the various administrations, see Marites Danguilan-Vitug, Forest Policy and National Politics, in Forest Policy and Politics in the Philippines: The Dynamics of Participatory Conservation 11-39 (Peter Utting ed., 2000).

⁶¹ BELLO, *id.* at 219; *see also* DEVELOPING THE NATIONAL BIOSAFETY FRAMEWORK FOR THE PHILIPPINES 48 (S. Halos et al. eds., 2004).

⁶² KRYSTYNA SWIDERSKA ET AL., DEVELOPING THE PHILIPPINES EXECUTIVE ORDER NO. 247 ON ACCESS TO GENETIC RESOURCES 15 (2001), available at http://www.cbd.int/doc/case-studies/abs/cs-abs-order-ph-en.pdf.

consent of indigenous cultural communities in accordance with customary law was required. While monitoring on the ground was the responsibility of the Protected Areas and Wildlife Bureau (PAWB) of DENR, the IACBGR recommended the approval of applications to the relevant Department Secretaries, decided on the amount of material to be taken and monitored observance of the conditions of the agreements, especially compliance with conditions imposed for the protection of indigenous and local communities. The Inter-Agency Committee consisted primarily of staff drawn from the Departments of Environment and Natural Resources, Science and Technology, Agriculture, Health and Foreign Affairs, joined by two scientists and representatives of the National Museum, as well as representatives from an NGO and from a People's Organization (PO) representing indigenous cultural communities.

3. The Indigenous Peoples' Rights Act

One initial criticism of EO 247 and its implementing regulations was the rather paternalistic manner of obtaining the prior informed consent of affected communities. In this regard, section 7 of the implementing rules and regulations in DAO 96-20 merely foresaw public notification and consultation with relevant officials and government agencies. More detailed provisions regarding the prior informed consent of indigenous people in particular followed from specialised legislation, enacted in 1997 and covering the rights of indigenous people. In the context of Asian governments' policies regarding indigenous people and local minorities, the Philippines is a rather exceptional case. The concept of indigenous people has a long history in this country and is constitutionally recognised. The distinction between Christianised Filipinos or *Indios*, Muslim Filipinos or *Moros* and the indigenous non-Christian tribes or *infieles* goes back to the Spanish colonial period. Rule by the United States after 1898 further strengthened the separate administration of the so-called 'uncivilized tribes' of the archipelago, for which President McKinley prescribed "the same course followed by Congress in permitting the tribes of our North American Indians to maintain their tribal organization and government." From 1903, Bureau of Non-

⁶³ Oscar B. Zamora, *The Philippines: A Bridle on Bioprospecting?*, SEEDLING, June 1997, *available at* http://www.grain.org/seedling/index.cfm?id=13.

⁶⁴ On the historical backgound, see Gerard A. Persoon, Being Indigenous in Indonesia and the Philippines, in TRADITIONAL KNOWLEDGE, TRADITIONAL CULTURAL EXPRESSIONS AND INTELLECTUAL PROPERTY LAW IN THE ASIA-PACIFIC REGION 195, 207-209 (Christoph Antons ed., 2009).

⁶⁵ A discussion of the historical development of these classifications can be found in *Isagani Cruz & Anr. v. Sec'y of Env't & Natural Res. & Ors.*, G.R. No. 135385, (S.C. December 6, 2000) (Phil.) (separate opinion of Puno, J., available at http://sc.judiciary.gov.ph/jurisprudence/2000/dec2000/135385_puno.htm); see also R. J. May, Ethnicity and Public Policy in the Philippines, in Government Policies and Ethnic Relations in Asia and the Pacific 321, 324 (Michael Brown & Sumit Ganguly eds., 1997).

Christian tribes became responsible for their administration. Interestingly, the responsibility of this agency extended not only to animist indigenous people, but also to the *Moros* of the Mindanao and Sulu islands in the South of the Philippines.⁶⁷ After independence, attempts at assimilation and integration were made and the 'cultural communities' were constitutionally recognised in the Constitutions of 1973 and 1987. Today, the National Commission on Indigenous Peoples (NCIP) identifies 95 distinct tribes in 14 regions of the country with an estimated population of 12-15 million people.⁶⁸ A World Bank study of 2007 pointed, however, to difficulties in establishing such figures and to discrepancies between lists of indigenous peoples drafted by various institutions, for example, because of different use of ethnic names or labels.⁶⁹

Against this background, it is perhaps less surprising that the Philippines is the only country in Asia that has made serious attempts to implement protection for a holistic notion of 'community intellectual rights' and 'cultural and intellectual rights' with elements of both traditional resource rights and folklore. The vehicle for this protection is currently the Indigenous Peoples Rights Act of 1997 (IPRA). At the time of its enactment, the IPRA was hailed as landmark legislation in this area of law in Asia. It provided broad recognition for the rights of Indigenous Cultural Communities/ Indigenous Peoples (ICC/IPs) to their ancestral domains and to the development of their cultures, traditions and institutions. To facilitate the exercise of these rights, the recognition of native title in Ancestral Domains and the granting of Certificates of Ancestral Domain Title (section 11, IPRA) were required.

Section 5 of the Act explains that the indigenous concept of ownership holds that ancestral domains are the ICCs/IPs' private but community property, which belongs to all generations and cannot be sold, disposed or destroyed.⁷⁰ This concept also covers traditional resource rights. Traditional resource rights are further defined in section 3 (o) as the "rights of ICCs/IPs to sustainably use, manage, protect and conserve (a) land, air, water, and minerals; (b) plants, animals

⁶⁷ James Eder & Thomas McKenna, Minorities in the Philippines: Ancestral Lands in Theory and Practice, in CIVILIZING THE MARGINS: SOUTHEAST ASIAN GOVERNMENT POLICIES FOR THE DEVELOPMENT OF MINORITIES 56, 60-61 (Christopher R. Duncan ed., 2004); May, *supra* note 65, at 331.

⁶⁸ Jose Mencio Molintas, The Philippine Indigenous Peoples' Struggle for Land and Life: Challenging Legal Texts, 21 ARIZ. J. INT'L & COMP. L. 269, 272 (2004).

⁶⁹ Josefo B. Tuyor et al., *The Indigenous Peoples Rights Act: Legal and Institutional Frameworks, Implementation and Challenges in the Philippines* 34-35 (Sustainable Dev. Dep't, E. Asia & Pac. Region, World Bank, Discussion Paper, 2007); Persoon, *supra* note 64, at 206 (quotes estimates from the International Working Group for Indigenous Affairs of 8-10 million indigenous people in the Philippines).

⁷⁰ See also § 3, Rule III (Part I), NCIP - Administrative Order No. 1/1998 (Phil.).

and other organisms; (c) collecting, fishing and hunting grounds; (d) sacred sites; and (e) other areas of economic, ceremonial and aesthetic value in accordance with their indigenous knowledge, beliefs, systems and practices."⁷¹ The rights to ancestral domains include, according to section 7 (a), the right to claim ownership over lands, bodies of water traditionally and actually occupied by ICCs/IPs, sacred places, and traditional hunting and fishing grounds. The right to develop lands and natural resources in section 7 (b) includes the following:

- the right to develop, control and use lands and territories traditionally occupied, owned or used:
- the right to manage and conserve natural resources within the territories and uphold the responsibilities for future generations;
- the right to benefit and share the profits from allocation and utilization of the natural resources found within the territory;
- the right to negotiate the terms and conditions for the exploration of natural resources in the areas for the purpose of ensuring ecological, environmental protection and the conservation measures in accordance with national and customary laws;
- the right to an informed and intelligent participation in project formulation and implementation and to receive just and fair compensation for any damages;
- the right to effective government measures to prevent any interference with, alienation and encroachment upon these rights.

A further and more detailed definition of these rights can be found in Rule III, Part II, Section 2 of NCIP Administrative Order No. 1 of 1998. According to section 2 (a) of this Order, at least 30 per cent of funds received will be allocated to the ICC/IP community for development projects or provision of social services or infrastructure in accordance with their Ancestral Domain Sustainable Development and Protection Plan (ADSDPP).

In cases of conflict, section 7 (h) gives priority to customary law as a means for conflict solving with amicable settlement and judicial procedures in the courts of justice as default mechanisms. This is further specified in Rule III, Part II, Section 8 of NCIP Administrative Order No. 1 of 1998, according to which conflicts unresolved under customary law are submitted to the NCIP and may be appealed to the Court of Appeals. Rule IV, Part I, Section 4 indicates that the traditional justice

⁷¹ See also § 2, Rule III (Part II), NCIP - Administrative Order No. 1/1998 (Phil.) (refers to the Ancestral Domain Sustainable Development and Protection Plan (ADSDPP)).

systems are recognised as long as they are compatible with national laws and accepted international human rights.

The most important rights relating to intellectual property and biological resources are to be found in Chapter VI of the Act under the heading 'Cultural Integrity.' Section 29 states generally that the State shall respect, recognise and protect the rights of ICCs/IPs to preserve and protect their culture. Section 32 guarantees 'Community Intellectual Rights' including those of various manifestations of culture and the right to restitution of cultural, intellectual, religious and spiritual property taken in an unauthorised manner and without prior informed consent.

Section 34 of Chapter VI further provides that ICCs/IPs are:

entitled to the recognition of full ownership and control and protection of their cultural and intellectual rights. They shall have the right to special measures to control, develop and protect their sciences, technologies and cultural manifestations, including human and other genetic resources, seeds, including derivatives of these resources, traditional medicines and health practices, vital medicinal plants, animals and minerals, indigenous knowledge systems and practices, knowledge of the properties of fauna and flora, oral traditions, literature, designs, and visual and performing arts.

A similar, but more extended definition of 'community intellectual rights' is given in Rule II, Section 1 (j) of the NCIP implementing Administrative Order No. 1 of 1998. Accordingly, community intellectual rights include:

rights of ICCs/IPs to own, control, develop and protect: (a) the past, present and future manifestations of their cultures, such as but not limited to, archaeological and historical sites, artefacts, designs, ceremonies, technologies, visual and performing arts and literature as well as religious and spiritual properties; (b) science and technology, including but not limited to, human and other genetic resources, seeds, medicine, health practices, vital medicinal plants, animals and minerals, indigenous knowledge systems and practices, resource management systems, agricultural technologies, knowledge of the properties of fauna and flora, oral traditions, designs, scientific discoveries; and (c) language, script, histories, oral traditions and teaching and learning systems.

Indigenous knowledge systems and practices are in turn defined in Rule II, Section 1 (p) of Administrative Order No. 1 of 1998 as:

systems, institutions, mechanisms and technologies comprising a unique body of knowledge evolved through time that embody patterns of relationships between and among peoples and between peoples, their lands and resource environment, including such spheres of relationships which may include social, political, cultural, economic, religious spheres, and which are the direct outcome of the indigenous peoples' responses to certain needs consisting of adaptive mechanisms which have allowed indigenous peoples to survive and thrive within their given socio-cultural and biophysical conditions."

The same definitions return once again in Rule VI of Administrative Order No. 1 of 1998. This time 'community intellectual property rights' as well as the 'right to protection of indigenous knowledge systems and practices' are listed among the right to cultural integrity (Rule VI, Section 3). The definitions used in Rule IV, Sections 10 and 14 are largely identical to those elsewhere in the order except that section 10 (c) adds 'music, dances, conflict resolution mechanisms, peace building processes' and 'life, philosophy and perspectives' to the term 'community intellectual property.' The rights are to be established in accordance with the Convention on Biodiversity, the Universal Declaration of Indigenous Peoples' Rights and the Universal Declaration of Human Rights. Administrative Order No. 1 foresees different procedures for research permits (Rule IV, Section 15) and for joint undertakings with commercial ventures (Section 17). Violations of the free and prior informed consent regulations will be subject to penalties under customary law and fines under both the Indigenous Peoples' Rights Act and Administrative Order No. 1 of 1998. However, if customary law is applied, cruel, degrading or inhuman penalties, the death penalty and excessive fines are prohibited (Rule XI, Part III, Section 1 of Administrative Order No. 1 of 1998 and section 72 of the Indigenous Peoples Rights Act).

Section 35 requires the free and prior informed consent of the communities in accordance with customary laws for access to biological and genetic resources, and section 36 encourages the recognition and promotion of sustainable agro-technological development among ICCs/IPs. The manner of obtaining free and prior informed consent is regulated in detail in Rule IV, Part III of the NCIP Administrative Order No. 1 of 1998. Section 7 of this part mentions examples where these procedures have to be followed, including the "exploration, development, exploitation and utilization of natural resources within ancestral domains/lands" and "research in indigenous knowledge, systems and practices related to agriculture, forestry, watershed and resource management systems and technologies, medical and scientific concerns, bio-diversity, bio-prospecting and gathering of genetic resources." Furthermore, section 8 foresees a Memorandum of Agreement between proponent, the host ICC/IP community and the NCIP covering benefits, measures to protect community rights, responsibilities of all parties, conditions in case of change

of proponent where appropriate, and penalties for non-compliance and violations of the terms and conditions.

The Act further created a National Commission on Indigenous Peoples with legislative and executive powers as the main representative body for indigenous interests. According to section 44 of the Act, the powers of the NCIP include the granting of certificates of ancestral domain title; the entering into contracts and agreements to achieve the objectives of the Act; the granting of permits to dispose, utilise, manage and appropriate parts of the ancestral domain with the approval of the ICCs/IPs; the decision about appeals regarding its own decisions and acts and the promulgation of implementing rules and regulations. The main set of implementing regulations followed in 1998 via Administrative Order No. 1 of the NCIP.

While Administrative Order No. 1 of the NCIP regulated the implementation of the IPRA in general, Administrative Order No. 3 brought specific guidelines for free and prior informed consent. In 2002, the NCIP issued a revised Administrative Order No. 3 concerning revised guidelines for the issuance of certification precondition and the free and prior informed consent. This order was again repealed by NCIP Administrative Order No. 1 of 2006. This latest implementing regulation distinguished between certification precondition issued by the NCIP for projects that have met all requirements of free and prior informed consent and certificates of non-overlap for projects that do not affect indigenous peoples or that fall outside of ancestral domains. The implementation of the IPRA in the IPRA in

4. The Traditional and Alternative Medicine Act

Further legislation introduced in 1997: Republic Act No. 8423 of 1997 covers aspects of traditional knowledge and created the Philippine Institute of Traditional and Alternative Health Care (PITAHC) to accelerate the development of traditional and alternative health care in the Philippines. It provides for a Traditional and Alternative Health Care Development Fund for these and other purposes. However, much of this legislation is in fact concerned with the integration of traditional and alternative health care into the national health care system and with safety standards, coordination and guidelines for such medicines. The inclusion of a definition of

⁷² See NCIP Administrative Order No. 3/2002 (Phil.).

⁷³ Tuyor et al., *supra* note 69, at 13.

⁷⁴ An Act Creating the Phillipine Institute of Traditional and Alternative Health Care (PITAHC) to Accelerate the Development of Traditional and Alternative Health Care in the Philippines, Providing for a Traditional and Alternative Health Care Development Fund and for Other Purposes, Rep. Act 8423 (1997) (Phil.).

'alternative health care modalities' specifically acknowledges that the Act is not confined to indigenous knowledge and not even necessarily to knowledge having a long tradition in the Philippines. In spite of occasional references to indigenous societies and the requirement in section 2 to acknowledge their contributions and to pay royalties to them, the Act does not establish any specific mechanisms for this purpose. The Act defines 'traditional healers' as 'the relatively old, highly respected people with a profound knowledge of traditional remedies.' While traditional healers and environmental sector organisations are represented on the Board of the Philippine Institute of Traditional and Alternative Health Care, there is no specific representation of indigenous communities.

5. New bioprospecting guidelines under Administrative Order No. 1 of 2005

On paper, the Philippines had a sophisticated bio prospecting and traditional knowledge system by the late 1990s. In practice, however, implementation of the legislation was disappointing and slow. Swiderska, Dano and Dubois report only two approvals for research agreements under EO 247 between 1995 and 2001, one of a commercial and one of an academic nature. Developments under the IPRA were not much better. In fact, the IPRA faced a constitutional challenge shortly after its enactment. The petition failed after an evenly divided Supreme Court upheld the legislation in 2000. Land claims remained suspended during this period, however, so that the implementation of the IPRA was delayed considerably. According to a World Bank study of 2007, the NCIP issued 29 certificates of ancestral domain titles from 2002 to 2004. Among the reasons for the relatively slow progress in issuing these certificates, the study cited lack of technical expertise in boundary delineation, lack of financial and logistical resources and disputes about ancestral domains between indigenous and non-indigenous communities as well as among different groups of indigenous peoples.

From 2001 onwards, the new Arroyo administration issued various pieces of legislation that attempted to harmonise and centralise the dispersed legislation on access to biological resources. Republic Act No. 9147 "providing for the conservation and protection of wildlife resources and their habitats, appropriating funds therefore and for other purposes" distinguished again between

⁷⁵ SWIDERSKA ET AL., *supra* note 62, at 28; *see also* Cecile Dumol, New Bioprospecting Guidelines in the Philippines (June 28, 2005), http://www.pchrd.dost.gov.ph/index.php/news-archive/70 (last visited July 9, 2010).

⁷⁶ See Isagani Cruz & Anr. v. Sec'y of Env't & Natural Res. & Ors., G.R. No. 135385, (S.C. December 6, 2000) (Phil.), available at http://sc.judiciary.gov.ph/jurisprudence/2000/dec2000/135385.htm.

⁷⁷ Eder & McKenna, *supra* note 67, at 67.

⁷⁸ Tuyor et al., *supra* note 69, at 48.

bio prospecting for commercial and for scientific purposes. Since this Act concerned collection activities within all areas of the country, including areas under the National Integrated Protected Areas System, these areas potentially overlapped with the ancestral domains and lands under the IPRA, a problem that had already been recognised in the original NIPAS legislation.⁷⁹ DENR and NCIP now jointly issued a memorandum for the harmonisation of the implementation of IPRA and Environmental and Natural Resources Laws and Policies.⁸⁰

Administrative Order No. 1 of 2005, a further joint initiative of the DENR, the Department of Agriculture (DA), the Palawan Council for Sustainable Development (PCSD) and the NCIP, brought a new set of guidelines for bio prospecting in the Philippines. They apply to all bio prospecting activities in the Philippines and to *in situ* as well as to *ex situ* collections. The guidelines also clarify that they apply to all areas, including ancestral domains and lands that are subject to the IPRA. Prior informed consent is to be obtained either from ICCs/IPs or, in the case of non-indigenous local communities, from a *Barangay* Assembly.⁸¹

Under the new guidelines, each bio prospector has to conclude a Bio prospecting Undertaking (BU) with the DENR and/or the DA, represented by its respective Departmental Secretary. There is a special regulation for activities in the Province of Palawan, where the BU must be co-signed by the Chairperson of the PCSD. The implementation is largely in the hands of the various departmental agencies. As for indigenous ancestral domains and lands, the NCIP shall assist with obtaining the prior informed consent of indigenous people and in the negotiation of benefit sharing agreements. The rules and regulations of the IPRA are to be followed for the securing of prior informed consent. As for benefit sharing agreements, a minimum bio prospecting fee, which may be higher if traditional knowledge is concerned, will go to the national government. Royalties are to be shared between the national government and local governments, if that are foreseen by local government regulation. Representatives of the various resource providing communities negotiate the benefit sharing agreements and these communities also receive any up-front payments. The bio prospecting fee will be used for a Wildlife Management or Protected Area

⁷⁹ See An Act Providing for the Establishment and Management of National Integrated Protected Areas System, Defining its Scope and Coverage, and for Other Purposes, Rep. Act 7586, § 13 (1992) (Phil.).

⁸⁰ See Joint DENR-NCIP Memorandum Circular No. 2003-1 on Harmonization of the Implementation of the Indigenous Peoples Rights Act (IPRA) and Environment and Natural Resources (ENR) Laws and Policies (Oct. 31, 2003), available at http://www.mgb.gov.ph/Files/Policies/DENR-NCIP%20MC%202003-1.doc.

⁸¹ The Barangay Assembly represents a 'barangay', a traditional Philippine administrative unit, usually consisting of between 100 to 500 families, see Jurgen Ruland, Politik Und Verwaltung in Metro Manila – Aspekte Der Herrschaftsstabilisier Ung in Einem Autoritaren Politischen System 120 (1982).

Fund. However, if the fee is collected for activities in areas under the IPRA, the IPRA also regulates the manner in which the funds will be used. DENR Administrative Order 96-20 is repealed, as is Executive Order No. 247 in so far as it is inconsistent with the Wildlife Act. The Inter-Agency Committee on Biological and Genetic Resources is dissolved and its functions are now exercised by the Secretary of the DENR or DA. Apart from royalties and fees, there is also provision for a rehabilitation/performance bond amounting to 25 per cent of the project cost as reflected in the research budget. This is to be posted before the bio prospecting activities begin.

The new guidelines foresee a compliance monitoring system via annual progress reports and various certifications for prior informed consent, benefit sharing and collection quotas. Forms for these purposes are to be found in Annexes to the Administrative Order. Monitoring overseas is to be undertaken by DFA and DOST. NGOs and POs are equally encouraged to participate in the monitoring process. Non-compliance with the BU will lead to cancellation/revocation of the agreement, confiscation of the material, forfeiture of the rehabilitation and performance bond, imposition of a perpetual ban on access to biological resources in the Philippines and imposition of administrative and criminal sanctions under the Wildlife Act. There is a further provision allowing for the 'shaming' of the violator in national and international media and the reporting of the violations to international and regional monitoring bodies. There is nothing, however, in either the Intellectual Property Code of the Philippines or in Administrative Order No. 1 of 2005 providing for the revocation of a patent that has made use of knowledge and of material obtained under circumstances that violated one or more of the prior informed consent, benefit sharing and collection quota requirements.

The guidelines exempt scientific research on agro-biodiversity and scientific research on wildlife under section 15 of the Wildlife Resources and Conservation Protection Act from the application of the guidelines, but in the latter case they subject any further transfer of material for commercial purposes to the guidelines. Also exempted is traditional use and subsistence consumption as well as use of *ex situ* collections, which are covered by international agreements. Finally, the development of medicinal plants for traditional and alternative medicine is primarily governed by the Traditional and Alternative Medicine Act.

For all other bio prospecting purposes, which are defined as "research, collection and utilization of biological and genetic resources for purposes of applying the knowledge derived there from solely for commercial purposes", the bio prospecting guidelines apply and the BU has to make reference

to certain standard terms and conditions contained in Annex I to the Guidelines. These conditions are very similar to those requested previously under EO 247. Thus, specimens are to be deposited with various agencies in the Philippines, research is to be in collaboration with Philippine agencies, ownership is to be retained by the Philippines of all material, and if there are third party recipients, a material transfer agreement with specified content is to be reached. While many of these conditions are compulsory, ⁸² some give preference to the BU or the benefit sharing agreement. Section 9 of the Standard Terms and Conditions requires that "all discoveries and commercial products made or derived from Philippine biological resources shall be made available to the Philippine government and resource provider", but only "as may be agreed upon in the BU." Equally, section 11 requires the royalty-free licensing of technology derived from Philippine endemic species to the Philippine government through a designated Philippine institution but provides further that "where appropriate and applicable, other terms may be negotiated by the parties." In the case of germplasm exchange, the technology shall be shared with the collaborating National Agricultural Research systems in line with mission statements of such centres and in accordance with protocols under international law.

According to the Philippines' 4th National Report to the Convention on Biological Diversity of 2009, NCIP records show that indigenous communities had benefitted by 2007 from 199 projects in various areas. However, until 2009 no access application had been processed under the 2005 bio prospecting guidelines of Joint Administrative Order No. 1. The report identified as the reason for the lack of applications, the perception that the regulation was restricting research and the royalty provisions were a disincentive to research. Consequently, the report identified "an urgent need to review provisions in the regulation in order to address the concerns of both researchers and regulators." According to the same report, progress has been made, however, with regards to the nationwide documentation of indigenous knowledge systems and practices. Administrative Guidelines to regulate such activities for sustainable traditional and indigenous forest resources management systems and practices have meanwhile been issued in DENR-NCIP Joint Administrative Order No. 1 of 2008.

⁸² See § 9.1, Joint DENR-DA-PCSD-NCIP Administrative Order No. 1/2005 (Phil.) ("The BU shall contain, in addition to the negotiated terms of benefit-sharing, standard terms and conditions relating to compliance with complementary regulations and other basic contractual terms. These terms and conditions are listed in Annex I.").

⁸³ Republic of the Philippines, Assessing Progress Towards the 2010 Biodiversity Target: The 4th National Report to the Convention on Biological Diversity 65 (2009), *available at* http://www.cbd.int/doc/world/ph/ph-nr-04-en.pdf.

⁸⁴ Id. at 66.

6. The Draft Bill for Community Intellectual Rights Protection

Finally, a far-reaching Draft Bill for Community Intellectual Rights Protection was introduced in 2001. Protection extends to parent strains and genetic material discovered or selected and conserved by local communities; seeds and reproductive material, agricultural practices and devices, medicinal products and processes, cultural products from local communities and all other products or processes discovered through a community process. While the draft on the one hand recognises indefinite rights to the material, royalties for registered forms of traditional knowledge may only be collected for ten years. Among the beneficiaries of the draft legislation are 'farmer-innovators', defined as:

i. an individual who has provided or was the source of parent strains used in the development of a new variety; ii. the local community, which has helped to conserve and develop the genetic stocks which have gone into the pedigree of a new variety; iii. the residents of an area rich in plant genetic resources from where breeders or breeding institutions responsible for the new variety have obtained donors of genes for resistance/tolerance/avoidance to biotic and/or abiotic stress or other valuable character.

This draft is based on model legislation developed by the Third World Network and is apparently still under consideration in the Philippine Senate, where it has been pending for some years.⁸⁵

B. INDIA

Indian policy makers seem torn between high technology ambitions in areas such as biotechnology and the need to account for a large rural sector. Ref The move from traditional to commercial farming is still a matter of hefty debate in India. Many Indian farmers have become heavily indebted. Press reports indicate that 95 per cent of cotton farmers are struggling with heavy debt and that an unusual large number have committed suicide over the past few years. At the same time, commercial farming in India has been boosted by a number of new laws and amendments, which India had to enact as a result of the country's accession to the WTO-TRIPS Agreement. The Indian Government has also taken steps to accede to the UPOV Convention, but these accession

⁸⁵ Draft Bill - Community Intellectual Rights Protection Act (July 24, 2008),

http://www.grain.org/brl/?docid=767&lawid=1469 (last visited July 9, 2010).

⁸⁶ Anand Giridharadas, Growing in India: Food for the World, N.Y. TIMES, May 26, 2006, available at

http://www.nytimes.com/2006/05/26/business/worldbusiness/26iht-wbfood.1829800.html; K. S. Jayaraman, *India Biotech Boom*, 436 NATURE 480 (2005); K. P. Prabhakaran Nair, *Seeds Bill: A rich harvest for MNCs?*, HINDU BUS. LINE, Mar. 30, 2005, *available at*

http://www.thehindubusinessline.com/2005/03/30/stories/2005033000240900.htm.

⁸⁷ Amelia Gentleman, *Despair takes toll on Indian farmers*, N.Y. TIMES, May 31, 2006, *available at* http://www.nytimes.com/2006/04/18/world/asia/18iht-farmers.1557902.html.

plans have remained controversial and their current status is unclear. The following part of this article will discuss changes to laws as well as newer laws and draft laws related to plant varieties and to associated traditional knowledge. These include amendments to the Indian Patents Act, the Protection of Plant Varieties and Farmers' Rights Act, the Biological Diversity Act, the Seeds Bill introduced in 2004 and the most recent Protection, Conservation and Effective Management of Traditional Knowledge Relating to Biological Diversity Rules, 2009.

1. The Indian Patents Act

The Patents Act of 1970 originally excluded methods of agriculture or horticulture from patentability (section 3(h)). Equally excluded were "any processes for the medicinal, surgical, curative, prophylactic or other treatment of human beings or any process for a similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products" (section 3(i)). The Indian courts further interpreted the term "manner of manufacture" in a restrictive way as exclusively related to processes resulting in non-living tangible products. This approach was only overturned in 2002 in *Dimminaco AG v. Controller of Patents*. ⁸⁹ For inventions related to substances intended for use or capable of being used as food or medicine or drug and to substances prepared or produced by chemical processes, only process patent protection was given; no product patent was available (section 5). ⁹⁰

With India's entry into the WTO, transitional measures such as mailbox applications and exclusive marketing rights were introduced at first via an ordinance and then via amendments to the Patents Act in 1999. In 2002, the Indian Patents Act was substantially amended. Section 3(c) referring to discoveries of scientific theory was extended to the "discovery of any living thing or non-living substance occurring in nature." The phrase has been interpreted restrictively as not including the isolation and purification of living substances or non-living substances involving human intervention. The reference to plants in section 3(i) was omitted, and a new exclusion clause 3(j) was added covering "plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for

⁸⁸ Ranjan, *supra* note 50, at 230-234.

⁸⁹ Shanti Kumar et al., *India: Patent regime comes of age*, MANAGING INTELL. PROP., October 2006: Supplement – Asia-Pacific IP Focus 2006, *available at* http://www.managingip.com/Article.aspx?ArticleID=1321297.

⁹⁰ See Philippe Cullet, Property Rights over Biological Resources: India's Proposed Legislative Framework, 4 J. WORLD INTELL. PROP. 211 (2001).

⁹¹ Shanti Kumar & Neeti Wilson, *Biotechnology in the limelight*, MANAGING INTELL. PROP., April 2006: Supplement – Life Sciences 2006, *available at* http://www.managingip.com/Article.aspx?ArticleID=1321387.

⁹² Supra note 89.

production or propagation of plants and animals." Commentators have pointed out that the section, in spite of the negative terms in which it is couched, in fact would allow the patenting of not only micro-organisms, but also of biotechnological process inventions requiring substantial human intervention. 93 Importantly, section 3(p) added a further exemption from patentability for "an invention which, in effect, is traditional knowledge or which is an aggregate or duplication of known properties of traditionally known component or components." Section 25(j) provides ground for opposition and section 64(p) the new revocation ground "that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention." Under sections 25(k) and 64 (q), the ground for opposition and revocation is "that the invention so far as claimed in any claim of the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere."94 Also newly worded is section 3(b), which henceforth holds non-patentable "an invention the primary or intended use or commercial exploitation of which would be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment." The Indian Patent Office has interpreted this as including "method(s) of adulteration of food." 95

Another amendment followed in 2005, which abolished with section 5 the restriction to process patents for substances and made product patents available. Because of the looming deadline of 1 January, 2005 for TRIPS compliance, this latest amendment was initially introduced via an ordinance and then signed into law in March 2005. Currently still controversial is in particular section 3(d) of the amended Patents Act declaring as not patentable "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use of a known substance or of

⁹³ Supra note 91; see also Vandana Shiva, The Indian Seed Act and Patent Act: Sowing the Seeds of Dictatorship (Feb. 14, 2005), http://www.grain.org/bio-ipr/?id=431 (last visited July 8, 2010); see also Swati Gola, IMC India -The Patent Bill 2005: Impact on Agriculture (Mar. 22, 2005),

http://india.indymedia.org/en/2005/03/210277.shtml (last visited July 8, 2010).

⁹⁴ On the 2002 amendments, see S. K. Verma, Plant Genetic Resources, Biological Inventions and Intellectual Property Rights: The Case of India, in INTELLECTUAL PROPERTY AND BIOLOGICAL RESOURCES 128, 147-148 (Burton Ong ed., 2004).

⁹⁵ See Robyn Ott, Patentability of Plants, Animals and Microorganisms in India, 2 OKLA. J.L. & TECH. 17 (2004).

⁹⁶ See the Patents (Amendment) Act, 2005, No. 15 of 2005; see also Gola, supra note 93.

⁹⁷ Rajnish Kumar Rai, Patentable Subject Matter Requirements: An Evaluation of Proposed Exclusions to India's Patent Law in Light of India's Obligations Under the TRIPS Agreement and Options for India, 8 CHL-KENT J. INTELL. PROP. 41, 42 (2008); Emma Barraclough, India patent reform under attack, MANAGING INTELL. PROP., February 2005; Donald G. McNeil, Jr., India alters law on drug patents, N.Y. TIMES, Mar. 24, 2005, available at http://www.nytimes.com/2005/03/24/international/asia/24aids.html.

the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant." The subsequent debate about "second medical uses" led to a court challenge to the constitutionality and TRIPS compatibility of section 3(d) by Swiss pharmaceutical manufacturer Novartis, which was dismissed in 2007. The remainder of the challenge regarding the rejection of the patent application was recently rejected by the Intellectual Property Appellate Board (IPAB), which hears appeals from decisions of the Registrar of Trademarks and Geographical Indications as well as from the Controller of Patents. Controversially also mentioning the cost factor of the drug as being detrimental to patent protection, the IPAB based its decision mainly on section 3(d) holding that the free form of the drug was known and that "enhanced efficacy" of the new drug over the know substance had not been demonstrated. The substance of the drug over the know substance had not been demonstrated.

The controversial section 3(d) was also one of the subjects of the report of the Mashelkar Committee, an expert committee appointed to examine whether it would be TRIPS compatible to:
a) limit the grant of a patent for pharmaceutical substances to new chemical entities or to new entities involving one or more inventive steps; and b) to exclude micro-organisms from patenting. The Committee concluded in its report that such a limitation of the patent would exclude an entire class of incremental innovations from patenting and would not be TRIPS compliant. It would equally not be TRIPS compliant to exclude micro-organisms from patenting.¹⁰²

2. The Protection of Plant Varieties and Farmers' Rights Act

India's reaction to the requirements of Article 27.3(b), TRIPS is the Protection of Plant Varieties and Farmers' Rights Act (PPVFRA) of 2001. The Act follows largely the 1978 UPOV model, but commentators have pointed out that it also includes elements of the 1991 UPOV version, such as

⁹⁸ Novartis refuses to back down in Indian patent dispute (Jan. 8, 2007),

http://www.managingip.com/Article/1257402/Novartis-refuses-to-back-down-in-Indian-patent-dispute.html (last visited July 8, 2010); Amelia Gentleman, Setback for Novartis in India Over Drug Patent, N.Y. TIMES, Aug. 7, 2007, available at http://www.nytimes.com/2007/08/07/business/worldbusiness/07drug.html; Linda L. Lee, Trials and TRIPS-ulations: Indian Patent Law and Novartis AG v. Union of India, 23 BERKELEY TECH. L.J. 281, 299 (2008).

99 Lee, id. at 287-288.

¹⁰⁰ Rahul Chaudhry & Aditi Sharma, *India: How IP protection has improved this year*, MANAGING INTELL. PROP., October 2009: Supplement – Asia-Pacific & Middle East IP Focus 2009 (7th ed.), *available at* http://www.managingip.com/Article.aspx?ArticleID=2311540.

¹⁰¹ Lex Orbis Intellectual Property Resource Centre – Lack of "enhanced efficacy" and High Price deprives Glivec of a Patent, http://www.lexorbis.com/Lack_of_enhanced_efficacy.htm (last visited July 8, 2010).

¹⁰² Lex Orbis Intellectual Property Resource Centre - Mashelkar Committee Report accepted by the Government, http://www.lexorbis.com/Mashelkar_Committee_Report_accepted_by_the_Government.html (last visited July 8, 2010).

the possibility to register essentially derived varieties.¹⁰³ On the other hand, the legislation attempts to balance in a rather unique manner the rights of commercial breeders and those of traditional small-scale and subsistence farmers. The conflicting goals come to expression in the preamble of the Act. On one hand, it speaks of the necessity "to recognize and protect the rights of farmers in respect of their contribution made at any time in conserving, improving and making available plant genetic resources for the development of new plant varieties", while on the other hand it regards plant breeders' rights protection as a necessary precondition "for accelerated agricultural development" and "to stimulate investment for research and development" as well as to "facilitate the growth of the seed industry."

Farmers' rights are regulated in Chapter VI of the legislation. Interestingly, and going beyond schemes for mere compensation of traditional contributions, the PPVFRA allows for the registration not only of new and essentially derived varieties, but also of "farmers' varieties" as well as of so-called "extant varieties." The definitions of these varieties can be collected from section 2. A "farmers' variety" is defined in section 2(l) of the PPVFRA as "a variety which: (i) has been traditionally cultivated and evolved by the farmers in their fields; or (ii) is a wild relative or land race of a variety about which the farmers possess the common knowledge". Farmers' rights are once again mentioned as a sub-category of "extant variety", which according to section 2(j) is a variety notified under section 5 of the Seeds Act, a farmers' variety, a variety about which there is common knowledge, or any other variety which is in the public domain. "Extant varieties" are, therefore, varieties recognised or in existence at the time of the coming into force. The PPVFRA allows for registration of extant varieties and of farmers' varieties (section 14 (b) and (c), PPVFRA), which, in the case of farmers' varieties, can be effected by "any farmer or group of farmers or community of farmers claiming to be the breeder of the variety" (section 16 (d), PPVFRA). While the registration requirements for new varieties are novelty, distinctiveness, uniformity and stability (section 15(1)), novelty has been dispensed with in the case of extant varieties, which need to conform only to "such criteria of distinctiveness, uniformity and stability as shall be specified under regulations made by the Authority" (section 15(2)). Of course, "a famer who has bred or developed a new variety shall be entitled for registration and other protection in like manner as a breeder of a variety under this Act." However, farmers' varieties are of course not new, but as a sub-group of extant varieties they still have to conform to the distinctiveness, uniformity and

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¹⁰³ See § 23, Protection of Plant Varieties and Farmers' Rights Act, 2001, No. 53 of 2001 (PPVFRA); see also supra note 90, at 219; see also S. K. Verma, Protection of Traditional Knowledge in the SAARC Region and India's Efforts, in Traditional Knowledge, Traditional Cultural Expressions and Intellectual Property Law in the Asia-Pacific Region 315, 330 (Christoph Antons ed., 2009).

stability (DUS) criteria. Critics have, therefore, concluded that the extent to which farmers will be able to make use of the registration option may remain quite limited.¹⁰⁴ First statistical figures discussed below seem to confirm that this is a justified concern.

Different from established forms of intellectual property rights, the legislation does not provide some form of royalties enforceable by the farmers against other private parties. Instead, farmers "shall be entitled in the prescribed manner for recognition and reward from the National Gene Fund" (section 39(1)(iii), PPVFRA). The National Gene Fund is constituted by the Central Government. Credited to this National Gene Fund are benefit-sharing payments, annual fees paid to the authorities, money received from compensation claims and contributions to the fund from national and international organisations and other sources (section 45(1)(a)-(d), PPVFRA). Rather than benefit sharing agreements freely negotiated between the users and the breeders of the farmers' varieties, the legislation foresees a determination of the benefit sharing by a government authority, the Protection of Plant Varieties and Farmers' Rights Authority (hereinafter 'Authority').

The Authority is regulated in Chapter II of the PPVFRA. It is the main government agency responsible for plant variety protection and for the registration of the various varieties. Its composition is prescribed in section 3 (5), PPVFRA. It was being established from the end of 2005 with the appointment of the Plant Varieties Protection and Farmers' Rights Board. The notification of the Protection of Plant Varieties and Farmers' Rights Regulations followed in December 2006. In 2007, the Authority began to publish the Plant Variety Journal of India as well as guidelines for the conduct of the Distinctness, Uniformity and Stability (DUS) testing. Initially, guidelines for twelve crops were published. According to the website of the Authority, 107 registration is now open for 31 crop species.

Statistics on the website of the Authority also indicate that extant varieties other than farmers' varieties thus far account for the bulk of the Authority's work. This was anticipated in the Protection of Plant Varieties and Farmers' Rights Regulations of 2006, which in Rule 6 prescribed

¹⁰⁴ Supra note 94, at 149; Verma, id. at 331.

¹⁰⁵ Verma, *supra* note 103, at 330-331.

¹⁰⁶ Farmers hail PVP & FR Act notification, FIN. EXPRESS, Nov. 14, 2005, available at http://www.financialexpress.com/news/Farmers%20hail%20PVP%20&%20FR%20Act%20notification%20%20/15 0181/

¹⁰⁷ See Protection of Plant Varieties and Farmers' Rights Authority, India – Registration Open For, http://www.plantauthority.gov.in (last visited July 8, 2010).

the constitution of an Extant Variety Recommendation Committee (EVRC). About 40 extant varieties covering nine crop species have been registered in 2008-2009. Section 28(1) PPVFRA confirms the essentially public character of many of the "extant varieties" notified under the Seeds Act of 1966 when seed production was still largely seen as a task for the public sector. In the case of an extant variety, "unless a breeder or his successor establishes his right", the Central Government or the State Government, where notification occurred for a state, shall be deemed to be the owner of such right. The 1003 applications for registrations of extant varieties contrast with 353 applications for new varieties, which are now under examination or DUS testing. Eighteen applications for farmers' varieties are equally under examination.

Where there is an entitlement for recognition and reward from the National Gene Fund, the Authority fixes the amount of benefit sharing after giving the parties the opportunity to be heard by taking into consideration the extent and nature of the use of genetic material of the claimant in the development of the variety and the commercial utility of and market demand for the variety (section 26, PPVFRA).

Apart from such benefit sharing claims of individual or collective breeders of traditional varieties, there is further under the heading "rights of communities" in section 41, PPVFRA a right to lodge a compensation claim against a commercial breeder for the contributions of a community to the evolution of a variety used in the breeding process. This claim may be raised by any person, group of persons (whether actively engaged in farming or not) or any governmental or non-governmental organisation on behalf of any village or local community in India. The decision whether or not to grant compensation and the amount of compensation is again a discretionary decision of the Authority. Commentators have raised concerns about the partly overlapping and partly diverging regulations on benefit sharing and compensation in the legislation, which may give rise to confusion and disputes. Equally, the lack of real property rights and the dependence on the Authority in the current scheme have been criticised. 109 In particular, it has been observed that the effect of the current legislation is that breeders may have to pay more than once for using traditional knowledge, because of the overlap between benefit sharing and compensation to the community. At the same time, commentators have found a "reluctance of Parliament to recognize that ownership of traditional knowledge rests with the community and to develop legislation from that perspective", so that "it can safely be concluded that the provisions to protect the traditional

¹⁰⁹ Supra note 90, at 220.

¹⁰⁸ Protection of Plant Varieties and Farmers' Rights Authority, Annual Report 2008-2009 (2009), available at http://plantauthority.gov.in/pdf/AnnualReport_08-09esum.pdf.

knowledge of the farming community are not going to work to the advantage of these communities."¹¹⁰

Apart from the benefit sharing and compensation mechanism, section 39(1)(iv), PPVFRA also provides for the traditional farmers' right to reuse saved seed, including to exchange, share or sell it. Here, however, the legislation follows the 1991 UPOV model in that the farmer is not allowed to sell branded seed of a protected variety.

Section 39(2), PPVFRA allows for a further compensation claim by farmers against commercial breeders on the grounds that the performance of a commercial variety remains below the performance projections that the commercial breeder had disclosed in advance. Again, the Authority will make the decision about such compensation after hearing the parties. Finally, commercial breeders need to disclose and acknowledge the contribution of traditional breeders in their applications. Failure to do so will result in a rejection of the application (section 40, PPVFRA).

3. The Biological Diversity Act

The Biological Diversity Act, 2002 constitutes India's implementation of the provisions of the CBD. In its preamble, the Act reaffirms the sovereign rights of states over their biological resources and explains that it wants to provide for conservation, sustainable utilisation and equitable sharing of benefits arising out of the utilisation of genetic resources. The Act creates yet another string of state agencies responsible for permits, guidelines and the supervision of the implementation of the Act. These agencies are the National Biodiversity Authority (NBA), the various State Biodiversity Boards (SBB) and, at the local level, Biodiversity Management Committees (BMC), constituted by *panchayats*¹¹¹ and municipalities. The NBA is largely an inter-ministerial committee with a number of non-official members to be appointed from the scientific community, industry representatives, conservers, creators and knowledge holders (section 8). One of the sub-committees of the NBA may deal with agro-biodiversity, defined as biological diversity of agriculture related species and

¹¹⁰ N. S. Gopalakrishnan, Protection of Traditional Knowledge: The Need for a Sui Generis Law in India, 5 J. WORLD INTELL. PROP. 725, 735 (2002).

¹¹¹ 'Panchayats' is a term widely used in India for dispute resolution institutions that can be caste based, territory or village based, or tribe based. For details, see Upendra Baxi, People's Law in India – The Hindu Society, in ASIAN INDIGENOUS LAW: IN INTERACTION WITH RECEIVED LAW 216, 234-256 (Masaji Chiba ed., 1986). The panchayat system finds constitutional recognition in Part IX of the Indian Constitution, where panchayats are referred to as democratic institutions of self-government for rural areas with specific responsibilities for economic development and social justice at the local level.

their wild relatives (section 13(1)). Responsibilities of the NBA important in this context relate in particular to the approval of activities under sections 3, 4 and 6 of the Act, dealing with access to biological resources and associated knowledge; transfer of research results; and acquisition of intellectual property rights (section 18(2)). The NBA further issues regulations and guidelines for these matters (section 18(2)). It has an advisory role to central and state governments and an important role in opposing the granting of intellectual property rights on Indian biological resources or associated knowledge outside of India (section 18(3) and (4)).

State Biodiversity Boards are also inter-departmental committees with additional members drawn from experts on biodiversity and sustainability. Biodiversity Management Committees at the local level are constituted to promote conservation, sustainable use and documentation of biological diversity including preservation of habitats, conservation of land races, folk varieties and cultivars, domesticated stock and breeds of animals and microorganisms, and chronicling of knowledge relating to biological diversity. They are only to be consulted by the other bodies in their decision making processes, although they may levy fees and charges for biological resources collected within their areas (section 41).

The Act has further been supplemented with the Biological Diversity Rules issued in 2004. Much to the disappointment of local activists and NGOs favouring decentralised decision-making and administration, 112 the Rules confirmed the central role of the Authority in decisions about access, knowledge transfer and intellectual property rights. According to Rule 14, it is the Authority that enters into an agreement regarding access with an applicant "after consultation with the concerned local bodies" and it is in the Authority's discretion to impose conditions, including the quantum of monetary and other incidental benefits, restrictions (Rule 16) or to revoke an approval under certain conditions (Rule 15). Local activists had hoped for a stronger role for the local Biodiversity Management Committees, whose role remained confined, however, to the collection of data for the so-called People's Biodiversity Registers and to the giving of advice to the Authority and State Biodiversity Boards during the granting of approvals (Rule 22). In 2007, *panchayats* and community representatives submitted over 3000 resolutions to the Prime Minister expressing their concerns over the reduced role of the Biodiversity Management Committees. 113

¹¹² Biodiversity Act, Rules opposed, HINDU, Dec. 8, 2004, available at http://www.hinduonnet.com/2004/12/08/stories/2004120815390300.htm.

¹¹³ The bio-diversity Act is progressive, but not fool-proof, FIN. EXPRESS, Apr. 30, 2007, available at http://www.financialexpress.com/news/The%20bio-diversity%20Act%20is%20progressive,%20but%20not%20fool-proof/106130/.

The Act develops rules for access to biological resources and associated knowledge by distinguishing between resident Indian nationals, on the one hand, and foreigners, foreign corporations or corporations with foreign shareholding or under foreign management, foreign residents and Indian non-residents on the other hand. The latter groupings require the approval of the National Biodiversity Authority to obtain biological resources occurring in India or associated knowledge for research or commercialisation or for bio-survey and utilisation (section 3). It is equally prohibited without approval of the NBA to transfer research results to foreigners or foreign residents, with certain exceptions for academic purposes and for certain collaborative research projects to be outlined in Central Government guidelines (sections 4 and 5). 114 The relevant guidelines for such collaborative projects have meanwhile been notified. 115 Importantly, the approval of the NBA is further required for any acquisition of intellectual property rights in or outside India, if the invention is based on research or information on a biological resource obtained from India. For patents, this is mitigated by the fact that the permission must be obtained before the sealing of the patent, but may come after acceptance of the patent by the patent authority (section 6(1)). Exempted are further applications for plant varieties regulated under the Plant Varieties Act (section 6(3)). The section provides the opportunity for the NBA to impose benefit sharing fees or royalties or conditions (section 6(2)).

The NBA largely determines any benefit-sharing conditions in accordance with mutually agreed terms and conditions between the applicants and local bodies concerned and benefit claimants (section 21(1)). While this implies a wide-ranging recognition of individually negotiated conditions, Rule 20 of the Biological Diversity Rules explains that "the quantum of benefits shall be mutually agreed upon between the persons applying for such approval and the Authority in consultation with local bodies and benefit claimers" (Rule 20(5)).

The BDA and the Rules empower the Authority also to impose far-reaching conditions, including the granting of joint ownership in intellectual property rights to the NBA itself or to the benefit claimants, technology transfer, requests for production or research and development (R&D) units in areas of the benefit claimants, the involvement of Indian scientists, benefit claimants and local people in R&D activities, the setting up of a venture capital fund for the benefit claimants or the payment of monetary compensation or non-monetary benefits to such claimants at the discretion

¹¹⁴ Verma, *supra* note 103, at 333.

¹¹⁵ National Biodiversity Authority, India - Notifications, http://www.nbaindia.org/notification.htm (last visited July 8, 2010). For an earlier critical expression of concerns over the effects of the Act on biodiversity research, *see also* K. D. Prathapan et al., *Biological Diversity Act* 2002: *Shadow of permitraj over research*, 91 CURRENT SCI. 1006 (2006).

of the NBA (section 21(2)). The formula for benefit-sharing shall be determined on a case-by-case basis and notified in the Official Gazette (Rule 20(1) and (3)). If the compensation or benefit sharing is paid in money, the NBA may direct these funds to individuals, groups or organisations that can be identified as the source of the resource or knowledge. If that is not possible, the benefits shall be deposited in the National Biodiversity Fund (section 21 (3), BDA, Rule 20(8), Biological Diversity Rules).

Indian citizens or corporations are treated differently under section 7. Indian citizens and corporations must give prior intimation to their relevant State Biodiversity Board to obtain biological resources for commercial utilisation or bio-survey and bio-utilisation. For local people and communities of the relevant area, growers and cultivators of biodiversity and for practitioners of indigenous medicine, even this requirement will be dispensed with. The SBBs are responsible for the granting of approval, where necessary, to Indian citizens for commercial utilisation or bio-survey/bio-utilisation and they also fulfil an advisory role to the state governments (section 23). For activities, which require only intimation to the SBB, the SBB may at its discretion prohibit or restrict such activities if it regards them as detrimental or contrary to the objectives of conservation and sustainable use of biodiversity or to the equitable sharing of benefits (section 24(2)). In other words, while commercial activities of foreigners are prohibited unless specifically approved, those of resident Indian nationals are mostly allowed unless specifically prohibited. It appears from sections 19(2) and 20(1), however, that even Indians must get approval to acquire intellectual property rights related to the resources/knowledge or to transfer such knowledge abroad.

The Act creates biodiversity funds at national, state and local levels for administration of benefits to claimants and community benefits, conservation purposes and management of heritage site. Some of the funds, however, may also be used for purposes of socio-economic development and to meet expenses incurred (sections 27, 32 and 44, BDA, Rule 20(9) Biological Diversity Rules). Under section 40, the Central Government after consultation with the Authority is empowered to exempt any items, including biological resources normally traded as commodities, from the provisions of the Act. The Act contains penalties for contraventions of the provisions governing access, knowledge transfer, acquisition of intellectual property rights and intimation to the SBB.

Apart from the concerns of local activists mentioned above, the Indian Biodiversity Act has also attracted criticism in the academic literature. First, the very lenient treatment of Indian citizens and especially companies and the limitations to knowledge holders vis-à-vis these local interests has

been noted. 116 Second, it has been noted that about 40 per cent of the world-wide accessions for food crops are in the collections of the Consultative Group for International Agricultural Research (CGIAR) and India is itself highly dependent on access to these resources and to resources from other regions. 117 Third, because of a lack of extraterritorial authority, the NBA cannot effectively monitor applications outside India 118 and it would neither have the time nor the resources to challenge patents in many foreign jurisdictions. 119 Fourth, the relationship between the discretionary decisions of the NBA on benefit-sharing and the agreements reached between applicants and knowledge holders remains unclear as does the relationship between the NBA and SBBs and the BMCs. 120 Fifth, local communities have not automatic right to the benefits, but depend on the direction of the funds by the authorities. 121 Sixth, benefit sharing and the formula for it needs fine tuning and the possibility of joint IP ownership as stipulated in section 21, BDA may hardly be acceptable to multinational companies. 122 Seventh, the legislation promotes a strong property rights framework under central control with little regard to common property arrangements. 123 And eighth, in spite of attempts to avoid overlaps with the plant varieties legislation, there clearly is such an overlap with regard to agro-biodiversity and related benefitsharing decision making. 124 One commentator concluded, therefore, that the Act "in practice does not provide effective measures for protection of biological resources and is heavily biased against the interests of tribal and local communities who are the guardians of associated knowledge." ¹²⁵ The lenient provisions for Indian nationals and especially for Indian industry "even seem to encourage commercial exploitation of resources rather than giving impetus to the conservation of biodiversity or to benefit-sharing with the local communities." ¹²⁶

¹¹⁶ Supra note 90, at 216; see also Rajesh Sagar, Intellectual Property, Benefit-Sharing and Traditional Knowledge: How Effective is the Indian Biological Diversity Act, 2002?, 8 J. WORLD INTELL. PROP. 383, 387-388 (2005); see also supra note 110, at 740; see also Verma, supra note 103, at 337-338 (in relation to the controversial benefit-sharing arrangements for the drug 'Jeevani' based on traditional knowledge provided by the Kani tribe of Kerala).

¹¹⁷ Supra note 90, at 216.

¹¹⁸ Verma, *supra* note 103, at 334.

¹¹⁹ Supra note 90, at 217 & 225; Sagar, supra note 116, at 391.

¹²⁰ Supra note 110, at 738.

¹²¹ Supra note 90, at 218; see also supra note 110, at 739; see also Verma, supra note 103, at 335.

¹²² Verma, *supra* note 103, at 335.

¹²³ Supra note 90, at 218; however, note the critical discussion of community intellectual property rights in Verma, supra note 103, at 335.

¹²⁴ Sagar, supra note 116, at 386-387; see also Verma, supra note 103, at 335; see also Ranjan, supra note 50, at 229.

¹²⁵ Sagar, supra note 116, at 400; see also Changes in Bio-Diversity Act sought, HINDU, Dec. 30, 2004, available at http://www.hinduonnet.com/2004/12/30/stories/2004123015730300.htm (appeal from over 200 panchayats and several NGOs to strengthen community control over bio-diversity).

¹²⁶ Id.

After the enactment of the BDA in February 2003, it took until 2005 until the necessary expert committees were formed and procedural guidelines were drafted. Meanwhile, the NBA has drafted and published on its website the application forms and standard agreements for access to biological resources and/or associated knowledge for commercial utilization, access for research/bio-survey and bio-utilisation, seeking intellectual property rights, transfer of research results and for third party transfer of bio-resources and/or associated knowledge. According to statistics on its website, the NBA approved from January 2006 to August 2008 twenty-four access applications, transfer of nine research results applications, two-hundred-and-sixty-six intellectual property rights applications, sixteen third party transfers and forty collaborative research projects under section 5, BDA. The agreement between NBA and the applicants has been signed for thirteen access applications, transfer of eight research results applications, thirty-three intellectual property rights applications and fourteen third-party transfer applications.

The Government of India is also undertaking major efforts to establish biodiversity registries and digital libraries to prevent patenting of Indian traditional knowledge abroad. These include the People's Biodiversity Registers, which are an important task for the Biodiversity Management Committees, and the Traditional Knowledge Digital (TKDL), which is currently focused on traditional medicine and medicinal plants. The TKDL has been translated into English, Spanish, German, French and Japanese and under a three-year agreement made available to patent examiners at the European Patent Office to assist with their prior art searches. Reportedly, prior art ascertained on the basis of the TKDL already prevented the patenting of a melon extract formulation, which is a traditional Indian method of treatment, for the treatment of leucoderma. The short period of only three weeks was contrasted favourably with the ten years it took Indian authorities to challenge the patents on neem and turmeric. It has also been reported that other developing countries wish to build similar databases and seek assistance from India.

¹²⁷ Looking after India's biodiversity, MANAGING INTELL. PROP., July-August 2005: Supplement – India IP Focus 2005, available at http://www.managingip.com/Article.aspx?ArticleID=1321448 (interview with K. Venkataraman – secretary to the National Biodiversity Authority, India).

¹²⁸ National Biodiversity Authority, India - Applications, http://www.nbaindia.org/applications/application.htm (last visited July 8, 2010); National Biodiversity Authority, India - Approvals,

http://www.nbaindia.org/approvals.htm (last visited July 8, 2010).

¹²⁹ National Biodiversity Authority, India - Status of Applications,

http://www.nbaindia.org/approvals/status approvals.htm (last visited July 8, 2010).

¹³⁰ See Verma, supra note 103, at 336.

¹³¹ Lex Orbis Intellectual Property Resource Centre - India Successfully Blocks Spanish patent on its Traditional Knowledge,

http://www.lexorbis.com/India_Successfully_Blocks_Spanish_patent_on_its_Traditional_Knowledge.html

4. The Seeds Bill

In 2004, the Indian Government introduced a new Seeds Bill to replace the Seeds Act of 1966. Since then it has generated much controversy. Government statements on the website of the Department of Agriculture and Cooperation explained the reasons for the new law. Among the more important reasons is the creation of a facilitative climate for growth of the seed industry, boosting of the export of seeds and encouragement of the import of useful germplasm and the creation of a conducive atmosphere for application of frontier sciences in varietal development and for enhanced investment in research and development. The latter reason refers especially to transgenic varieties, which are now included in the draft. The government points out that GM seeds are generally not notified under the previous Act. As the seeds are very costly and farmers have sometimes been cheated, there is a need for regulation and strengthening of testing and seed testing laboratories involved. The draft seeks to achieve this by widening the circle of institutions accredited to conduct agronomic trials and testing, which, besides public centres and universities, would also include private organisations and private seed testing laboratories.

Whereas under the current legislation only notified varieties have to be registered, all seeds for sale must be registered under the Seeds Bill. The Bill foresees Central and State Seed Committees as well as a Registration Sub-Committee to keep a National Register of Seeds. There are provisions for transgenic varieties and for fines and imprisonment for contravention of the Act and for providing false information.¹³⁵

Critics of the bill argue that traditional and small-scale farmers should be concerned in particular that it regulates not only the selling, keeping for sale, offering to sell, import or export of seed, but mentions in the same context also bartering, a typical manner of seed exchange among traditional farmers.¹³⁶ This, it is argued, has the potential to further limit the avenues for exchange of seeds.¹³⁷

(last visted July 8, 2010).

¹³² Lex Orbis Intellectual Property Resource Centre - MoU between India and US on IPR Protection, http://www.lexorbis.com/MoU_between_India_and_US_on_IPR_Protection.htm (last visited July 8, 2010).

¹³³ New Policies Initiation In Seed Sector - New Seeds Bill (Apr. 1, 2005),

http://agricoop.nic.in/PolicyIncentives/NewSeedBill.htm (last visited July 8, 2010).

¹³⁴ New Policies Initiation In Seed Sector – Use of Biotechnology in Agriculture (Apr. 1, 2005), http://www.agricoop.nic.in/PolicyIncentives/UseOfBiotechnology.htm (last visited July 8, 2010).

¹³⁵ For a detailed comparison between the provisions of the Bill and the 1966 Seeds Act, see M. R. Madhavan & Kaushiki Sanyal, Legislative Brief: The Seeds Bill, 2004 (2006), available at

http://www.prsindia.org/uploads/media/1167468389/legis1167477737_legislative_brief_seeds_bill.pdf.

¹³⁶ See, e.g., §§ 22(1), 25, 28(1), 38(b), 38(c), 38(d), Seeds Bill, 2004.

¹³⁷ Shiva, supra note 93.

The Bill has further been criticised for its potential contradictions to and undermining of the provisions of the Protection of Plant Varieties and Farmers' Rights Act. 138 For while the Seed Bill confirms the farmers' privilege that "nothing shall restrict the right of the farmer to save, use, exchange, share or sell his farm seeds and planting material", this comes with the restriction "except that he shall not sell such seed or planting material under a brand name or which does not conform to the minimum limit of germination, physical purity, genetic purity prescribed...". Critics point out that this could make farmers anxious about small local sales in village sales and could prevent the registration of their traditional varieties, which may not pass the required standards. While the Bill is concerned with compensation for farmers if commercial seeds do not perform to expected levels, it refers potential claimants to the Consumer Protection Act of 1986. However, this is a less straightforward avenue than under similar compensation provisions in the PPVFRA, in which the Protection of Plant Varieties and Farmers' Rights authority assesses the case and grants the compensation. This latter avenue would seem far preferable, particularly as the urban based consumer courts are not very accessible for farmers in rural areas. 141 Observers in the Indian media concluded, therefore, with regards to the Seeds Bill, 2004 that "public interest demands that its legal incongruities and farmer-unfriendly provisions are corrected before the Seeds Bill is passed by Parliament." The discussion may soon be back in Parliament, as the government is expected to table in the next session a report from the Parliamentary standing committee on agriculture on the Seeds Bill. 143

5. The Protection, Conservation and Effective Management of Traditional Knowledge Relating to Biological Diversity Rules, 2009

In early 2010, the NBA released a number of draft amendments and requested public comments, including on the Protection, Conservation and Effective Management of Traditional Knowledge

¹³⁸ Bala Ravi, Seeds of Trouble, HINDU, Mar. 8, 2005, available at

http://www.hinduonnet.com/thehindu/2005/03/08/stories/2005030801761000.htm.

¹³⁹ GRAIN & Devinder Sharma, *India's new Seed Bill*, SEEDLING, July 2005, *available at* http://www.grain.org/seedling_files/seed-05-07-5.pdf.

¹⁴⁰ See supra note 135; see also Shiva, supra note 93; see also id.

¹⁴¹ See supra note 138.

¹⁴² See supra note 138.

¹⁴³ MNCs will dominate if Seeds Bill adopted: Farmers Associations, BUS. STANDARD, June 29, 2009, available at http://www.business-standard.com/india/news/mncs-will-dominate-if-seeds-bill-adopted-farmers-associations/65912/on; Bhavdeep Kang, Why the US is so keen to sell Bt brinjal to India (Nov. 19, 2009), http://business.rediff.com/column/2009/nov/19/why-the-us-is-so-keen-to-sell-bt-brinjal-to-india.htm (last visited July 7, 2010).

Rules). 144 Relating to Biological Diversity Rules (subsequently Traditional Knowledge Commentators are intrigued that this sui generis legislation for traditional knowledge protection is not introduced as a Bill and as such subjected to parliamentary scrutiny, but as delegated legislation in the form of rules under the Biological Diversity Act of 2002. Given the broad scope of some of the provisions, the question has been raised whether this is constitutional. 145 The Traditional Knowledge provisions go significantly beyond and frequently contradict those of the Biological Diversity Act. The NBA has just collected public reactions to the Traditional Knowledge Rules. These reactions were collected jointly with those related to the further debates on an international regime on access and benefit sharing and on amendments to the Biological Diversity Act, 2002, and the Biological Diversity Rules, 2004. Since the parent legislation for the Traditional Knowledge Rules could also be amended, it is unclear at this stage how these various laws and rules will ultimately relate to each other and which form the Traditional Knowledge Rules will finally take. Nevertheless, a few preliminary comments can be offered. First, it is interesting to note that the Rules apply a very wide definition of 'traditional knowledge', which includes traditional cultural expressions. Thus, 'traditional knowledge' relates not only to "properties, uses and characteristics of plant and animal genetic resources; agriculture and healthcare practices, food preservation and processing techniques and devices developed from traditional materials", but also to "cultural expressions, products and practices such as weaving patterns, colours, dyes, pottery, painting, poetry, folklore, dance and music." Equally wide is the definition of beneficiaries belonging to a 'traditional community', which includes "families, people belonging to Scheduled Tribes as per Article 342 of the Constitution of India, and other notified tribal groups including nomadic tribes..." The inclusion of families shows that tradition is, quite rightly, not supposed to remain confined to tribal groups. However, in view of the definition of 'misuse of traditional knowledge' as "access to and/or use of traditional knowledge by persons not belonging to the traditional community" without license or in breach of licensing terms, it brings back the question how group/community membership is defined and who decides about membership. This is all the more important, because the Traditional Knowledge Rules differ from the regulations in the Biodiversity Act in that they provide for direct negotiations between a user (or 'accessor' in the terminology of the Rules) and a traditional community and for direct payment of the benefits to the traditional community.

Prashant Reddy, The National Biodiversity Authority invites comments on draft amendments (Feb. 2, 2010), http://spicyipindia.blogspot.com/2010/02/national-biodiversity-authority-invites.html (last visited July 7, 2010).

¹⁴⁵ Prashant Reddy, A Comment on the Vires of 'The Protection, Conservation and Effective Management of Traditional Knowledge relating to Biological Diversity Rules, 2009' (Feb. 15, 2010),

http://spicyipindia.blogspot.com/2010/02/comment-on-vires-of-protection.html (last visited July 7, 2010).

While the Rules in so far strengthen the role of the communities, the national and state authorities still have the final say in many instances, for example, if traditional knowledge is already in the public domain, not specifically owned by any particular community or is owned by communities spread out over more than three states. It gives the NBA decision-making powers over access by one traditional community to the knowledge of another community, if this is for earning their livelihood and not for commercial gain. It requires from communities to comply with the registration requirements of the Traditional Knowledge Register, if they want to receive benefits. Users, on the other hand, have to await the outcome of fairly complicated and potentially lengthy procedures, involving national and state authorities as well as local communities, to finally get access. These procedures include a potential waiting period of up to one year to allow states to set up State Biodiversity Boards and/or Biodiversity Management Committees, where they do not yet exist. Assessment further involves a report by such committees on such complicated matters as sustainability of resources, social and environmental implications and potential value of the knowledge as well as a resource management plan.

VIII

CONCLUSION

The last few decades have seen a shift from an understanding of agricultural and biological resources as the "common heritage of mankind" to an understanding where such resources are under the sovereign control of nation states. This has been accompanied by a strengthening of the intellectual property rights system for biological material in the wake of the WTO-TRIPS Agreement and more recently on the basis of bilateral Free Trade Agreements between developed and developing nations. The result has been a further shift in the agricultural sector of developing countries from public research institutions to private R&D. Under the circumstances, traditional knowledge and farmers' rights are defended as a crucial counterweight in societies that are still dependent on the farming sector.¹⁴⁶

The debate about traditional knowledge protection links up to a larger debate about approaches to the environment and to sustainable development in developing countries. Here, the failure of statist planning has led to a move away from top-down solutions to development and to environmental management and to a search for bottom-up approaches. At first, these were mainly

¹⁴⁶ Shiva, *supra* note 93; Janak Rana Ghose, *The Right to Save Seed* (Int'l Dev. Research Ctr., Rural Poverty and Environment Working Paper Series – Working Paper No. 13, 2003), *available at* http://www.idrc.ca/uploads/user-S/11205983131The_Right_To_Save_Seed.pdf.

seen in the form of privatisation and private monopoly rights, but more recently there is also a renewed interest in limited common property rights of communities and in a revitalisation of customary law systems.¹⁴⁷

This article has examined two examples from Asia for attempts to implement a system for traditional knowledge protection using a variety of intellectual property and sui generis mechanisms. However, there is a significant difference in the approaches used in the Philippines on the one hand and in India on the other hand. The Philippines case study presents an attempt at a bottomup approach focusing on the country's indigenous communities. Because the country inherited US administrative models for indigenous communities, it is the only country in East and Southeast Asia that appears not dissimilar in its approach to the settler societies of North and South America, Australia or New Zealand. Its legislation for the protection of indigenous peoples' rights and its regulations for access to biological resources were also the first in this part of Asia and, at the time, widely praised as model solutions. At the time the Philippines government departed from an ecological perspective inspired by the Rio Earth Summit. Subsequent developments, however, did not live up to the high hopes that the initial legislative measures had generated. For example, while the Indigenous Peoples' Rights Act gives recognition to 'community intellectual rights', their concrete implementation has been lacking. Because of its link to issues of indigenous selfdetermination and land claims, the legislation soon came under pressure from powerful mining interests. Further, the holistic understanding of 'community intellectual rights' did not lend itself to any concrete implementation in the form of mainstream intellectual property laws. What remains is a centrally administered bio prospecting and access legislation safeguarding the need for prior informed consent from and benefit-sharing with indigenous communities as far as their areas are concerned. The results thus far have been disappointing, because no applications were submitted since the bio prospecting rules were revised in 2005 indicating that their stricter conditions may scare off potential applicants.

In contrast to the Philippines, India has from the outset taken a much more centralist approach to traditional knowledge. India belongs to a group of countries that have resisted attempts by international organisations to focus on 'indigenous people' and prefers to speak of 'local and indigenous communities.' Not surprisingly then, and also in view of the differences in economic structure between India and the Philippines, the focus of the debate in India is on agricultural biodiversity and on farming, with farmers' rights featuring particularly prominently in the

¹⁴⁷ See, e.g., supra note 53, at 245 & 338.

Protection of Plant Varieties and Farmers' Rights Act. While this Act allows for the registration of farmers' varieties, it falls short of establishing a real property right of farmers to their knowledge and instead makes them dependent on the national authority for most benefit sharing and compensation claims. Confirming the nationalist and centralist approach further, the Biological Diversity Act distinguishes sharply between foreign and Indian national access to biological resources and leaves local communities with little protection against the latter group of users and with little immediate influence in negotiations about benefit-sharing. This would change to some extent, if the Traditional Knowledge Rules drafted under the Biodiversity Act in 2009 and currently presented for public discussion would find approval. The Rules decentralise the negotiation process over access and benefit sharing and strengthen in so far the role of communities. Otherwise, however, national and state authorities retain a central role and the procedures are overall quite complicated and bureaucratic, which in the end could put off potential users and traditional communities alike from using the system.

Developing countries seem torn between a desire to develop high tech and biotechnology industries and a need to look after the interests of a large traditional farming sector. It is in this latter context that traditional knowledge has received great significance and raised hopes that so far have rarely been justified by the relatively meagre benefits. In fact, traditional knowledge may only assist in safeguarding the traditional farming sector or biodiversity, if it is accompanied by policy decisions that go far beyond the relatively narrow field of intellectual property. It seems further important that the focus is redirected towards the original conservationist goals of the CBD. Thus, if royalties for the use of traditional knowledge are collected at the national or state level, then it is important that such benefits are passed on to those communities at the grassroots level that are regarded as the most important stakeholders in the new 'bottom up' environmental protection models. It is further important to gain a realistic understanding of the expectations of users and those who are seeking access, so that access regulations do not become overly complicated and unwieldy for users and knowledge holders alike. The traditional knowledge discussion has certainly sensitised IP academics and practitioners to imbalances in the system that require correction. The successful prevention of a traditional knowledge based patent with prior art information from the Indian TKDL shows that this adjustment process is making progress.

Beyond this, the traditional knowledge debate has put intellectual property into an unfamiliar environment where it is no longer concerned with clearly delineated territorial rights in the modern sector of nation states. The debate takes place at the grassroots level, it involves local

development plans as well as communities and their customary laws and it is messy and intensely political. Here, in discussions about decentralisation, environmental problems and new development paradigms, new rights discourses emerge that use elements from customary law and from different traditions. In how far all of this will affect intellectual property law remains to be seen, but as increasingly influential developing countries decentralise, intellectual property will to some extent have to adjust or risk to become marginalised outside of the commercial enclaves of big cities.