

# Access and Benefit Sharing Systems: An Overview of the Issues and the Regulation

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March 2003

## ABSTRACT

This study aims to illustrate the issues at hand within Access and Benefit Sharing (ABS) mechanisms for Plant and Genetic Resources (PGR). An overview of the main components and terminology of ABS is presented, along with a description of the current international policy instruments. Analysis of ABS experiences via an example of the Kani Tribe in the state of Kerala, India follows, along with a consideration of the relevant national regulatory frameworks on ABS that have arisen in India as a result of their obligations in the international arena. The efficacy of these national frameworks is considered in light of the Kani example. The main conclusions are that attempts at protecting PGR via Biodiversity Registers may not be possible in light of prior art requirements, and that efforts at the national level require strong coordination with other national instruments to be effective.

## 1. AN INTRODUCTION

Access and Benefit Sharing (ABS) issues within the context of plant and genetic resources (PGR) comprise a substantial portion of the current debates regarding the formation and adoption of intellectual property regulatory frameworks. Access in this context refers to the ability of individuals to acquire or use genetic resources found in PGR for a multitude of purposes, not limited to commercial application. However, benefit-sharing issues are explicitly within the context of commercialization; financial incentives to access PGR for commercialization is substantial, particularly if there is sufficient demand for the resultant product. Yet, if the resource was originally held by someone other than the party who successfully commercialized it concerns arise as to whether or not those who originally held the resource are to receive a portion of the monetary (or non-monetary) benefits accrued from its sale. The relevance of access and benefit sharing is significant due to the large amount of genetic resources that have commercial viability in a number of formal sectors, including (but not necessarily limited to) pharmaceuticals, biotechnology, seed, horticulture, botanical medicine, cosmetic and personal care and food and beverage sectors (ten Kate and Laird 1999: 1). Newman and Laird (1999) have found, for instance, that of the 25 best selling drugs worldwide in 1997, 42 percent of the sales of these drugs were of those derived from PGR. Similarly, Grifo et al (1997) considered the top 150 drugs prescribed in the United States and found that 57 percent of the prescriptions filed for these drugs were for pharmaceuticals that contained at least one major compound "derived or patterned after compounds from biological diversity".

This commercial aspect of PGR has been the driving force behind the search for as yet undiscovered (at least by industry) genetic resources that may have significant commercial potential. However, in this search for genetic resources, the methodology by which those searching for genetic resources for commercial purposes has been an issue of contention. More specifically, the concerns relate to how these resources are acquired, and what the formal relationship between those who have historically held this knowledge and those parties who wish to seek out the knowledge for commercial ends is. The majority of the genetic resources that are of interest to industry are located between the two tropics. Myers et al (2001) have shown that 44% of all species of higher plants are confined to 25 “hotspots” of biological diversity. These 25 areas only account for 1.4% of available land on Earth. While not all the areas are within the tropics, those areas within the tropics have the richest concentration of biodiversity. Much of the focus of these so-called bioprospectors has been in these areas.

#### BOX 1: Of Prospectors and Pirates

The term “bioprospector” refers to those individuals or parties who actively seek out genetic resources found primarily in plants, but also in animals and micro organisms, with the aim of isolating a compound or active ingredient and marketing the resultant product as a market good. Posey and Dutfield (1996: 14) define bioprospecting as the search for “commercially valuable genetic and biochemical resources, with particular reference to the pharmaceutical, biotechnological and agricultural industries”. Actively searching for genetic resources for these industries is not necessarily new; however, advances in technology have allowed researchers to isolate those elements of genetic resources that are of particular interest much more efficiently. The result has been a significant increase in the research and development of new products, with individuals often targeting indigenous communities for information on how the plant varieties found in and around their communities have been used for their benefit<sup>1</sup>.

It is in this context that the term “biopiracy” has come into use. Implicit in the term is the notion that something is being taken from somebody else without the consent of the party originally owning the good, or indeed by blatant thievery. The context of the term is within experiences where genetic resources have been acquired from one country and then subject to private ownership via an intellectual property right, often a patent, in another country. The ETC Group defines biopiracy as “the appropriation of the knowledge and genetic resources of farming and indigenous communities by individuals or institutions seeking exclusive monopoly control (usually patents or plant breeders rights) over these resources and knowledge”. The Commission on Intellectual Property Rights (2002: 74) identifies the following two broad delineations of what constitutes biopiracy:

**The Granting Of “Wrong” Patents:** These are patents on knowledge that are neither novel nor non-obvious, in the sense that the knowledge has previously existed and been utilized in indigenous communities. In these patents, the fact that the knowledge exists could not be established by the patent granting body, as the information was not in written form, though it may have existed by word of mouth for generations in the community from where it originated. The “invention” is determined because of it being new or novel, as there was no written proof to convince the authority otherwise.

**The Granting Of “Right” Patents:** These are patents that are accorded legally within the context of the law of sovereign nations on traditional knowledge. While they are legal, they may be contested due to patent standards being insufficiently stringent to require a thorough international search to establish that the knowledge did not exist previously. Also, they may be contentious due to the fact that no prior informed consent was obtained from the communities originally holding the resource before it was extracted, and no mechanisms for the sharing of benefits arising out of commercialization were established.

While in both these cases the patent may be accorded to the “inventor”, some argue that acquiring knowledge that was within the realm of common knowledge previous to the IPR being conferred on it is theft, and those parties who acquire the information, even if acting within the confines of extant law, are biopirates. The knowledge may have existed for years, but the act of isolating the formal properties of, for instance, a plant, arguably adds sufficient value to the plant so as to make it worthy of private ownership; it is this that is the basis of contention. Of course, the benefits of private ownership of this knowledge can be huge, as a patent essentially confers monopoly rights to the owner, who, provided the knowledge

<sup>1</sup> For an idea of what kind of biological resources have recently been acquired by formal industry, refer to GRAIN and Kalpavriksh (2002: 8).

holds elements that can be marketed successfully, can potentially make millions in profit. Whether or not the original holders of the knowledge are given any portion of these profits depends on the existence of an agreement that establishes the sharing of benefits, which may or may not be the case.

The concerns regarding the commercialization of such knowledge is by no means limited to benefit sharing arrangements; the deeper issue at hand is whether or not biodiversity should even be considered as something that can be owned by individuals via an intellectual property right. Granted, most people would agree that if a genetic compound exists in nature that could potentially save the lives of people all over the world, then efforts to ensure the availability of the resource via the pharmaceutical industry are warranted. The concerns, however, relate to the costs, both in terms of financial metrics, but also in terms of the value that the resource is given in the community that holds it, which is much more difficult to ascertain. There are internationally recognized (if not internationally ratified) instruments that attempt to ensure that if elements of our biodiversity are to be subject to private ownership, proper measures are to be taken to arrive at an agreement that is acceptable to both parties; those who desire the resource and those who own them. Yet, these instruments are often at odds with each other, and it is far from a straightforward exercise to implement these instruments at a national level taking into consideration the distinct and unique realities countries face.

The purpose of this exploration then is to provide an overview of the current “state of play” regarding ABS issues, in terms of both identifying and evaluating the relevant policy instruments, but also in providing insight on how this policy affects the communities that hold the knowledge. First, an identification must be made of what are the underlying issues behind ABS, both from a commercial standpoint, but also from a broader focus including how the commercialization of these resources ultimately will affect the welfare and livelihoods of the keepers of these resources. Section two begins with a discussion of what the issues are, presented within the context of what any agreement required before resources are to be considered for exchange and potential commercialization should contain. Section three follows with a more detailed analysis of the international regulatory frameworks that exist within the context of ABS issues. This will serve to provide a sense of what sovereign states are then to do to implement the regulation. Section four presents a case study of the Kani Tribe of southern India to illustrate more clearly how the issues relate to indigenous communities. With the experiences of those who hold the resources detailed, section five follows with an exploration of the relevant domestic policy in India that has arisen out of obligations accepted at an international level, with reference to the case study provided in the preceding section. Finally, the sixth section concludes.

## 2. THE ISSUES

To consider the issues that are of primary importance within the context of ABS, we will consider the relevant aspects of what many debate should be included in any regulatory framework on ABS. By doing so, we will inevitably touch on why these issues are important outside of the explicit context of regulatory frameworks, and more to the driving reasons behind why they are being debated. That is, while the architecture for the forthcoming analysis is based on regulatory frameworks, the resulting analysis is rooted in what concerns the primary holders of PGR.

### 2.1 WHAT CONSTITUTES A PATENT?

If resources are to be appropriated from communities for potential commercial purposes, there is a strong likelihood based on past experiences that the isolated chemical compound that comprises the base of the commercial embodiment of the resource may become a privately owned resource via some intellectual property right (IPR) mechanism, most often a patent. The basis of a patent being granted is based on the resource being **useful, novel** and **non-obvious**. Usefulness implies having industrial application, novelty implies not previously existing in the public domain, and the non-obvious criterion implies that the idea must be “not obvious to a person skilled in the technology and more inventive than mere discovery of what already exists in nature (such as a gene with no known function)” (Posey and Dutfield 1996: 77). Non-obviousness is also often referred to as the “inventive step”.

Clearly, the first criterion of being useful is an obvious incentive for a firm to pursue a patent, and it is generally clear that if a compound has been isolated for commercial purposes, then it must be useful in this sense. However, the second and third criteria are contentious in light of the number of patents recently awarded to resources that have been used by communities for many years. The criterion of novelty, as that of usefulness, seems intuitive. However, the term novelty in the context of patents does not imply what one would generally assume in everyday knowledge. One only has to prove that the resource is novel, and precisely how to do so varies among jurisdictions. The basic premise that exists among all jurisdiction however is that the only factor that can really challenge novelty is **prior art**. Prior art relates to dissemination of the usage of the resource. More specifically, prior art exists to alert those potentially seeking to invoke a patent on a resource of knowledge of the resource previously existing in the public domain.

This dissemination is generally required to be in print form, but again, this varies among jurisdictions. For instance, the US considers sources of prior art to be “written texts, databases, published herbarium specimen (in the case of plant patents) or other sources, or when it is provided by the applicant as part of his disclosure obligation” (CIEL 1999). On the other hand, Japan recognizes prior art if found “through public telecommunication lines in Japan or elsewhere”, which could conceivably include texts found on the Internet (Ruiz 2002). The EU lies somewhere in between, specifying acceptable prior art along similar lines as the US, but also inclusive of “non-patent literature” (EPO 2002). The point being, that before any patent warranting authority actually gives a patent, the authority must make an international search to determine whether or not the novelty criterion can be defeated via proof of prior art. The question however, is what really constitutes prior art.

Given the wide range of interpretations of what prior art really means among those developed countries that file the vast majority of patents worldwide (i.e. the US, EU and Japan), what is required for developing countries is an indication of how resources within their own communities can be shown to constitute the prior art. Much attention as of late has been devoted to prior art databases. The purpose of these databases is to provide evidence of prior art by providing a record of the fact that these resources have indeed been within the public domain. Yet, given the explicit definitions provided by the EU, US and Japan, it is debatable as to whether these types of databases can really constitute the prior art in those jurisdictions. Moreover, it is not clear as to whether or not a prior art database will truly serve the best interests of those holding the resources.

As mentioned previously, various jurisdictions consider the form of acceptable prior art in different ways, though generally what is required is a written record. However, this is not to say that merely stating that a given resource is capable of facilitating a specific outcome and recording it in written form is sufficient to establish prior art. Dutfield (2002: 27) considers Japan as a case study; in particular, he considers the implications of the examination guidelines developed by the Japan Patent Office. The guidelines state, “an invention described in a

publication means an invention which a person skilled in the art can identify on the basis of matters both described and essentially described, though not literally, in a publication". What this means is that any novelty-defeating prior art has to be described in such a manner as to guide someone "skilled in the art" (i.e. someone capable of understanding the technical specifications of the patent) to create and utilize the resource. This can be construed as meaning that the description of the resource must be technical in nature; this indicates that merely stating that the given resources exists, has been used for a specified amount of time by certain individuals, and has particular properties described in a qualitative sense will more than likely be insufficient to constitute the prior art.

The particular format of the database and the syntax of how resources are described in the database is thus of extreme importance. Indeed, if databases are not developed in such a way as to enable someone skilled in the art to fully comprehend the characteristics of the resource, thus establishing the resource as being in the public domain and constituting the prior art, then documenting the resource may actually have the potential to further jeopardize the resource in question. If a resource is entered in a database in terms that describe what it can be used for in non-technical terms (i.e. medicinal uses or agricultural application) and the database is publicly available, it could potentially be used by those seeking commercial uses of PGR as a wish list of sorts. Given that novelty-defeating prior art must be described in a particular manner, not anything described as such could be considered unprotected. A firm could theoretically isolate the particular elements of the resource that are of commercial usage, acquire a patent on it, and market it. Assuming novelty requirements are along the lines of those adhered to by the US, EU and Japan, then the acquisition of a patent by parties within these jurisdictions is a distinct possibility if the prior art is not defined along the lines prescribed by them. As a corollary to this potential outcome, there has been debate as to whether or not these databases should be made publicly available at all.

## 2.2 PRIOR INFORMED CONSENT, FULL DISCLOSURE AND MATERIAL TRANSFER AGREEMENTS

**Prior informed consent** (PIC) and **material transfer agreements** (MTAs) are instrumental in any agreement relating to access and benefit sharing issues, as they together formulate a potential strategy in determining the terms by which genetic resources are to be transferred from one party to another. There are many arguments stating that the granting of any patent should be legally conditional on two factors; PIC and **full disclosure** of where the resources were sourced from, or the geographic origin of the resource. The rationale is straightforward; if it is clearly stated where the resources came from and whether or not the original holders had agreed to provide them to the interested party, disputes regarding biopiracy can be avoided.

The concept of PIC is not new, and has been considered in a legal context mainly within the realm of the parties consenting to the transboundary movement of hazardous wastes (Hardison 2000: 1). The rationale for PIC is to allow for any transfer of resources to be undertaken under a set of explicit circumstances; more specifically, it ideally provides for the "green light" on whether or not resources are to be transferred or not. In terms of regulatory frameworks, current debates relating to PIC stem from their inclusion in Article 15.5 and 19.3 of the Convention on Biological Diversity (CBD). In their guide to the CBD, Glowka et al (1994) define PIC as:

(1) consent of the Contracting Party which is the genetic resource provider, (2) based on information provided by the potential genetic resource user, (3) prior to consent for access being granted...the PIC requirement gives

a Contracting Party the authority to require a potential genetic resources user – whether another Party or, for example, a collector or company in the private sector – not only to gain its authorization before accessing genetic resources within its jurisdiction, but also to require the potential user to outline the implications of access by, among other things, specifying how and by whom the genetic resources will be subsequently used. This information, or lack of information, may be important for the provider to decide whether, and on what terms, to grant access.

The rationale then is to ensure that if resources are to be exchanged across boundaries, they will mobilize only if there exists an agreement or statement that ensures that those originally holding the resource are indeed aware and in agreement that the resource can be provided to an outside party. It is, in essence, to recognize those original holders as the keepers of the resource by ensuring that their permission has been granted before any resources are taken (or provided) by them. The application of PIC within the context of Article 19.3 is not such a leap from previous interpretations of PIC, as this article deals with biosafety issues. The contentious aspects of PIC are more related to Article 15.5, which deals with PGR. The need for regulation is clear; the transfer of PGR from developing countries are extremely hard to track as it could be as small as a letter envelope, and there exists very little in the form of legislation at national levels to regulate this flow. This is, however, changing due to the terms of reference provided by the CBD and the legally binding obligation of CBD member states to “endeavour” to create such legislation<sup>2</sup>.

While PIC exists for resource holders to allow the transfer of resources, MTAs are more explicit in creating a mechanism to determine how much the resources are worth in their raw form, either in monetary or non-monetary terms. Posey and Dutfield (1996: 68) define MTAs as those agreements that “establish standards for the transfer of biological resources for research and possible commercialization in exchange for benefits to the party recognized as the supplier...In exchange, MTAs usually grant the recipient of the material the right to apply for patents if any of the material has commercial potential”. Generally, these agreements are implemented by assuring the supplier a fixed percentage of the revenues acquired from the commercialization of a product that had resulted from the raw genetic material provided, combined with a fixed amount for the bulk of all genetic resources accessed. The actual remuneration varies from agreement to agreement, as do the precise terms of the remuneration. While the precise details of agreements within intermediary institutions (i.e. botanical gardens, gene banks) are often publicly available, those between the private sector and ad their suppliers are generally confidential. Thus, it is difficult to ascertain what best practices for MTAs entail. To date, very few firms in the private sector have developed their own codes of conduct for MTAs that would be CBD compliant (ken Tate and Laird 2002).

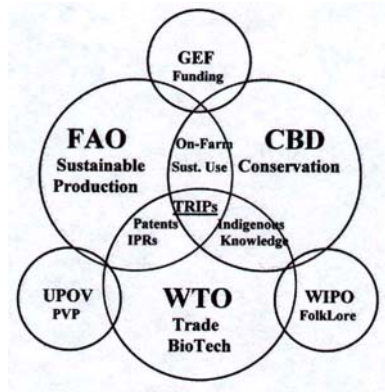
### 3. REGULATORY FRAMEWORKS

By considering what the surrounding architecture is regarding policy, we can gain a better understanding of what initiatives currently exist within intergovernmental bodies such as the UN (i.e. the FAO, UNEP and WIPO), as well as within the multilateral trading system (i.e. the WTO and more specifically, TRIPS). The interaction between international regulatory frameworks is complex and rich with interlinkages.

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<sup>2</sup> We will consider the CBD in more detail in section 3.1.

Figure 1: The Interlinkages of International Regulatory Frameworks on ABS



While the ultimate purpose of a multilateral trading system is to facilitate the creation of rules that apply to all uniformly, we will see that there are discrepancies between the current status of the two main paradigms (i.e. the United Nations and the World Trade Organization) in their treatment of the issues.

### 3.1 THE CONVENTION ON BIOLOGICAL DIVERSITY

The formalization of concerns relating to ABS can be traced back to the 1992 Earth Summit in Rio de Janeiro, with the adoption of the Convention on Biodiversity (CBD). Of course, the issues predate the CBD, but the convention was the first to explicitly state its relevance within the context of PGR in an international framework. That said however, the CBD, while legally binding, does not serve as a substitute for national legislation. It is a terms of reference or best practice, and it is hoped that CBD member states will undertake reforms within their national legislation to become more in line with what the CBD outlines. In essence, what the CBD achieved is to facilitate a shift from the common opinion that genetic resources are part of the common heritage of humanity to a regime that recognizes these resources as being subject to the sovereign ownership of the nations that hold them. The main objectives of the CBD are threefold. They are:

- The conservation of biological diversity;
- The sustainable use of its components;
- The fair and equitable use of the benefits arising out of the utilization of genetic resources.

Of these three, the third is particularly relevant to our current discussion. In particular, Article 15 is of significance here, as it refers to ABS issues explicitly. The Article states, among other things, that:

- Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.
- Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.

- Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.

The sixth meeting of the conference of parties to the CBD in April 2002 (COP 6) deliberated on the interpretation of article 15, and arrived at Decision VI/24. This decision brought forth the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization. The Bonn Guidelines are voluntary, but do comprise the first widely accepted criteria for the licensing of access to genetic resources and they are expected to be influential in the formation of national legislature. The most salient provisions of the guidelines are (Vivas 2002):

- The facilitation of prior informed consent of both the national government of the country of origin of the resource for transmittal as well as indigenous and local communities;
- The development of mutually agreed terms to facilitate legal certainty and the minimization of cost;
- The specification of non-monetary and/or monetary benefits the collector will provide, and whether, and under what conditions, the collector may transfer the collected genetic resources to another party.

Appendix I of the Guidelines offers a detailed list of provisions that should be included in any MTA, which is relevant considering one of the goals of the Guidelines is to facilitate a harmonization of the way that MTAs are created. However, this is not to say that these rules are exhaustive. Indeed, when one considers the wide variety of circumstances that exist regarding how communities hold these resources and in identifying exactly who is the true holder, any set of guidelines must be considered as being, at the most, suggestive.

Interestingly, in the section of the guidelines that refers to its relationship with other “relevant international regimes, only the Food and Agriculture Organization (FAO) and the World Intellectual Property Organization (WIPO) are mentioned; there is no mention of the World Trade Organization (WTO). The Bonn Guidelines seek to link issues relating to ABS with IPRs, as well as issues relating to genetic resources and traditional knowledge, yet a link with the multilateral trading system that arguably is at the heart of current concerns regarding the legislation of access to genetic resources in developing countries is missing. This is not entirely surprising however, given that the scope of the guidelines is limited to ABS issues, which are nowhere to be found in TRIPS to begin with.

The CBD has received the bulk of attention regarding the implementation of ABS related provisions in national legislation, as it is the only international agreement that explicitly states the requirement for member states to incorporate ABS concerns within their national legislation. Yet, as it ultimately can only act as a terms of reference, we need to consider what agreements exist that act in a more prescriptive fashion.

### 3.2 THE WORLD TRADE ORGANIZATION

The WTO is unique in the sense that it is prescriptive rather than proscriptive. That is, the 15 agreements that comprise the WTO lay down a set of rules that all 145 member states are to adhere to, rather than stating what cannot be done (WTO 2003a). This is a somewhat subtle but crucial distinction; while a prescriptive system exists to control the means by which a task is completed, a proscriptive system prohibits certain actions. The precursor to the WTO, the General Agreement on Tariffs and Trade (GATT) was more proscriptive in nature. What this

implies is that the 15 agreements provide minimum standards that all member states are to meet. Of these 15 agreements, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is of particular relevance to our discussion. The WTO (2003b) considers TRIPS as addressing five main issues. They are:

- How basic principles of the trading system and other international intellectual property agreements should be applied;
- How to give adequate protection to intellectual property rights;
- How countries should enforce those rights adequately in their own territories;
- How to settle disputes on intellectual property between members of the WTO;
- Special transitional arrangements during the period when the new system is being introduced.

Clearly, the CBD and TRIPS have distinct and different (though not necessarily opposing) objectives. Member states are to adhere to the minimum standards set forth by TRIPS, and are required to reform their own IPR regulation to conform by these standards. Upon its adoption in January 1995, developing countries were initially given until January 1, 2000 to implement these changes. However, as of June 2002, of the 112 developing countries that are party to TRIPS, only 30 have enacted *sui generis* legislation (GRAIN 2002a). This is due to a number of reasons, not limited to the fact that the task itself is gargantuan, considering that many countries would be starting from scratch.

Within TRIPS, there are a number of Articles that have received attention as of late in debated relating to ABS issues. Perhaps the most contentious is Article 27.3 (b). The Article states that members may exclude from patentability:

plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Most debate on this article has focused on the term *sui generis* and the implications of what the terms means. The term itself is Latin for unique or without equal; the implications of this are that member states, while required to provide some sort of system to protect plant varieties, have the choice of either a patent system, or something else entirely, with the only requirement that it is "effective". Moreover, while member states can exclude plants and animals from patentability, the exclusion does not apply to micro organisms. This is to say that while an entire variety of plant can be excluded, perhaps a particular genetic component of the plant can be protected via a patent. This of course raises the question of whether or not simply isolating a particular genetic resource from a plant then differentiates it from a plant, thereby enabling it to fit within the realm of what is patentable, but ultimately, this is a distinction that national governments are to make for themselves (CIPR 2002).

The lacking clarity that surrounds Article 27.3 (b) has led to a review of the Article to establish precisely what the distinction are between plants and animals on the one hand, and micro-organisms on the other, and the difference between essentially biological processes and microbiological processes, as well on more clarification on what "essential" means (Oh 2001). This process began in 1999 and is still currently underway. More recently, the EU has submitted

a concept paper on the review of Article 27.3 (b); this paper is worth mentioning as it strives to highlight how TRIPS and the CBD are related and how the two relate to the protection of traditional knowledge and folklore (EU 2002). The position of the EU is that the Article does not require any further amendments, as it arguably leaves sufficient room to suit developing countries interests via the *sui generis* option. This paper, submitted to the WTO in September 2002, is considered by many to be a response to a statement submitted by the Brazilian mission and circulated to TRIPS council members in June 2002<sup>3</sup>. In it, it is argued that the fact that TRIPS allows for patents while the CBD promotes sovereign rights over biological resources is indicative of a distinct asymmetry. Moreover, TRIPS provides no mention of PIC issues, which is, as we have seen, of central importance within the Bonn Guidelines. Finally, it is argued that TRIPS offers no provisions to prevent biopiracy; that is, there is not mention of how TRIPS deals with issues relating to circumstances where the genetic resources of one country are being patented in another. Ultimately, the paper called for an amendment of 27.3 (b) to ensure that the awarding of a patent should be conditional on:

- Disclosure of the source and country of origin of the biological resource and of the traditional knowledge used in the invention;
- Evidence of prior informed consent through approval of authorities under the relevant national regimes; and
- Evidence of fair and equitable benefit sharing under the national regime of the country of origin.

Of course, this is all stated within the Bonn Guidelines, but is very much lacking in TRIPS. The opinion of the EU in their paper is that TRIPS offers room to allow for national legislation to take into account these concerns via the *sui generis* option. The review continues, and these issues are at the centre of the debate.

Given that there is flexibility then within TRIPS, it is possible that member states can enact *sui generis* legislation that does take ABS issues into consideration. Indeed, it is considered that Article 15 of the CBD and the Bonn Guidelines in particular should be used as the normative framework to develop *sui generis* options. Note however, that much of the debate surrounding Article 27.3 (b) has related to what can and cannot be patentable. This is not to say, however, that ABS issues have not formed part of this debate. While access to a resource does not necessarily imply that a patent mechanism will be invoked, access more often than not will result in some sort of private ownership conferred to the resource. Recall that most MTAs result in access with private protection in return. So, while the concerns surrounding Article 27.3 (b) may have initially been focused primarily on definitions (i.e. what is “effective”, what does *sui generis* mean) more recent debates have focused on wider breadth of issues, and how the *sui generis* option can incorporate these concerns.

### 3.3 THE FOOD AND AGRICULTURE ORGANIZATION

The International Treaty on Plant and Genetic Resources for Food and Agriculture culminated in November 2001 after almost seven years of negotiations<sup>4</sup>. The Treaty is unique; its main objective is the “conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security<sup>5</sup>.” The treaty

<sup>3</sup> The paper was submitted by Brazil on behalf of China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia and Zimbabwe.

<sup>4</sup> For the sake of brevity, we will refer to the ITPGFRA simply as the Seed Treaty from this point onwards.

<sup>5</sup> Refer to Article 1.1 of the Seed Treaty, which can be found at <http://www.ukabc.org/ITPGRe.pdf>.

also establishes a multilateral system of access and benefit sharing for plant genetic resources for 64 food crops; these crops were chosen as they account for approximately 85% of global human nutrition (ETC 2001a)<sup>6</sup>. It proposes to achieve this through “information exchange, technology transfer, capacity-building, and the mandatory sharing of the monetary and other benefits of commercialization of products incorporating material accessed from the Multilateral System” (FAO 2003). This list broadly applies to all germplasm held by the contracting states as per the list, but also applies to PGR held *ex situ* in the collections held by the International Agricultural Research Centres (IARCs) of the Consultative Group on International Agricultural Research (CGIAR). However, access within the multilateral system is limited. Only those wishing to access PGR for “research, breeding, and training for food and agriculture are permitted”. Those wishing to use PGR within the multilateral system for “chemical, pharmaceutical and/or other non-food/feed industrial uses” are not allowed access.

The Seed Treaty is of particular relevance due to the multilateral system of ABS that it allows for. Article 12.4 of the treaty refers to a

standard material transfer agreement, which shall be adopted by the Governing Body and...[will] contain the benefit sharing provisions set forth in Article 13.2 (d) ii and other relevant provisions of this treaty, and the provision that the recipient of the plant genetic resources for food and agriculture shall require that the conditions of the MTA shall apply to the transfer of plant genetic resources for food and agriculture to another person or entity, as well as to any subsequent transfers of those plant genetic resources for food and agriculture.

What this essentially means is that if a signatory of the seed treaty wishes to access one of the resource outlined in the 64 plants identified, then the party is subject to pay an equitable share of the benefits arising from the commercialization of that resource. The exact amount will be determined by Article 19.3 (f), which outlines that the Governing body must establish “an appropriate mechanism” to determine these amounts. Of course, this payment is not required for resources that have previously been determined to be available without restriction; in such a case, the treaty can only “encourage” payment (ETC 2001).

Concerns have been raised concerning which food crops have been included within the 64 that the Seed Treaty considers. The ETC Group (2001) provides an interesting analysis:

Much depends on where you are hungry. If you are hungry in South Asia or the Middle East for example, you will not be happy to learn that “minor millets” have been kept off the list. If you are hungry in Sub-Saharan Africa, that absence of cassava’s wild relatives – the ones that scientists are trying to use to increase crop protein – is certainly bad news. If you are among the world’s pastoralists – always among the poorest and most exploited – then the absence of almost all the tropical forages from the list means that just about nobody is going to be doing any breeding work for you in the years ahead. Then there are some major crops that have been kept off. Soybeans, groundnuts, and sugarcane are excluded. Most vegetables are excluded. In some cases, the commercial potential for bilateral deals for specialist germplasm makes it understandable that certain material is being withheld.

It is not explicitly clear why these particular crops were isolated in this list, though many (including the ETC Group) argue that vested interests regarding the commercial viability of certain crops have led to their being included in the list, and have precluded any concerns regarding food security and the maintenance of biodiversity (ETC 2001b).

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<sup>6</sup> For the full list of crops, refer to ETC (2001b), p. 6.

Another criticism has been the treatment of Farmers' Rights within the Treaty<sup>7</sup>. The relevance of Farmers' Rights to our discussion relates to the threat that imported seed may have on the maintenance and existence of varieties currently held by farmers, which ultimately threatens biodiversity as a whole<sup>8</sup>. Rather than presenting Farmers' Rights within the context of the International Human Rights mechanism as outlined by the UN, the Seed Treaty has relegated them to being subject to national legislation<sup>9</sup>. Article 9.3 states that "nothing in this Article shall be interpreted to limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate." Thus while the Seed Treaty is legally binding, ultimately the decision to implement Farmers' Rights at the domestic level lies squarely on the shoulders of sovereign states, who may or may not choose to enact legislation that strengthens these rights. Moreover, other domestic legislation may place more stringent IPR mechanisms before Farmers' Rights, thus making these rights impossible to implement. These rights may be superseded due to the primacy of TRIPS compliant standards for IPR protection adopted by WTO member states, but in the future may also be marginalized by the ongoing reforms taking place in WIPO.

### 3.4 THE WORLD INTELLECTUAL PROPERTY ORGANIZATION

The World Intellectual Property Organization (WIPO) is in a somewhat curious position. The relevance of the organization diminished considerably after the implementation of TRIPS as the one international agreement relating to Intellectual Property Rights. Because WIPO essentially acts as a organization that dictates procedure rather than law, its relevance in current debates has been overshadowed by TRIPS. WIPO in itself is an administrative treaty only; it has 129 contacting parties, the majority of which are developing countries. However, within the context of ABS issues WIPO is indeed relevant, and for two reasons. The first being the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), and the second being the three main pillars of the WIPO patent agenda; the Patent Law Treaty (PLT), the Patent Cooperation Treaty (PCT) and the Substantive Patent Law Treaty (SPLT). We will consider these in turn.

The IGC was established at the 26<sup>th</sup> General Assembly of WIPO in Geneva in September 2000. The mandate of the IGC is to "provide for a forum where governments can discuss matters relevant to three primary themes" (WIPO 2003). These are:

- Access to genetic resources and benefit sharing;
- The protection of traditional knowledge, innovations and creativity;
- The protection of expressions of folklore.

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<sup>7</sup> Farmers' Rights is defined as the ability of farmers to save, use, resow, exchange, share of sell his farm produce. More broadly, Rammanna (2003) identifies three basic aspects of farmers' rights. The first element is along the lines of what has been stated above, that being the farmers' privilege to save seed. The second is that of benefit sharing, which is central to our discussion; finally, the third aspect is the recognition of farmers as owners of the seed. That is, the recognition of farmers as breeders in their own right, and as having the right to claim ownership over their varieties as formal plant breeders do.

<sup>8</sup> We will consider Farmers' Rights in more detail within the context of the Indian experience in section .

<sup>9</sup> The ETC Group (2001a) has pointed out the possible links to human rights instruments such as the Right To Food, which is a FAO initiative. Given that the Seed Treaty and the Right to Food were both introduced by the FAO, the lacking inclusion of any reference to the Right to Food is somewhat ironic, though not surprising given the political dimensions implicit in the drafting of the Seed Treaty, and the resultant difficulties that arose in incorporating Farmers' Rights into the Treaty's agenda.

Clearly, the objectives of the IGC are quite similar to those detailed in the Bonn Guidelines, and there are ongoing efforts to ensure that the CBD and the IGC harmonize their efforts. The second session of the Committee in 2002 resulted in efforts to create a mechanism that would facilitate international patent searches by requesting all WIPO member states to contribute to a database comprising prior art. More specifically, the committee requested the secretariat of WIPO to compile (CBD 2003):

- An inventory of existing traditional knowledge-related periodicals, gazettes or newsletters which document and disclose traditional knowledge data, and
- An inventory of existing online traditional knowledge-related databases.

However, as mentioned in section 2.1, there are concerns regarding prior art databases and their efficacy in challenging prior art at the national regulatory level. Yet clearly, the objective of such a harmonization of prior art databases is rooted in making attempts to document traditional knowledge, which could be used to facilitate an international search when processing patent applications.

WIPO adopted the Patent Law Treaty (PLT) in June 2000 (GRAIN 2002). The objective of the treaty is to harmonize the procedure by which patent offices process patent applications. To facilitate that aim, the treaty presents a set of standardized requirements for national and regional patent offices to adhere to when processing applications. At this point, there are only four parties who have ratified the treaty; 10 are required for it to come into force<sup>10</sup>. Preceding the PLT is the Patent Cooperation Treaty (PCT), which was adopted in 1970. This Treaty is distinct from the PLT in that it provides an opportunity to file one application that would then be processed by WIPO among different countries. A party wishing to seek protection via a patent would have the option to only file it once at WIPO, who would then process the application simultaneously among all WIPO member states. Ultimately, the decision rests with national governments as to whether or not the patent will be granted; the advantage to those wishing to pursue a patent under the PCT is that the system allows for less paperwork and an international prior art search. This is where the database proposed by the IGC could be utilized.

The process of reforming the PCT began in 2000, as a result of the formation of the PLT. (Correa 2002). The main thrusts of the recent reforms have been to make the process easier, efficient and more cost effective. However, it has become apparent that these are not the only driving forces. While the PCT does facilitate the ease of application in a number of countries, the ultimate decision still lies within national governments. WIPO can facilitate the process, but it cannot grant a patent. Yet, many WIPO members (particularly the US) have expressed their desire for the PCT to “move away from its current, non-binding patentability opinions and adopt procedures where substantive rights could eventually be granted via the PCT” (WIPO 2001). Since the adoption of the PCT, efforts within WIPO have been focusing on creating a mechanism to harmonize not only the procedural elements of the patent process, but also the basic rules of patenting.

The first draft of the Substantive Patent Law Treaty (SPLT) was tabled in November 2001; a revised draft was completed in May 2002 (GRAIN 2002). What is unique about the SPLT is that, unlike TRIPS, it goes beyond setting minimum standards for WTO member states to adhere to regarding what can be patented. The SPLT has the potential to actually state what can or cannot

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<sup>10</sup> Refer to Article 10 of the PLT, which can be found at <http://www.wipo.int/clea/docs/en/wo/wo038en.htm>.

be patented, and does not have (at least at this early stage) the *sui generis* option that Article 27.3 (b) of TRIPS has. Thus, there is little room for movement or divergence. With regards to ABS, the SPLT is of particular concern with regards to what will constitute the prior art. If there is one uniform standard by which novelty-defeating prior art is to be measured by, one can only speculate that it will follow those norms currently pursued by the US, Japan and the EU, namely a technical specification that allows one skilled in the art to produce the “invention”. This is interesting, considering that the IGC has not laid down any specific guidelines that state what form submissions to the database proposed in the second meeting will take.

As mentioned previously, simply stating the resource as being utilized in the past without providing a technical explanation does not constitute the prior art in many developed countries. The concern here is that the SPLT would define what is patentable under much more narrow lines than what is currently the norm, with particular consequences on which biological resources can fall under the realm of what is patentable under national law. This has clear implications to ABS issues as currently, authority regarding what can and cannot be patented lies squarely on the shoulders of national governments; moreover, the ability to incorporate any of the elements discussed in sections 2.2 would conceivably be far more limited than what currently is available within the WTO framework; the ability to incorporate the Bonn Guidelines or the Seed Treaty into any domestic regulation could be curtailed by the SPLT. The SPLT has the potential to supersede national legislation, thereby creating a situation where national law is less relevant, if not irrelevant altogether. Indeed, a recent proposal submitted by some developing countries in WIPO suggesting to incorporate Article 27.3 into the SPLT was opposed by the US on the basis that TRIPS already provides minimum standards, while the SPLT aims at “establishing best practices at an international level” (WIPO 2001b). The concern here is the potential binding nature of these best practices.

## 4. DOMESTIC REGULATION AND EXPERIENCES

In this section, we will consider what governments have actually implemented in terms of ABS legislation at the national level. The legislation stems from their own unique experiences and environments, but has come about primarily in the context of Article 8 (j) of the CBD. Countries are at varying stages with regards to the implementation of the policy; while some have created explicit regulatory frameworks that deal with issues such as, prior informed consent, full disclosure and material transfer agreements, others are at preceding stages. In light of the currently existing international regulatory architecture that exists around patents and ABS mechanisms, and the room offered by article 27.3 (b) of TRIPS, it is worthwhile to consider what countries have done to enact their own *sui generis* legislation. There are a wide variety of such legislation in current practice, as the table below indicates.

**BOX 2: Some Examples of National ABS Legislation**

ABS Legislative Strategy Options	Selected Countries Pursuing These Options
General Environmental Framework laws (which only enable future legislation on ABS)	Gambia, Kenya, Malawi, Republic of Korea, Uganda
Framework sustainable development, nature conservation or biodiversity laws (which establish some ABS principles but require further legislation)	Costa Rica, Eritrea, Fiji, Mexico, Peru
Specific stand-alone national laws or executive orders that regulate access to genetic resources	The Philippines and, at the state level, Sarawak (Malaysia)

Modification of existing laws and regulations – such as those governing wildlife, national parks, forestry and fisheries – to include ABS provisions	Nigeria, Malaysia and, at the state level, Western Australia
Regional framework legislation (establishing common principles and procedures but requiring follow-up national legislation)	Countries of the Andean Pact (Bolivia, Colombia, Ecuador, Peru and Venezuela); regional framework agreements or legislation also under discussion by countries grouped in the Association of South-East Asian Nations (ASEAN) and the Organization of African Unity (OAU)

SOURCE: Glowka et al (1998)

In order to facilitate a more focused analysis, we have chosen to look at regulatory frameworks in the Indian context. The rationale for this is twofold; first, India has had a substantial history of debate, both within government and within civil society, of the issues surrounding the drafting of this legislation. Secondly, India is one of the world's most biodiversity rich regions, with approximately 8% of the world's total variety of plants and animals (UNEP 2003). This is the context that India accounts for 2.4% of the world's total landmass (US Department of State 2000). In particular, we will focus on the experiences of the Kani Tribe in Kerala, as well as the two most relevant pieces of Indian legislation that relate to ABS, the Biological Diversity Act (2002) and the The Protection of Plant Varieties and Farmers' Rights Act (2000). While the Kani example will highlight what some of the main issues and concerns are regarding the practical implementation of ABS strategies, the regulatory examples will provide insight on how domestic policy deals with these issues.

#### 4.1 THE KANI TRIBE AND THE CASE OF *JEEVANI*

The Kani tribals are an essentially nomadic group who live primarily in the forested areas of the Western Ghats, a mountainous area along the south western coast of India, as well as in the Thiruvananthapuram district of the state of Kerala<sup>11</sup>. They number around 16,000 and live in groups, or "hamlets", of approximately 10 to 20 families (Mashelkar 2001). For years, the Kani people have used the fruit of a particular plant found in the area, known to botanists as *Trichopus Zeylanicus Trivancoricus*, to the Kani as *Arogyappacha*, and to practitioners of *Ayurveda* as *Varahi*<sup>12</sup>. Specifically, they used the plant due to its ability to act as an energy boost to combat fatigue. The Kani Tribe is believed to be the descendants of Agasthya Muni, founder of *Sidha*, the Tamil system of medicine<sup>13</sup>. They believe the fruit is a gift from their ancestor Agasthya Muni to help them survive in the forest (Khan 2002). Though formal science identified the plant, the particular trait of providing an energy boost was unknown to others outside of the Kani tribe until 1987. At that time, a team of ethno biologists were on a botanical expedition in the areas inhabited by the Kani, and were accompanied by a few Kani men as guides. During their excursions throughout

<sup>11</sup> The bulk of the references found for the section on the Kani people and their experience with *Jeevani* was culled from two reports by the Indian NGO Kalpavriksh. In particular, Arunadha (2001) and Arunadha et al. (2001) were used as primary resources. Any other sources are duly noted.

<sup>12</sup> *Ayurveda* (Sanskrit for "knowledge of life") is an ancient system of healing that originated in India around 6,000 years ago. It incorporates not only medicines into its practice (there is a wealth of information regarding plant varieties, their traits, and how they can be used to treat various afflictions that has been passed on from generation to generation), but also diet, breath control, and physical posturing. Interested readers can refer to <http://www.mic.ki.se/India.html> for more detailed information.

<sup>13</sup> Current political boundaries place the majority of Tamil people in the state of Tamil Nadu, which borders Kerala on the east. The Western Ghats traverse both states, and the Kani have lived throughout the area over time.

the hilly areas of the Ghats, the scientists noticed the men consuming the fruit of the plant at regular intervals. They also found that while the walk required significant effort on their part, the two Kani men seemed full of energy. The scientists asked the two men what they were eating, and when offered the fruit, they found a “sudden flush of energy and strength” (Pushpangadan 1988). According to the Kani people, one can survive for 15 days on the unripe fruit of the plant alone (Khan 2002).

#### 4.1.1 A Proposition

After much persuasion, the scientists obtained PIC from the Kani men to be allowed to take some samples of *Arogyappacha* with them for further investigation. The Kani men agreed only after the scientists promised that if there was any commercial potential within the plant, that any financial returns earned from the plant would be shared with the Kani people. Upon analysis, the scientists found that the plant did in fact have the properties they had experienced, as well as anti-stress and anti-hepatotoxic elements (Pushpangadan 1996). After isolating the components of the fruit that held these properties, the results were given by the scientists to the Tropical Botanical Garden Research Institute (TBGRI), the largest botanical garden in Asia<sup>14</sup>. Dr. Pushpangadan, who subsequently became director of TBGRI, adopted an ethno-pharmacological approach to evaluate the plant; that is, the two-year scientific study involved experts from botany, pharmacology, phytochemistry, biochemistry, pharmacy and *ayurveda*. Further tests for toxicity, shelf life and clinical properties were undertaken, and by the end of 1994, Jeevani was ready for commercialization (Krishnakumar et al 2002).

After some deliberation, it was decided by TBGRI in 1996 to license this compound to interested parties, conditional on a license fee. The winning applicant was the Arya Vaidya Pharmacy (Coimbatore) Ltd. (AVP), who wished to market the drug under the name *Jeevani*<sup>15</sup>. The conditions of the MTA were that AVP would pay to TBGRI INR 1,000,000 (USD 20,000) annually for a seven-year period<sup>16</sup>. In a separate agreement, it was decided by TBGRI that half of this license fee would go back to the Kani, along with 2% of all royalties earned by TBGRI from the sale of the drug in the future. The State of Kerala has had concerns regarding the amount of the license set aside for the Kani; the opposition party of the state legislature felt that the amounts set aside for the Kani were very low, particularly in light of the commercial potential that exists for *Jeevani*. However, after the end of the seven-year period, the Kani can deal directly with parties interested in acquiring the plant, thereby opening up the potential for more substantial license fees.

#### 4.1.2 An Agreement

TBGRI scientists felt that the amount of *Arogyappacha* growing in the wild was insufficient to meet potential market demand; as a result, they were of the opinion the plant would require cultivation. The scientists, however, did feel that the plant would grow best in natural conditions. During the period between 1994 and 1996, an agreement was made between the

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<sup>14</sup> In 1982, the Ministry of Environment and Forests of the Government of India launched the All India Coordinated Research Project on Ethnobiology (AICRPE); TBGRI is the coordinating centre of this programme. It has a field gene bank, seed bank, tissue repository and cryobank of rare and endangered medicinal and aromatic plants of tropical India. While the TBGRI is an autonomous organization, it was established by the State Government of Kerala in 1979 (MoEF 1998). It should be mentioned that the ethnobiologists were led in 1987 by the current director of TBGRI, Dr. P. Pushpangadan. However, at that time Dr. Pushpangadan were affiliated with Regional Research Laboratory in Jammu, Northern India, not TBGRI.

<sup>15</sup> The English translation of *Jeevani* is “giver of life”. *Jeevani* itself is not created exclusively from *Arogyappacha*, though it is the main component among three other compounds.

<sup>16</sup> INR is the currency code for Indian Rupees; similarly, USD refers to US Dollars.

Integrated Tribal Development Programme (ITDP) of the Government of Kerala and fifty Kani Families to facilitate the cultivation of the plant. Fifty families were given INR 1,000 each (USD 20) to cultivate the plant. The agreement was such that the ITDP would provide the Kani families with the financial resources required for cultivation, and the families would provide TBGRI with the plant; TBGRI would then supply these to AVP for production.

Before this could occur however, some issues had to be addressed. First, the Kani live on forestlands administered by the State Forest Department; this department maintains (and enforces) a list of “minor forest produce” that can be collected by individuals, particularly tribals. Initially, *Arogyappacha* was not on this list. Thus, it technically would have been illegal of the Kani people to cultivate this plant. The department was hesitant to allow cultivation of the plant as they had feared the possibility of many others making attempts to acquire the plant illegally, without permission. Their fears were not unfounded; in one incident, the Forest Department found 10,500 plants in two trucks collected by Kani tribals for a private nursery in Kerala. However, note that in this example, the entire plant was uprooted. Cultivation of the plant need not require this, as only the berries and leaves are required for *Jeevani*. After much debate and a long period of uncertainty, the Forest Department recently relented on their previous decision, and now allows the Kani to cultivate the plant (Pushpangadan 2002).

Second, the Kani themselves are of differing opinions regarding the commercialization of *Arogyappacha*. While some are pleased with the agreement, others are not. Indeed, while those Kani close to the area where the scientists initially made their forays in 1987 are relatively pleased with the outcome, other Kani are not at all, and feel as though they have not even been asked whether or not they were in favour of the decision. The latter also feel that any attempt at the creation of a benefit sharing mechanism is overshadowed by the fact that not all Kani have not been consulted nor involved in the exercise. There is far from complete uniformity among the Kani people regarding a positive or negative opinion on whether or not commercialization of *Arogyappacha* is a good thing overall.

Lastly, the Kani as a group of people did not have a bank account, or any other way to receive the money. Recall that the Kani were supposed to be given INR 50,000 (i.e. half of the amount given by AVP to TBGRI) on an annual basis. Until 1999, the funds owed to the Kani people were locked, as there was no way to transfer the funds to the entire tribe. Moreover, it was not really clear as to who would get the funds, how it would be shared among all Kani people, and what it would be used for, among other considerations. In order to address this, eight Kani tribals with assistance from TBGRI set up a trust in 1997, the *Kerala Kani Samuduya Kshema Trust*, or Kani Welfare Trust. The trust was registered with nine Kani members; its existence, use and other parameters were agreed upon via a meeting of forty other Kani tribals. The aim of the Trust is to eventually incorporate all Kani as members, though those Kani who showed opposition to the commercialization of *Arogyappacha* were not initially approached.

With this trust established, the payments could finally be disseminated to the Kani people. In March 1999, the first payment of INR 535,000 (around USD 11,000) was made to the trust. As per the decision of the Kani people, the funds will be used to support “welfare activities” of the Tribe.

#### 4.1.3 Current Situation

As of 2002, over 60% of all Kani people in the state of Kerala have become members of this trust (Pushpangadan 2002). *Jeevani* is currently very much available to consumers from a number of

different suppliers<sup>17</sup>. AVP sells *Jeevani* at the rate of INR 160 (USD 3.30) for 75 grams (Iype 2002). It currently constitutes the majority of what they export; most of their clientele are from Southeast Asia and the US, who then resell the drug to their clients. Families cultivating *Arogyappacha* earn on average INR 30,000 (USD 630) per acre annually, and the plots are usually between one and two acres in size (Moran 2002). These families are initially trained by TBGRI on how to cultivate the plant (Pushpangadan 2002). The income earned from cultivation is expected to increase over time given the demand that exists for the plant; currently, several private firms are negotiating with the Kani people for the transfer of *Arogyappacha* (Krishnakumar et al 2002).

Pushpangadan and his colleagues at TBGRI along with the leader of the Kani tribe, Kuttimathan Kani, were recognized for their work by being awarded the UN Equator Initiative Prize in August 2002 (Nandakumar 2002). It is worth mentioning that while India became a member of the CBD in 1992 (with the convention then taking effect in late 1993), the efforts made by Pushpangadan and his Kani colleagues were, in 1987, without precedent. That is, there was no real model on which to base this particular benefit sharing mechanism on; the exercise was based on mutual trust and cooperation. While the agreement is not without its flaws (i.e. not all of the Kani people were in favour of the commercialization of *Arogyappacha*), it is worth discussing here as it provides insight on the types of issues that can arise when negotiating such an agreement. Yet given that the agreement arose without precedent, we need to consider whether national legislation can offer guidelines for similar circumstances in the future, and if so, how successful it can be in achieving that aim.

#### 4.2 INDIAN LEGISLATION

Given that India has signed and ratified both the CBD and the Seed Treaty, it is bound to make a concerted effort to ensure that the broad objectives of the Convention, the Bonn Guidelines and the Seed Treaty are addressed at a domestic level, and that proper guidelines for ABS mechanisms are in place. While concerns relating to biodiversity in the Indian context certainly predate the CBD, the formal process of interaction and debate around the issues within access and benefit sharing at the national level began in India after the conclusion of the UN Conference on Environment and Development towards the end of 1992 (Arunadha et al 2001: 14). After a very long process of national and state level consultations, the Indian government in May 2000 (Ramesh 2000) finally adopted the Biological Diversity Act (BDA). The Act is clearly rooted as a response to the obligations imposed on India by the CBD, but perhaps more importantly, its existence is due to the need for national legislation on issues related to the access and benefit sharing of genetic resources.

During the same time as the development of the BDA, efforts were also underway to draft legislation to satisfy the *sui generis* provision that Article 27.3 of TRIPS presented. The Indian government in August 2001 passed the resulting law, the Protection of Plant Varieties and Farmers' Rights Act (PPV). The PPV is unique in the sense that it establishes the existence of farmers' rights at a national level. More specifically, it establishes the right of farmers to sell their seed to others (except branded seed), thereby ensuring that this source of income is retained<sup>18</sup>.

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<sup>17</sup> There are many websites that currently offer *Jeevani* for sale; refer to The Jeevani Company, <http://www.jeevani.com/> (USD 34.95 for 75 grams); Bodybuilding.com, <http://www.bodybuilding.com/store/pin/adrenerlin.html> (USD 17.69 for 60 capsules); The Himalayan Yoga Meditation Center of New Jersey (which refers to the drug originating from the "Himalayas of Kerala"), [http://www.yogaunity.com/merchandise\\_jeev.html](http://www.yogaunity.com/merchandise_jeev.html) (USD 29 for 75 grams). All of the firms listed here selling *Jeevani* are based in the US.

<sup>18</sup> This provision allowing farmers to sell seed is crucial; farmers provide around 85% of the seed planted by farmers in India. If farmers could not sell seed due to IPR that would restrict a farmers' ability to do so, the most likely party to fill this void would be private seed firms who, if industrialized economies can be considered a proxy for an alternative scenario, would offer seeds according to their ability to act as monopolists. This scenario is even more relevant in light of

With respect to access and benefit sharing, the PPV is relevant here as it contains a provision for a funding source that would allocate financial resources for the holders of varieties. This fund, termed the National Gene Fund, would act as a conduit for funds that would be disseminated among communities who could be shown to hold claim to the resources accessed.

Clearly, there is a strong potential for overlap between these two Acts, especially with regards to those elements of the Acts that relate to ABS issues. It is clear, particularly within the context of experiences such as the Kani and TBGRI example discussed earlier, that proper legislation is required to guide future benefit sharing agreements. Yet, as we shall see, the creation of such a framework is a long and difficult process, particularly when there are a plurality of agreements that could have direct relevance to the issues at hand<sup>19</sup>. Our discussion then will first consider the BDA and its relevant aspects, followed by a similar treatment for the PPV. After sufficient exploration of these two frameworks, we can then consider the implications of the regulations and how the two complement (or frustrate) each other in light of the Kani experience.

#### 4.2.1 *The Biological Diversity Act*

The BDA outlines a framework for allowing which parties can access PGR. The Act outlines a process by which resources can be accessed, and details the procedural hierarchy that exists for those parties interested in doing so. The objectives of the Bill are:

- The conservation of biological diversity;
- The sustainable use of its components;
- The equitable sharing of benefits arising out of the use of biological resources.

These are precisely the three objectives of the CBD, with one small change; rather than genetic resources, the third objective refers to **biological** resources. The Bill defines biological resources as “plants, animals and micro organisms and parts thereof, and their genetic material and by-products, with actual or potential use or value, but does not include human genetic material.” Note the inclusion of micro organisms here; micro organisms are not offered protection via a *sui generis* regime as per Article 27.3 (b) of TRIPS. The BDA, however, includes these, thus attempting to ensure that even if micro organisms cannot be protected via a patent or *sui generis* system, at least any commercialization of them will be subject to the laws outlined in the Act.

#### *Access Issues*

There are three levels by which any application to access resources must pass; the national, the state, and the village level. The Bill states that one level cannot act without the others permission; that is, no decision at the national or state level can be taken without consultation at the village

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the limited (and diminishing) budget allocations given to public sector breeding efforts in India, who would arguably be the other relevant source of seed for farmers.

<sup>19</sup> In what follows, we will contain our analysis to the BDA and the PPV. However, this is by no means and indication that these are the only two pieces of Indian legislation that are relevant in our context. Sahai (2002) points out that the Indian Forest Act, 1927 (rights over and administration of forest produce), the Wildlife (Protection) Act, 1972 (notification of the protection of certain plants by the state with exceptions for indigenous peoples), the Forest Conservation Act, 1980, and the Environment Protection Act, 1986, all have relevance to the issues at hand. Kaushik (2002) also mentions the Transfer of Property Act, 1882 as it relates to common property. However, to facilitate a more meaningful exploration, we will only consider the BDA and PPV. It should be kept in mind however, that there is overlap among extant policy, and in what follows the problems that can arise from this will be considered.

level<sup>20</sup>. At the national level, the National Biodiversity Authority (NBA) will be the first contact or any party wishing to access PGR. The NBA considers applications on a proposal-by-proposal basis, and ensures that any terms and conditions of these proposals include an acceptable benefit-sharing component. Moreover, before obtaining any PGR from India, the party must go through the NBA. Similarly, at the state level, State Biodiversity Boards (SBB) will be established, and will perform tasks very similar to that of the NBA, but at a state level. However, the role of the SBB is distinct as it operates within the policy environment of the state, which is far from uniform across all states. Finally, the Act establishes Biodiversity Management Committees (BMC), which will be governed by the existing village level political mechanisms.

The Act is explicit regarding how parties from India (i.e. Indian nationals) and foreigners are to be treated under the regulations. Specifically, approval is granted to Indian citizens only after “prior intimation”; approval to foreigners is only granted after prior approval<sup>21</sup>. The distinction is because, while it could be possible to prosecute nationals within the Indian legal system, it would more than likely not be possible for foreigners. Research activities are also subject to prior approval by the NBA; the BDA is not limited to monitoring access to resources alone, but also the results of research. The transfer of research results “to any person who is not a citizen of India or a body corporate or organization which is not registered or incorporated in India or which has any non-Indian participation in its share capital or management” cannot be disseminated without approval of the NBA<sup>22</sup>.

Similarly, “no person shall apply for any intellectual property right by whatever name called in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority before making such application”<sup>23</sup>. However, it is unclear how the sovereign jurisdiction of India would act as law in an international context. Uniformity with regards to patent law, while an underlying goal of multilateral instruments such as TRIPS, is far from embodied in current realities. Implementation of the BDA will also necessitate changes in the Indian Patent Act, 1970 to ensure that disclosure of origin will become a requirement in any IPR application (Kaushik 2002). In particular, efforts are being made to amend the Act to ensure that traditional knowledge can be excluded, as well as technical information regarding the invention to facilitate full disclosure, both in terms of geography but also prior art.

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<sup>20</sup> Village level political processes are established in the Constitution of India. While *Panchayats* have existed in India before Independence, they were only recently formally recognized as a system of governance. In 1993, the Constitution of India was amended via the 73<sup>rd</sup> Amendment Act; this amendment formally institutionalizes the *Panchayat* as the third level of governance, with the national and state being the first and second respectively. Arunadha et al (2002: 11) offer the following: “In essence, the *Panchayati Raj* comprises the following: each village has an assembly of all the adult members called the *Gram Sabha*; a group of villages have a *Panchayat*. The gist of the Constitutional amendment is that states are mandated to recognize *Panchayats* as institutions of self-government, and have the responsibility to prepare plans for economic development and social justice...A greater role for the *Panchayat* in ecosystem management as envisaged by the Constitution 73<sup>rd</sup> Amendment Act, 1993, by placing new matters under its jurisdiction, including land improvement, land consolidation and soil conservation, social forestry and minor forest produce. These provisions there provide scope for local communities to play a role in governance relating to natural resources.” It is within this context that the BMCs at the village, or *Panchayat* level of operates. While this amendment applies nationally, certain states have been more successful than others in this process of decentralized governance; on the one hand, Kerala has been relatively quite successful in decentralizing authority, due to its politically left leaning government. The state of Bihar on the other hand, has hardly made any efforts to further this process, due to the general lack of the rule of law that is prevalent there. In the end, it is a very much state driven process, and depends substantially on the willingness of the state government to introduce the reforms needed to decentralize.

<sup>21</sup> “Intimation” is defined as “to make known publicly or formally”; refer to Article 7 of the BDA, which can be found at <http://www.grain.org/docs/india-biodiversityact-2002.pdf>.

<sup>22</sup> Refer to Article 4 of the BDA.

<sup>23</sup> Refer to Article 6.1 of the BDA.

### *Benefit Sharing Issues*

Of particular relevance here is the establishment of a National Biodiversity Fund, which will be administered by the NBA, and State Biodiversity Funds, which will be administered by the SBBs. Article 6(2) states that “the National Biodiversity Authority may, while granting the approval under this section, impose benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising out of the commercial utilization of such rights.” As per the law, the purpose of these funding mechanisms are to channel benefits to the conservers of biological resources and creators and holders of knowledge, the conservation of areas where biological resources are found, and the socio-economic development of such areas in consultation with the local self-government concerned<sup>24</sup>.

A similar mechanism is slated to exist at the village level, composed of transfers from the State Funds and other grants (Arunadha et al 2001). This Local Biodiversity Fund shall be used “for conservation of biodiversity in the areas falling within the jurisdiction of the concerned local body and for the benefit of the community in so far such use is consistent with conservation of biodiversity”<sup>25</sup>. Nowhere in the text of the Act however is it stated how the fund would be set up, and more importantly, how actual amounts designated for the sharing of benefits will be calculated. It is ultimately up to the SBBs to determine this. In the case of the Kani, the amount decided (namely 50% of revenues earned by TBGRI) was arrived at via consulting standards proposed by the Council for Scientific and Industrial Research (CSIR)<sup>26</sup>. Presumably, SBBs would look to similar standards by which to gauge the actual amounts that would apply.

#### *4.2.2 The Protection of Plant Varieties and Farmers’ Rights Act*

The PPV relates primarily to the protection of farmers’ varieties of seed via a *sui generis* IPR mechanism. The implications of this are not only within the scope of maintaining biodiversity, but also in maintaining the livelihoods and sources of income of farmers. Moreover, the PPV directly relates to ABS issues, as IPRs are the starting point for any discussion of the policy implications of access issues, and benefit sharing concerns are explicitly dealt with within the PPV.

The first efforts at drafting the current PPV began almost ten years ago; in August 2001, the current form of the act was passed by the Indian government (Seshia 2002: 2). Prior to the late part of the eighties, trade policies in India were relatively closed to foreign investment; reforms by the party in power at that time, Congress (I), and the then prime minister of the country, Rajiv Gandhi (son of Indira Gandhi) opened up markets in India in a manner unprecedented by previous administrations. Previous to this new economic environment, most plant breeding was undertaken by the public sector. Incentives for the private sector to provide seed to farmers were not particularly substantial, as the public sector had been filling that role successfully. There was not a prevailing need at that time to establish rules for the private sale of seed (Dhar 2002: 40).

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<sup>24</sup> Refer to Article 27.2 (b) of the BDA.

<sup>25</sup> Refer to Article 44.2 of the BDA.

<sup>26</sup> CSIR is an autonomous body formed in 1942 before India gained independence; its broadly stated mission is to “provide scientific industrial research and development that maximizes the economic, environmental and societal benefits to the people of India”, though more recently it has been “to promote development of indigenous technologies and utilization of indigenous resources.” Refer to the CSIR website at <http://www.csir.res.in>.

After the changes in policy, it became easier for both domestic and foreign private firms to invest in seed production, as well as for non-domestic seed to enter India. The introduction of TRIPS in 1995 certainly acted as a catalyst for further development of policy around PGR, though it was not the sole catalyst. The emergence of TRIPS, however, did consolidate the need for India to develop a mechanism to protect plant varieties, as outlined in Article 27.3(b). The objective of the PPV as stated in its preamble is to establish “an effective system for the protection of plant varieties, the rights of farmers and plant breeders, [and] to encourage the development of new varieties of plants.” Dhar (2002: 41) has outlined three factors as being the main catalysts for the PPV:

- Protection of the rights of the 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;
- Protection of Plant Breeders’ Rights to stimulate investment for research and development, both in the public and private sector, for the development of new plant varieties, and;
- Giving effect to Article 27.3 (b) of the Agreement on TRIPS relating to protection of plant varieties.

Note the balance between Farmers’ Rights and Breeders’ Rights; the PPV makes an attempt at balancing both, thus satisfying both the concerns of farmers’ regarding their ability to save, acquire, and sell seed, but also the concerns of breeders who desire adequate protection for their research and resultant technologies. The PPV is thus very much in line with the Seed Treaty within the context of Farmers’ Rights, as it has made efforts to include references to them in their national legislation. More specifically however, the PPV makes explicit reference to the protection of Plant Breeders’ Rights (PBR).

#### BOX 3: What Is A Plant Breeders’ Right?

A Plant Breeders Right (PBR) is a form of Intellectual Property Right for parties developing new plant varieties. PBR differ from patents with respect to the criteria that determines whether or not protection can be conferred on the variety. Recall that the criteria for allowing a patent on an invention as discussed in section 2.1 is that the invention must be useful, novel and non-obvious. With a PBR, the criteria are that the variety be **distinct, uniform, stable** and **novel**. To be distinct implies that the variety should be easily distinguishable from other varieties; uniformity implies that the variety will reproduce in a similar manner. Similarly, stability implies that the variety will not change over generations<sup>27</sup>. Novelty however, has a somewhat different interpretation than it has with reference to patents.

In the case of PBRs, novelty is conferred more along the lines of market concerns rather than existing knowledge. That is, while novelty in the patent context hinges on the prior art, within PBRs “the variety shall be deemed to be new if, at the date of filing of the application for a breeder's right, propagating or harvested material of the variety has not been sold or otherwise disposed of to others, by or with the consent of the breeder, for purposes of exploitation of the variety” (UPOV 1991). Here, the concern is not that the variety previously existed, but rather that it was not previously available on the market.

Many developing countries, including India, have based their *sui generis* on a framework developed by the International Union for the Protection of New Varieties of Plants; also known as UPOV (as per the French translation of the title of the union). UPOV currently exists in two forms, a 1978 version and a 1991 version. As of April 1988, the 1978 convention can no longer be acceded to; that is, only UPOV 1991 can be adopted or joined by interested parties<sup>28</sup>. UPOV is the de facto internationally recognized set of

<sup>27</sup> For a more detailed description of how precisely these criteria are defined, interested readers can refer to Articles 6 through 9 of the UPOV 1991 convention, which can be found at

<http://www.upov.int/en/publications/conventions/1991/content.htm>.

<sup>28</sup> See UPOV (2002). Briefly, there are three main differences between UPOV 1978 and 1991 for the purposes of our discussion. First, concerning novelty, the 1978 formulation states that varieties that have been available on the market for more than a year cannot be offered protection, though this is an optional criterion. In the 1991 formulation, this option is

guidelines for defining PBR. Many have argued that the *sui generis* option within TRIPS was included with UPOV in mind. However, UPOV is, in many ways, more geared towards those countries that practice industrialized, input intensive, high output farming, where the private sector is the main source of seed. This is in contrast with smaller plot, community based, subsistence farming as is more the case in countries such as India; moreover, the private sector may not be the major source of seed in these countries (as it is not in India). The novelty criterion provides a sound indication of that, as it presumes at the outset that seeds are a marketable commodity rather than an input that is owned not by private parties, but by communities. Moreover, nowhere in the text of UPOV are farmers' rights mentioned.

Yet regardless of these potential asymmetries, PBRs are valuable, as some form of protection is certainly useful for formal plant breeders, be they public or private. The point is that while patents on PGR may be inappropriate for developing countries (both for moral and ethical reasons, but also for logistical reasons; substantial costs are incurred in applying and processing a patent application), they can be used to protect the interests of farmers' seed by offering an internationally recognized form of formal IPR. The concern however is whether or not UPOV should be adopted by developing countries as the *sui generis* option, or whether a more concerted effort is needed to not simply adopt UPOV, but to develop *sui generis* options that more accurately reflect the requirements of individual countries.

The Indian legislation models itself after UPOV with regards to the four criteria that determine a PBR, but diverges from UPOV in two main ways; first, their treatment of what types of seed can be given PBR, and second, the inclusion of Farmers' Rights to balance those rights held by breeders.

Article 14 of the PPV identifies three classes of seed that can be protected: new varieties, extant varieties, and essentially derived varieties (EDVs). New varieties are self explanatory; this class includes seeds that have been developed and satisfy the four criteria that a PBR implies. An extant variety is essentially one that is currently in the public domain, or where there is common knowledge regarding this seed. This includes farmers' varieties. The PPV makes a departure from UPOV in including extant varieties; nowhere in UPOV are extant varieties even mentioned. Lastly, EDVs, as defined by UPOV, are "predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety"<sup>29</sup>. Most genetically modified varieties are based on material found in extant varieties, and are thus considered EDVs; for instance, Bt Cotton is a variety of cotton identical to its parent except for the inclusion of a bacterial gene from *Bacillus Thuringensis*, thereby protecting the cotton plant from a particular insect, the cotton bollworm<sup>30</sup>. The inclusion of

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revoked and is embodied as a prescriptive criterion. Second, concerning commercialization, the 1978 formulation disallows parties to commercially market a variety without permission from the owner of the variety. The 1991 version goes further and disallows the "production or reproduction, conditioning for the sake of propagation, offering for sale, selling or other marketing, exporting or importing and stocking [of the variety] for any of these purposes". In effect, the 1991 version is far stronger with respect to the protection offered by a PBR, and approaches the rigor of a patent; the duration of protection is also extended. Thirdly, the 1991 version treats breeders' and farmers' exemptions differently. With regards to breeders, the 1978 formulation allows breeders free access to varieties as an initial source of variation; the 1991 version follows along similar lines, with the caveat that EDVs cannot be used as source material without the permission of the owner if they are protected. As for farmers, the 1978 formulation allowed farmers to save and replant a portion of their seed (i.e. plant-back rights, or to a limited extent farmers' rights), or to exchange limited amounts seed with other farmers. In the 1991 version, this exemption is removed and is left to the discretion of member states as an option, and this only applies to seed on the farmers' own plot; that is, exchange is not allowed. For further details on the asymmetries between UPOV 1978 and 1991, refer to GTZ (2003).

<sup>29</sup> Refer to UPOV 1991, Article 15.5(b). The PPV adopts the UPOV definition of an EDV almost exactly.

<sup>30</sup> Bt Cotton in itself makes for a fascinating exploration of how varieties developed *ex situ* often fail in environments that are not as well suited to the seed as was previously imagined. There is a wealth of literature on the Bt Cotton experience in India, much of it very new as the consequences of a test planting in India of Bt Cotton are still very much being discussed. Recently, it was formally announced by the Minister of Agriculture for the state of Andhra Pradesh in southern India that the recent trials of Bt Cotton were a failure. This has been the prevailing sense for some time,

extant varieties in the PPV distinguishes it from merely being a UPOV variant; it is a distinct departure from that framework.

#### *Access Issues*

Under the PPV then, farmers' varieties of seeds are offered protection under a PBR; moreover, an EDV can only be granted if explicit permission is granted by the farmers who hold the original genetic material that the EDV is sourced from (Sahai 2002: 3). The question then is how precisely farmers' varieties are to be catalogued and thus conferred a PBR, though Sahai states that "any one is entitled to register a community's claim [on a seed] and have it duly recorded at a notified centre". The Act states that a National Register of Plant Varieties "shall be kept at the head office of the Registry, wherein shall be entered the names of all the registered plant varieties with the names and addresses of their respective breeders, the right of such breeders in respect of the registered variety, the particulars of the denomination of each registered variety, its seeds or other propagating material along with specification of salient features thereof and such other matters as may be prescribed<sup>31</sup>." Do "the particulars of the denomination" include a detailed scientific explanation of the resource that would allow someone "skilled in the art" to reproduce the "invention"? It is not clear from the legislation, though arguably it was written in a strategic manner so as to reflect this. India certainly has the right of a sovereign state to formulate their own laws relating to PGR, but the ability to defeat a claim outside of India based on the varieties being documented in a Community Biodiversity Register (CBR) may or may not constitute the requirement of novelty with regards to a patent. This is regardless of the fact that it may be novel within the context of a PBR. More concretely however, the PPV states that a PBR cannot be awarded if the application for protection does not provide information on where the genetic material was found, and what the parental lineage is of the variety. This amounts to full geographic disclosure being conditional on accessing a PBR, which is perfectly within the right of India to pursue<sup>32</sup>.

#### *Benefit Sharing Issues*

With regards to Benefit Sharing provisions, the PPV, like the BDA, introduces a National Gene Fund. The purpose of the Fund is collect funds that are owed to the original holders of the genetic resource that is being accessed, with the value of the amount to be determined by<sup>33</sup>:

- The extent and nature of the use of genetic material of the claimant in the development of the variety relating to which the benefit sharing has been claimed;
- The commercial utility and demand in the market of the variety relating to which the benefit sharing has been claimed.

The rationale for the fund is to act as a source of financial resources that is based on payments made, either via a license or via benefits accrued, by those parties wishing to access genetic resources owned by farmers or other groups in India. The Act states that Fund will contain transfers relating to<sup>34</sup>:

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particularly in light of farmers in Southern India resorting to suicide due to spurious Bt Cotton seed, but formal recognition by the state was, until recently, unprecedented. See, for instance, the March 3, 2003 edition of GENET News at <http://www.gene.ch/genet/2003/Mar/msg00025.html>, or the February 7, 2003 issue of Nature at <http://www.nature.com/nsu/030203/030203-12.html>.

<sup>31</sup> Refer to Article 13.1 of the PPV, which can be found at <http://www.grain.org/docs/india-pvp-act-2000-en.PDF>.

<sup>32</sup> Refer to Article 18.1 (e) of the PPV.

<sup>33</sup> Refer to Article 26.5 of the PPV.

<sup>34</sup> Refer to Articles 35.1, 41.4 and 45.1 of the PPV.

- The benefit sharing received in the prescribed manner from the breeder of a variety or an essentially derived variety registered under this Act or propagating material of such variety or essentially derived variety, as the case may be;
- The annual fee payable to the authority by way of royalty for resources acquired from a breeder of a variety registered under the Act;
- The compensation that may arise is a successful claim is presented arguing that the genetic material was sourced from local communities;
- The contribution from any national and international organisation and other sources.

The Gene Fund is a distinct and separate entity from the NBF of the BDA, though the aim of each is rather similar. However, the NBA has nothing to do with the administration of the Gene Fund; this fund is administered by “the Central Government”<sup>35</sup>. Swaminathan (2001) offers the following analysis of the fund:

This Fund is likely to be very modest. It should be used mainly for recognizing and rewarding the contributions of tribal and farmwomen and men to the conservation and enhancement of agro biodiversity. The administration costs relating to this Fund should be borne by the Government of India. Transparent and credible methods of recognizing individual and community contributions will have to be developed. This can be done by a Standing Committee on Farmers’ Rights set up by the Authority. Since a majority of primary conservers are women, there must be adequate representation of tribal and farm women on such a Committee. The manner in which the Community award should be utilized should be left to the community. In this respect, there could be linkages between the provisions of this Act and the Biodiversity Management Committees proposed to be set at the Panchayat/Local Body level under the Biodiversity Act now before Parliament.

It is clear that there are similarities between the PPV and the BDA. However, unlike the BDA, the PPV does not detail how PIC could be accomplished. That is, it does not provide the hierarchical framework that the BDA provides.

#### 4.2.3 *A Comparison and Evaluation*

Critics of the BDA point out that while such legislation is certainly necessary, the legislation in its current form is excessively broad with respect to what it covers. Gadgil (2000: 280) asserts that the regulation of “the use of all biological resources throughout the length and breadth of the country...[is a] stupendous task anywhere in the world; it is quite impossible in a biomass-based civilization such as ours.” Rather than such a broad focus, Gadgil argues that particular focus should be given on crops that focus on diversity related end-uses “such as drugs, industrial enzymes, cosmetics, dyestuffs, plant growth regulators, emulsifiers, oleoresins and genes used for improving livestock through breeding and genetic intervention.” Arguably, this list of possible uses could incorporate an equally broad range of resources from which to source genetic materials (particularly in light of our relatively small bank of knowledge about how PGR can be used in these ways), but a narrower focus on particularly relevant varieties would certainly lessen the burden on the NBA to do their work and would perhaps minimize bureaucratic procedures, thereby acting not only to make the process more tractable, but also in facilitating domestic research.

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<sup>35</sup> Refer to Article 45.1 of the PPV.

Sahai (2002) argues that in its current form, “instead of encouraging research in this important area of medicinal plants and ecosystems, the [BDA] is likely to frighten off potential researchers with strong tangles of bureaucratic red tape...The last thing the Indian research systems need is more red tape.” Moreover, nowhere is PIC referred to in direct terms with the original holders of the knowledge. All PIC efforts are to be through the NBA, who presumably would then take the necessary actions through the bureaucracy down to the village level to ensure that PIC is achieved. Sahai further contends that the introduction of the Bill runs the risk of duplication of, and, in the worst case, could actually undermine currently extant legislation, both domestically and internationally. As mentioned previously, India has a wide variety of other relevant regulatory frameworks that address some of the issues the BDA concerns.

Consider the Kani example; if TBGRI had to approach the NBA, who then approved the agreement, but did not consider the relevant state level legislation that the Forest Department is to enforce, the NBA could actually serve to undermine the relevance of the State Forest Department, which undoubtedly would cause a wide array of logistical problems. Moreover, at the village level, given that not all of the Kani were in favour of the benefit sharing agreement, and were not administered by the same *Panchayat* due to their geographic dispersal, how could the village level authority come to a decision? The essence of the problem is that given the wide number of policy bodies involved in such a case, accountability becomes very difficult to define.

The main problems with the BDA is that it will more than likely prove difficult to implement due to its hierarchical structure and unclear system of accountability. Moreover, there exists a potential for difficulties to arise when attempting to harmonize the different regulatory frameworks that currently exist and are of relevance to ABS issues. In particular, the role of a body such as the NBA with respect to patents is not explained in the Bill within the context of the other relevant laws that also focus on patents; this is of direct relevance since access issues and formal IPR issues, namely patents, cannot really be separated.

Similarly, the PPV, while successful in providing Farmers’ Rights, may potentially undermine these Rights due to the safeguards provided to industry. Sahai (2002b) argues that the legal recourse available to parties who contend that their PBR has been violated is excessive, ranging from a fine of INR 50,000 (USD 1,000) to the maximum of a two-year jail term. Moreover, those parties that have suspicions regarding the violation of the PBR can place the burden of proof on the alleged violator, which differs from the normal course; normally, the accuser is to furnish proof before accusing the other party. However, one could argue that “it cuts both ways”, in the sense that if an indigenous variety such as *Arogyappacha* was being marketed without the consent of the Kani people, then they could take legal action, assuming they owned a PBR on *Arogyappacha*. This is purely theoretical however, as the cost of legal action may prove excessive; though funds allocated to *Panchayats* through the BDA plausibly could be a source for funding such litigation.

The Kani example illustrated how difficult it can be to truly acquire PIC. Given that not all members of the Kani tribe agreed to commercialize *Arogyappacha*, yet commercialization occurred regardless, was the process, and ultimately, the aim of PIC compromised in any way? Moreover, the Kani people initially had no way to receive the portion of the benefits allocated to them in the MTA. This was only achieved with assistance from TBGRI. Yet what of situations where such assistance is not available? The purpose of the Fund is well defined in both the BDA and PPV, yet in cases where an obvious location to deposit the benefits (i.e. a bank account) is not available, it is not clear how the benefits will be disseminated.

The PPV allows for the registry of extant varieties, thereby assuring that farmers can be offered some sort of ownership over their resources. Similarly, the BDA disallows patents in jurisdictions

outside of India on genetic material found in India without prior approval by the NBA. Yet these elements of the Acts are both contingent on one thing; the availability of novelty defeating prior art. If the prior art is not stated in a manner to allow a party “skilled in the art” to reproduce the “invention”, then are these safeguards intended to protect biopiracy effective? Though alluded to, will the register referred to in the PPV be adequately detailed to provide details that could successfully defeat novelty? The plurality of legislation around IPR and ABS issues would perhaps benefit from an overarching set of guidelines with which to construct an MTA, establish the syntax of the registries to account for international prior art searches. Moreover, the fact that there is a plurality of legislation around these issues needs to be addressed; the regulatory frameworks require consolidation to ensure that the efficacy of the legislations are not compromised by a lack of clarity on how the different instruments relate to each other.

## 5. CONCLUSION

The issues discussed in this overview are particularly topical, both in light of increasing trends of bioprospecting, but also in terms of the reforms currently underway in many countries to conform both to TRIPS as well as CBD standards. The responsibility for implementing the elements of international regulatory frameworks on ABS is owned by national governments. Technically, frameworks such as TRIPS were written in such a way as to allow for the text to allow room for the unique environments that contracting parties exist in, and this should be fully exploited. Yet, in light of bilateral agreements that exist outside of the purview of multilateral instruments such as the WTO, the spirit of this “room to move” runs the very real risk of being nullified. Moreover, the emergence of the WIPO agenda, particularly the SPLT, may further erode the flexibility offered by TRIPS. The need for national governments to draft their legislation to best suit both their environment and the environment of others who may desire access to their PGR is thus crucial. With that in mind, the CBD remains arguably the best set of terms of reference for countries to develop their *sui generis* obligations. But even beyond the CBD, national governments need to ensure that any reform or new legislation is harmonized with what already exists. Also, it must fully take into account the ground realities faced by those parties who hold marketable PGR to ensure the successful implementation of the policy. Given that TRIPS is the only truly legally binding agreement (due to its dispute settlement mechanism), all efforts should be directed at fulfilling Article 27.3 (b) in a way that tailors itself to the environment.

This is not to say that all the issues at hand merely relate to ensuring that national policies are compliant with international obligations. There are far deeper issues at hand; the objectives of fulfilling international obligations are one aspect, but there are other reasons why PGR requires protection. PGR is an embodiment of years and years of experience, pride and identity. They require protection just as physical manifestations of history such as architecture require preservation. The difference however, is that there are substantial financial incentives at stake with PGR. There is both room within current prescriptive obligations and frameworks that can be referred to in order to ensure a balance of both.

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## APPENDIX I - LIST OF ACRONYMS AND ABBREVIATIONS

ABS	Access and Benefit Sharing
AVP	Arya Vaidya Pharmacy
BDA	Biological Diversity Act (India)
BMC	Biodiversity Management Committees (India)
CBD	Convention On Biological Diversity
CBR	Community Biodiversity Register
EDV	Essentially Derived Variety
FAO	Food and Agriculture Organization
IGC	Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore
INR	Indian Rupees
IPR	Intellectual Property Right
PGR	Plant and Genetic Resources
MAT	Mutually Agreed Terms
MTA	Material Transfer Agreement
NBA	National Biodiversity Authority (India)
NBF	National Biodiversity Fund (India)
PBR	Plant Breeders' Right
PCT	Patent Cooperation Treaty
PGR	Plant Genetic Resources
PIC	Prior Informed Consent
PLT	Patent Law Treaty
PPV	Protection of Plant Varieties and Farmers' Rights Act (India)
SBB	State Biodiversity Boards (India)
SPLT	Substantive Patent Law Treaty
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
TBGRI	Tropical Botanical Garden Research Institute
UNEP	United Nations Environmental Programme
UPOV	International Union for the Protection of New Varieties of Plants
USD	US Dollars
WTO	World Trade Organization
WIPO	World Intellectual Property Organization