

# The WTO and patenting of life forms: policy options for developing countries

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**ABSTRACT** *This paper argues that whether developing countries will be able to protect their plant genetic resources and the right of local communities to control and enjoy the benefits of their traditional knowledge will be determined both by policies adopted by the World Trade Organization (WTO) and by the domestic policies these nations implement within their respective countries. Drawing on empirical data from a survey of various stakeholders on the issue of 'patenting of life forms', we argue that developing countries must unite behind the demand for a minimum WTO standard that recognises and upholds the principle of 'prior informed consent'.<sup>1</sup> The paper also presents a number of domestic policy options available to developing countries to protect their key social, cultural and economic rights with regard to the patentability of life forms.*

The patenting of life forms and the international campaign on the right to drugs for HIV/AIDS patients has damaged the credibility of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement as well as that of the World Trade Organization (WTO) system as a whole. TRIPS sets out minimum intellectual property rights (IPRS) standards for all WTO members. In requiring 'wholesale conformity' to IPRS, TRIPS firmly espouses the ideology of liberal capitalism, which places financial rewards over social and cultural rights. The current backlash against this ideology, especially with regard to the use of plant genetic resources from the developing world by scientists and corporations based in richer countries, is clearly illustrated by the global outcry over the development of genetically modified Jasmine rice by a scientist in the USA. At the Fourth WTO Ministerial Meeting in Doha in November 2001 resistance against private property rights resulted in the adoption of an historic declaration on the drugs issue. The declaration cedes developing countries the right to override TRIPS rules where they are convinced this needs to be done to protect public health. This is an unprecedented development in the WTO system, for it declares that a human right can override a property right.<sup>2</sup> As far as the role of patenting life forms and food security are concerned this raises the possibility that the right to food and the right of nations and local communities to control and enjoy the benefits of their traditional knowledge and resources can also override the property rights

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protected by TRIPS.

We argue that whether developing countries will be able to realise this possibility will be determined by the policies adopted by the WTO as well as by the domestic policies these nations implement within their respective countries. The Doha ministerial Meeting of the WTO issued a declaration which sanctioned an examination of 'the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge ... and other relevant new developments' (WTO, 2001: 4). In participating in this examination one lesson the drugs issue provides developing countries is that strategic coalitions between these nations around a positive agenda can produce outcomes that would not be forthcoming if they remain passive, bargain individually or simply attempt to block action.

This paper is divided into two sections. We begin by outlining the controversy surrounding the issue of the patentability of life forms by discussing bio-piracy and food security and by drawing on historical analysis of the issue with regard to the TRIPS Agreement. We then proceed to outline policy options for developing countries to protect their economic, social and cultural rights. A novel feature of this paper is that it outlines the views of key stakeholders from developing countries on the various policy options. We do this by using empirical data gathered from a survey conducted in May 2002 during a conference held in Nairobi, Kenya. The conference was convened by two international NGOs, World Vision and Catholic Relief Services, and was attended by scientific organisations, NGOs, academics, a government body, a donor agency and a UN body, all which are heavily involved in the issue of patentability of life forms in over 20 developing countries.

The evidence suggests that there is a consensus view among both NGOs and scientists that developing countries must unite behind the demand for a minimum WTO standard that recognises and upholds the principle of 'prior informed consent'. It also suggests that the TRIPS Agreement on 'criteria of patentability' and 'patentable subject matter' is vague, and that developing countries can capitalise on this lack of precision by instituting strong domestic policies which include the adoption of national legislation that defines key terms in Article 27 of the TRIPS Agreement.

### **Patenting of life forms: bio-piracy and food security concerns**

In November 2001 more than 1000 Thai farmers from Isaan protested over the development of genetically modified (GM) Jasmine rice by US scientist Chris Deren.<sup>3</sup> Enraged by what they felt was the blatant piracy of their traditional rice, the farmers burnt effigies of President George W Bush and WTO Director-General Mike Moore, condemning the USA as well as the WTO for threatening their livelihoods (Westcott, 2001: 1). The continuing protest against the development of GM Jasmine rice has not only affected Thai-US relations, but has also become yet another addition to a series of public outbursts against the WTO.<sup>4</sup>

Bio-piracy has become a major global concern since the adoption of TRIPS in 1995. If a third party such as a corporation obtains a plant genetic resource from an international seed bank and alters the seed genetically, there are concerns that

that third party may claim the right of ownership over the seed through a patent, even though the original plant genetic resource was in the ‘public domain’ and contains ‘traditional knowledge’ that has been developed through many generations. Correa (2001: 6), sums up this issue by asserting that ‘while commercial breeders and farmers benefit downstream from the value created in the system, there is no compensation for those who contributed upstream to the available pool germ plasm’.

Who is keeping count of this knowledge, and can this knowledge be so freely usurped? This would not be such a big question if a tiny minority of people on a small island used the seeds that are currently being modified. What has fanned the flames of this controversy is that some of the seeds in question are major staple food crops, as well as key export crops, of developing countries, such as the Enola bean and Jasmine rice. Many farmers in poor developing countries depend directly or indirectly on the production of these crops for their survival.

### **The TRIPS Agreement and patentable subject matter**

The issue of patentability of life forms during the TRIPS negotiations stemmed from the evolution of case law in developed countries. Domestic legislation in the OECD countries largely shaped the TRIPS negotiations on patenting biotechnological inventions and plant varieties. When the TRIPS negotiations were taking place, patent offices in the USA, Europe and Japan chose not to define the term micro-organism in order to ensure the patentability of such organisms (Adcock & Llewelyn, 2000: 9–10).<sup>5</sup> Most developed countries deemed micro-organisms (cells as well as sub-cellular components) patentable, thus spurring the growth of the biotechnological industry (Correa, 1994: 13; Garmon, 2002: 1148).

Developing countries were in a different position. The majority did not engage in research in the area of biotechnology, and therefore had no need to introduce domestic legislation to allow the patentability of life forms. They strongly argued for the exclusion of life forms from patentability for development and technological reasons (GATT, 1989: 4–5).<sup>6</sup>

During the TRIPS negotiations, the final outcome on patentable subject matter—which was covered by Article 27.3(b)—was a compromise for most parties, with the provisions being similar to those set out in the European Patent Convention. According to Article 27.3(b) of the final TRIPS agreement, members could 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’.

Therefore, plants, animals and ‘essentially biological’ processes of producing them cannot be patented. However, micro-organisms and ‘non-biological’ processes of producing plants and animals are patentable. The terms ‘non-biological’ and ‘essentially biological’ are not defined in the TRIPS Agreement. TRIPS therefore lays down minimum IPR standards that each country has to institute and enforce through a legal domestic regime.<sup>7</sup>

Article 27.3(b) is of particular concern to developing countries because, although it restricts the patentability of plants and animals *per se*, in allowing micro-organisms to be patented, it contains inbuilt loop holes, since a micro-

organism, such as a cell, can eventually grow into a plant or an animal (WTO, 1999a: 4). A patent on a micro-organism from a plant could easily extend to the whole organism (which could be a seed, or a plant).<sup>8</sup> The term micro-organism is not defined in the TRIPS Agreement and, as explained above, this was in line with the patent laws in the richer countries. Moreover, the fact that non-biological methods of producing plants and animals open up the way for biotechnological companies to patent their so called creations—since they are not using ‘essentially biological’ methods of production—is of paramount importance to the ethical debates on the issue of owning life. The main question that critics ask is: does the act of isolating an already existing gene, using a ‘non-biological method’, make it patentable?

During the TRIPS negotiations the European countries argued that, although plants and animals could be exempted from patentability, plant varieties needed to be protected through a legal system of property rights such as those outlined in the International Union of the Protection of New Varieties of Plants (UPOV). The Convention harmonises international standards on plant-breeders’ rights (PBRs).<sup>9</sup> This was in line with the provisions set out in the European Patent Convention.<sup>10</sup>

The UPOV Convention entered into force in 1968 and was revised in 1972, 1978 and 1991.<sup>11</sup> It undertakes to grant exclusive rights to plant breeders’ to produce, offer for sale and market propagated material of a new variety.<sup>12</sup>

Many food rights and farmers groups from developing countries have argued over the years that the UPOV Convention has been a lobbying vehicle used by rich countries to force the developing world to adopt ‘patent like’ exclusive rights over plant varieties (TWN, 1999; GRAIN, 1996; Mangeni, 2000). Generally UPOV was not endorsed by developing countries because they felt that the Convention, through the introduction of private property rights, would introduce legal and economic restrictions on the livelihoods of poor farmers in their countries (WTO, 1999c: 3). They argued that small farmers would be the last to benefit from a private system of rights, which could only guarantee exclusive rights to those who could produce a stable, distinct and uniform variety.

The final outcome of Article 27.3(b) of the TRIPS Agreement on patenting plant varieties was that:

Members shall provide for the protection of plant varieties either by patents, or by an effective *sui generis* system or by any combination thereof.

If developing countries choose not to protect their plant varieties through patents, they will have to adopt a *sui generis* (specifically tailored) IPR system. Many of these countries have been under pressure from developed countries to adopt the UPOV 1991 Convention as a *sui generis* option (GRAIN, 1996). Third world countries have been concerned that the 1991 amendments to UPOV have given way to the wishes of large multinational corporations (WTO, 1999c: 3; WTO, 2000d: 3).<sup>13</sup> Whereas UPOV 1978 upheld farmers’ rights by allowing them to save, exchange and to a limited degree market protected varieties, the 1991 amendments leave it to governments to decide whether or not farmers should be permitted to save seeds from their own holdings. In the majority of developing countries where agriculture is still the dominant economic sector and where small

farmers depend upon saving and exchanging seeds for their survival, acceding to the UPOV 1991 Convention so as to comply with TRIPS obligations is problematic.

### Criteria for patentability

Article 27 of the TRIPS also stipulates that:

patents shall be available for any invention, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

TRIPS does not define the terms ‘new’, ‘inventive step’ or ‘capable of industrial application’. Members can exclude from patentability commercial exploitation which is necessary, to protect *ordre public*, or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment.

### Controversy over TRIPS

Most WTO members had to make changes to their IPR national legislation or in some cases develop and enact new laws to ensure that their domestic legal systems were TRIPS compliant. Analysis of what TRIPS actually entails (especially in the area of plant breeders’ rights) was undertaken during the post-1995 stage in many developing countries, since they had just gone ahead and accepted the TRIPS Agreement, as part of the whole single undertaking package which also created the WTO.

Soon after the WTO was established the conflicts between the TRIPS Agreement and the Convention on Biological Diversity (CBD) were illustrated by governments in developing countries and several large NGOs such as Erosion Technology and Concentration (based in Canada, formerly known as RAFI), Research Foundation of Science, Technology and Ecology (based in India), Genetic Resources Action International (GRAIN), Third World Network, SEATINI, Oxfam, and Action Aid. The CBD was negotiated under the auspices of the United Nations Environment Programme. It has been ratified by 183 countries and therefore, one could argue, has become part of customary international law. Article 15 of the CBD stipulates that access to genetic resources where granted, shall be on mutually agreed terms ... and subject to prior informed consent.

Critics of TRIPS note that these principles are not recognised in the TRIPS Agreement and therefore could easily lead to the bio-piracy of genetic resources from the developing world to the developed (WTO, 2000b). If TRIPS set a minimum standard, which required members to ensure that their domestic legal regimes enforced the principle of prior informed consent for example, then an innovator would have to disclose the origins of the genetic resource as well as obtain consent from the country whence the resource was obtained (WTO, 2000a: 2). This would contain the incidence of bio-piracy and developing countries could also set out parameters for granting consent under ‘mutually agreed terms’.

Article 8(j) of the CBD obliges contracting parties, as far as possible and as appropriate:

subject to its national legislation [to] respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities ... and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.<sup>14</sup>

The food rights campaigners argue that, since TRIPS does not recognise traditional knowledge, or even the fact that it is communities and farmers in developing countries who preserve precious genetic resources which are used world wide, TRIPS in a sense offers a free licence to innovators from more developed countries to build on the knowledge that essentially belongs to communities (Zerbe, 2001: 669). The communities get nothing in turn and in some cases, such as with the Jasmine rice, their dependence on rice exports for a living makes them very vulnerable in the absence of such recognition.

Protecting traditional knowledge has stirred quite a debate within both the WTO and the World Intellectual Property Organization (WIPO). The criteria for patentability covered by the IPR model in the TRIPS Agreement, are inappropriate to protect traditional knowledge. Aguilar, for example, questions how an IPR can be 'given to an indigenous person' if 'to qualify for a patent, the process or product is required to be an innovation, and it must have industrial applicability?' (Aguilar, 2001: 250). He contends that traditional knowledge is collective and accumulated over generations. Nijar argues that this can be overcome if WTO member states define the term novel to mean 'innovations of communities in relation to biological resources and anything derived from them' (Nijar, 1998: 12). He suggests that ownership of such inventions could be vested in the community as a whole (as opposed to a single individual) and therefore would 'never become private property'.

Similarly critics point out that the TRIPS treaty conflicts with the International Undertaking on Plant Genetic Resources (IU), which was established in 1983 under the aegis of the Food and Agriculture Organisation (FAO). The IU's main aim was to ensure that 'plant genetic resources are explored, collected, conserved, evaluated, utilised and made available for plant breeding and other scientific purposes' (Article 4). Food rights campaigners and some developing countries are of the opinion that the TRIPS Agreement should recognise the provisions of the IU, in particular that countries have the right to take appropriate and other legislative measures to protect and conserve their plant genetic resources.

Article 27.3(b) of TRIPS was due to be revised in 1999.<sup>15</sup> The African Group seized the opportunity of the provision and prepared a strongly worded communication during the preparations for the WTO ministerial meeting in Seattle that year, which vehemently questioned the overall provisions of Article 27.3(b). The Group suggested that the revision of the article should take into account the Convention on Biological Diversity as well as the FAO International Undertaking. Insinuating that a review of 27.3(b) could lead to changes in its substantive nature, the Group highlighted the artificial distinctions that it made 'between biological and microbiological organisms and processes'. The communication pointed out that:

there is a lack of clarity on the criteria/rationale used to decide what can and cannot be excluded from patentability ... By stipulating compulsory patenting of micro-

organisms (which are natural living things) and microbiological processes (which are natural processes), the provisions of Article 27.3 contravene the basic tenets on which patent laws are based: that substances and processes that exist in nature are a discovery and not an invention and thus not patentable (WTO, 1999a: 4).

The African Group proposed that the review of the Article should clarify why plants and animals are exempt from patentability and micro-organisms are not. Furthermore, it proposed that the review should clarify that 'plants and animals as well as micro-organisms and all other living organisms and their parts' cannot be patented, and that 'natural processes that produce plants, animals and other living organisms are also not patentable' (WTO, 1999a: 4).<sup>16</sup>

Also, the Group wanted the review of 27.3(b) to make changes which would allow member states to develop a *sui generis* law to protect innovations of indigenous and local farming communities in developing countries (consistent with the CBD and the IU); the continuation of traditional farming practices (including the right to save and exchange seeds, as well as sell their harvest) and allow states to prevent any anti-competitive rights or practices which would threaten the food sovereignty of people in developing countries, (WTO, 1999a: 5). In July 1999 India also issued a communication, which expressed similar sentiments. India argued that, since it was widely agreed that the TRIPS Agreement was incompatible with the Convention on Biodiversity, there was a need therefore, 'to incorporate a provision that patents inconsistent with Article 15 of the CBD must not be granted' (WTO, 1999c: 1).

A year later, after the failed WTO ministerial meeting in Seattle, the USA issued a communication to the TRIPS Council on 3 October 2000. It confirmed the fact that the term 'micro-organism' was not defined in US, EU or Japanese laws, and, as noted by the European Patent Office (EPO), it did not seem expedient to introduce such a definition as the rapid evolution in the field of microbiology would necessitate its frequent updating (WTO, 2000c: 4).

The USA insisted that the Oxford dictionary definition of the term micro-organism—organism not visible to the naked eye, eg bacterium or virus—was sufficient to determine what it meant. The US proposal also sought to explain that patent claims could only be made to inventions, and not mere discoveries. This was a controversial assertion since, according to Section 101 of the US patent law, patents can be granted to anyone who 'invents or discovers any new and useful process'.

A communication to the TRIPS Council from Brazil in November 2000 challenged the claim made in the US communication that only inventions were patentable, since according to Brazil, 'there is evidence to prove that patent offices in some developed countries do not necessarily follow such a policy and they tend to accept overly broad claims on genetic resources'. Furthermore, such broad patents are defined by 'loose criteria to establish novelty, inventive step and industrial application' and therefore undermine the patent system as a whole, since they yield 'high legal uncertainty' (WTO, 2000d: 2–3). According to Brazil, while some countries contended that micro-organisms 'were an important element to encourage research in biotechnology', too broad patents ran the risk of restricting research, since the patent holder had exclusive rights to exploit the genetic material.

On 16 September 2002 a 178-page report entitled *Integrating Intellectual Property Rights and Development Policy* was launched by the UK-sponsored Commission on Intellectual Property Rights. The report raises serious doubts as to whether the international IPR regime is in the interests of developing countries (Dutfield, 2002: 19). According to Dutfield the commission does not 'break any new ground' in raising these doubts, but what is 'truly significant is their source'. The Commission was comprised of experts on intellectual property rights from developed and developing economies who are all 'eminent and widely respected authorities on intellectual property' and have expertise in various disciplines and work in 'industry, government academia and the legal profession'. Given its membership, Dutfield argues that the Commission 'can hardly be accused of bias against the intellectual property system'. Key recommendations from the Commission include that developing countries should not provide patent protection for plants and animals and that they should develop *sui generis* legislation to suit their agricultural systems. Furthermore, on the issue of traditional knowledge and genetic resources, the Commission recommends that all countries should, through domestic legislation, require the 'obligatory disclosure in patent applications of the geographical source of the genetic resources from which an invention is derived' (Dutfield, 2002: 19).

#### **Policy options for developing countries: views from developing countries**

A conference on genetically modified organisms (GMOs) was held in Nairobi, Kenya, 14–16 May 2002. It was organised by two international NGOs, World Vision and Catholic Relief Services. Together, these two bodies operate in more than 100 developing countries. Food security, especially in the African region is key to their programme and policy work. The conference was attended by representatives from five of the biggest biotechnology agencies in Africa and 16 NGOs. In addition a representative from the FAO, a major donor agency, a farmers organisation and a Kenyan government official also attended the conference. There were several representatives from other agencies. The common theme bringing together such a diverse group of specialists from a wide range of developing countries was GMOs. The issue of patentability of life forms was high on the agenda for both the scientists and the NGOs throughout the duration of the conference. A survey through the use of a questionnaire was conducted during the conference and a 100% response rate was recorded. Table 1 summarises the responses from the survey, which focused on policy options for developing countries with regard to this issue.

Over half the respondents listed the threat to food security from bio-piracy and monopoly control of biotechnological processes and products by corporations in rich countries as their main concerns with regard to the patentability of life forms in developing countries. The rest listed farmers' rights, ethical concerns and the rights of indigenous communities.

#### **The principle of prior informed consent**

In its 2000 submission (WTO, 2000b: 3), the African Group advanced the proposi-

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TABLE 1  
Questionnaire on TRIPS and the patentability of life forms

|                                                                                                                                                                                                                | <i>Strongly disagree</i><br>% | <i>Disagree</i><br>% | <i>Not sure</i><br>% | <i>Agree</i><br>% | <i>Strongly agree</i><br>% | <i>N</i> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|----------------------|----------------------|-------------------|----------------------------|----------|
| a. Life forms should be patented                                                                                                                                                                               | 51.9                          | 18.5                 | 22.2                 | 7.4               | 0                          | 27       |
| b. Developing countries should control patents over plants and plant genetic resources by clarifying that mere discoveries of nature are unpatentable                                                          | 0                             | 0                    | 7.4                  | 37.0              | 55.6                       | 27       |
| c. Naturally occurring micro-organisms such as bacteria, fungi and algae should be unpatentable                                                                                                                | 0                             | 0                    | 30.8                 | 23.1              | 46.2                       | 26       |
| d. Biotechnological innovations (where the organism has been modified by direct means of human intervention in their genetic composition) should be patentable                                                 | 7.4                           | 25.9                 | 11.1                 | 40.7              | 14.8                       | 27       |
| e. Resources that have been used over many generations by communities and are held in the public domain should be regarded as unpatentable                                                                     | 0                             | 0                    | 3.7                  | 29.6              | 66.7                       | 27       |
| f. An invention should be unpatentable if it can be demonstrated that it will have a negative effect on the public (such as the right to food or the right to good health)                                     | 0                             | 3.8                  | 3.8                  | 23.1              | 69.2                       | 27       |
| g. Developing countries must continue to lobby for the principle of prior informed consent (consent of a country from where the plant genetic resource is obtained) within the WTO                             | 0                             | 0                    | 3.7                  | 29.6              | 66.7                       | 26       |
| h. In the case where a patent on a genetically modified plant resource threatens basic food security in a developing country, the government of the given country should have the right to override the patent | 0                             | 0                    | 3.7                  | 22.2              | 74.1                       | 27       |

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tion that ‘the TRIPS Agreement should contain a provision to promote and not undermine the conservation and sustainable use of genetic material, and to prevent the associated bio-piracy’.<sup>17</sup> Like the African Group, India takes the position that the problem of bio-piracy cannot be solved through domestic laws,

and that ‘there is a need to provide appropriate legal and institutional means for recognising the rights of tribal communities ... at the international level’. India has further proposed that the CBD and the TRIPS treaties should be harmonised and that: ‘patent applicants should be required to disclose the source of origin of the biological material utilized in their invention under the TRIPS Agreement and should also be required to obtain prior informed consent (PIC) of the country of origin’ (WTO, 2000a: 2). According to India, if this were done, it would enable the relevant domestic institutions to ensure the sharing of benefits from the commercial utilisation by the patent holders who make use of traditional knowledge that belongs to local and indigenous communities.

In a hypothetical situation, for example if a third party tried to patent the genetically modified Jasmine rice in the USA, the Thai government would have to go through a costly battle to challenge the patent in the US courts. The Thais would have to prove that the Jasmine rice ‘invention’ was not novel (given the US definition of novel). On the other hand, if the US patent law recognised the principle of ‘prior informed consent’—which would oblige an inventor to seek permission from the country from which the genetic material was obtained—then the Thais would stand a chance of having the patent revoked, since permission to use the resource was not sought by the third party. The only way in which developed countries could establish such a principle is through the WTO. The USA, for example, is not a contracting party to the CBD and therefore has no obligation to establish the principle of prior informed consent in its domestic laws. Yet out of the total of 16 327 biotechnology patents held worldwide in 1997, the USA alone held 5775 (Correa, 1999: 11).

Interestingly, during the same week when the UK-sponsored Commission on Intellectual Property Rights report was published, the UK government dropped its opposition to an EU proposal to the TRIPS Council to introduce a multilateral system to disclose and share information about the geographical origin of biological material used in patent applications, so as to prevent bio-piracy (Dutfield, 2002: 19). The EU, however, does not support any formal or additional patentability criterion, but rather that the issue of disclosure should be regulated through civil or administrative law. While this is a positive step, it does not go far enough to prevent bio-piracy through upholding the principle of prior informed consent.

Roughly 92% of the participants interviewed during the conference on GMOS agreed that the principle of prior informed consent should be recognised by the WTO. Developing countries should continue to try and lobby for this principle to be adopted as the negotiations on the revision of Article 27.3(b) of the TRIPS Agreement proceed within the WTO.

### *Domestic policy options*

Developing countries have several domestic policy options that they could pursue. However, they can at any time make use of the provision within Article 27 of the TRIPS Agreement to exclude certain inventions from patentability to ‘protect morality, human, animal or plant life or health, or to avoid serious prejudice to the environment’. The following are some practical steps that

developing countries can take to balance the rights of investors with those of farmers and local communities.

*Defining the criteria of patentability.* Under the TRIPS Agreement developing countries are obliged to provide a patent to any process or product which is new, non obvious and capable of industrial application. Developing countries can tighten the criteria of patentability by defining the term 'novel'.<sup>18</sup> An invention that relates to plant material cannot be excluded from patentability by virtue of the fact that it is a form of life because micro-organisms as well as non-biological processes of producing plants and animals are patentable under TRIPS. However, developing countries have the option of controlling patents over plants and plant genetic resources by stipulating that mere discoveries of nature are unpatentable. WTO member states could raise the threshold of the term 'novel' by clarifying that an invention involving biological material is not novel if it merely replicates biological material, or the function of biological material which occurs naturally (Adcock & Llewelyn, 2000: 17).

Second, resources that have been used over many generations by communities and are generally held in the public domain should also be regarded as unpatentable. This relates to the concept of 'prior art', which developing countries can define broadly. Prior art could include 'any material deposited in a gene bank or other deposit institutions', as well as 'knowledge or materials developed by and diffused within local or indigenous communities' (Correa, 2000: 232).

Among the respondents 70.4% disagreed that life forms should be patentable, with the NGOs recording an average response of 'strongly disagree' and the scientists recording 'not sure' ( $p < 0.05$ ). That developing countries should control patents over plants and plant genetic resources by clarifying that mere discoveries of nature are unpatentable was agreed by 92.6% of respondents, while 96.3% of them agreed that resources that have been used over many generations by communities and are held in the public domain should be regarded as unpatentable; NGOs and scientists did not record a statistical difference in their response to this particular point.

With regard to the condition of non-obviousness (or involving an inventive step), developing countries could define the term so that any invention, which 'merely identifies the biological material and/or the natural function of the biological material', is not patentable (Adcock & Llewelyn, 2000: 18). Similarly an invention that involves biological material could be regarded as incapable of industrial application—and therefore patentability—if it can be demonstrated that it will have a negative effect on the public. Public benefit could be defined as food security, the right to good health, etc. Table 1 illustrates that most respondents agreed with this point.

TRIPS does not prevent developing countries from taking these measures since it has not defined the conditions of patentability.

*Protecting traditional knowledge and farmers' rights.* Strong laws could be enacted to ensure policy coherence between the provisions of the CBD and those of the TRIPS Article 27.<sup>19</sup> While developing countries, (especially the African

Group) signalled the importance of the CBD during the meetings on the review of 27.3(b), their words have to be supported by domestic laws which recognise traditional knowledge and ways in which it can be preserved.

Article 9 of the revised IU stipulates that ‘the responsibility for realising Farmers’ Rights as they relate to plant genetic resources for food and agriculture, rests with national governments’. Developing countries have to make sure that their domestic laws protect the rights of farmers. According to Article 9.2 of the revised IU, laws to protect ‘traditional knowledge relevant to plant genetic resources for food and agriculture’ as well as to protect the rights of farmers ‘to equitably participate in sharing benefits arising from the utilisation’ of such resources, could in fact go hand in hand with the principle of prior informed consent. Therefore, if an inventor wanted to patent a plant genetic material in a given country, in deciding to give consent, the given country could also decide on how to share the benefits from the commercial or other exploitation of the resource on mutually agreed terms.

Peru has become the first country to establish a comprehensive legal system to protect the traditional knowledge of indigenous communities. The law that came into force on 10 August 2002 seeks to implement Article 8(j) of the CBD, as well as the principle of prior informed consent. The legislation requires the written consent of local and indigenous communities for the use of their traditional knowledge by third parties (Ruiz & Lapena, 2002: 15). South Africa, India and other countries are in the process of putting in place legislation to protect their biological resources and traditional knowledge.<sup>20</sup>

*Patentable subject matter: defining the term micro-organism.* The term micro-organism means different things to different people and institutions. Adcock and Llewelyn have identified seven different definitions of the term (2000: 16). Developing countries should make use of the fact that TRIPS has not defined this term by conducting serious analysis of it and defining it according to their own national interests. This would ensure that they have effective control over their plant genetic resources. According to the Brazilian patent legislation, for example, all plants and animals except transgenic micro-organisms are unpatentable. Transgenic micro-organisms are defined as ‘organisms, except for all or part of plants or animals, that express, by means of direct human intervention in their genetic composition, a characteristic normally not attainable by the species under natural conditions’ (WTO, 2000d: 2).

Developing countries could clarify that micro-organisms do not include naturally occurring organisms such as bacteria, fungi, algae, protozoa and viruses. This would ensure that these naturally occurring micro-organisms cannot be patented. Around 70% of the respondents agreed with this point. Developing countries could also clarify that, in order to qualify for patentability, any micro-organism will have to be modified through direct human intervention. Over 55% of the respondents agreed with this, and there was no statistical difference between the view of the scientists and that of the NGOs with regard to both these options.

*The protection of plant varieties through a sui generis system that complements the protection of traditional knowledge and farmers' rights.* Article 27.3(b) of TRIPS gives developing countries the option of protecting plant varieties either through patents or through an effective *sui generis* system. The protection of plant varieties through patents would restrict further research and development since in patent laws there is no breeders' exemption as there is in the case of plant breeders' rights. According to UPOV the breeders' exemption includes 'breeding acts done privately and for non-commercial purpose, acts done for experimental purposes and acts done for the breeding of other varieties'.<sup>21</sup> Therefore, developing countries do not have to protect varieties through patents. They can use alternative IPRs such as plant breeders' rights. Any *sui generis* system has to provide for an IPR and, therefore, if they wish to do so, developing countries could develop an IPR system which complements the principles within the CBD and the revised IU with special provisions to incorporate farmers' rights and traditional knowledge (Leskien & Flitner, 1997: 30). Developing countries wishing to accede to the UPOV Convention (so as to meet their obligations under TRIPS) currently only have the option of joining the 1991 Convention. Therefore, in order to meet their TRIPS requirements, they need to devise better options than merely acceding to the UPOV 1991 Convention.

Mangeni (2000) claims that to date the debate has focused on 'which form' of *sui generis* rather than what an 'effective' *sui generis* system should be. TRIPS does not define the word 'effective' and therefore developing countries can use this to their advantage and ensure that a *sui generis* system is based on public interest and, according to Article 7 of the TRIPS Agreement, is 'to the mutual advantage of producers and users of technology and in a manner conducive to social and economic welfare'. Similarly, members could use the provisions in Article 8 of the TRIPS Agreement, which stipulates that 'in formulating or amending their laws and regulations' member states may 'adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development'.

According to Nijar a *sui generis* system could include the principles of prior informed consent of communities, disclosure of origin of the source of products or processes, and farmers' rights (1998: 12). Aguilar (2001: 253) cites the example of Costa Rica, which has established an entitlement called 'The Community Intellectual Rights, *Sui Generis*' which recognises the knowledge, practices and innovations of indigenous communities. The modalities of the entitlement are yet to be worked out.

### Conclusion

The review of Article 27.3(b) of TRIPS has admittedly produced little in terms of results hitherto, despite being in progress for over two years. Nevertheless, much to the irritation of most developed countries, it has generated some highly controversial debates around the issues of bio-piracy, prior informed consent, farmers' rights and the protection of traditional knowledge within the WTO. All these issues directly or indirectly affect food security in developing countries.

It is widely acknowledged that intellectual property rights issues were introduced into the WTO largely as a result of pressure from the USA and later the other OECD countries, even though most developing countries opposed doing so. While developing countries may have conceded to TRIPS during the Uruguay Round, the review of Article 27.3(b) illustrates how the debate has backfired in the face of the very powers that wanted to ensure that the TRIPS treaty would set minimum standards in all countries allowing the patentability of the processes and products of biotechnology. Proposal after proposal submitted to the WTO from developing countries challenges the very basis of patenting life forms, and seeks clarification on the terms and key issues surrounding the patentability of life forms. Developed countries are using their best legal and diplomatic skills to portray these concerns as irrelevant.

Article 27 is legally vague and therefore developing countries have the opportunity to use it to develop strong national laws to curb bio-piracy and to make sure that they can indeed gain from any research that builds on their traditional knowledge or makes use of the rich biodiversity that their farmers and local communities have sustained and nurtured over many generations. They should also continue to lobby strongly for a worldwide standard on the recognition of traditional knowledge and the principle of prior informed consent within the WTO in the upcoming period.

The protection of traditional knowledge was to be debated following the decision taken during the fourth WTO ministerial meeting in Doha. This is therefore the time for developing countries to take strong action to ensure that the Doha development agenda is indeed focused on development issues such as food security.

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## Notes

- <sup>1</sup> Consent of a country from where a plant genetic resource is obtained.
- <sup>2</sup> While it is clear that the TRIPS Agreement allows for exceptions to IPR rules particularly to protect human, plant and animal life, in reality it took a world-wide campaign which lasted for over six months for developing countries to assert this right in the WTO, which took the form of a non-binding declaration. The declaration points to a political victory as opposed to a legal one.
- <sup>3</sup> American scientist Chris Deren obtained the Jasmine rice strain in 1995 from the International Rice Research Institute (IRRI), which is based in the Philippines (Westcott, 2001: 1). American companies such as West Palm Beach-based Sem-Chi Rice Products would like to invest in this 'new variety' if it proves to be worth their while by planting 9000 acres of it (Kimpel, 2001: 1).
- <sup>4</sup> It is important to point out that, in a legal sense, the Jasmine rice issue has nothing to do with the WTO, since to date no patent has been granted to US scientist Deren either in Thailand or in the USA. However, there is no real guarantee that Deren will not apply for a patent, which is the first problem. The second is that the present knowledge that Deren has developed—by building on Thai knowledge—could be further built on by another party, which could patent the supposedly 'novel' seed.
- <sup>5</sup> It should be noted that the term 'micro-organism' has still not been defined in these countries.
- <sup>6</sup> For more information on what transpired during the TRIPS negotiations, especially with regard to the extreme reluctance of developing countries to negotiate a treaty on intellectual property rights within the multilateral trading system, see Stegenann (2000) and Raghavan (1990).
- <sup>7</sup> The patent owner has the exclusive rights to prevent anybody from making, using, selling, offering for sale, or importing the product without the consent of the owner. Patents have to be provided for any process or product. Also, the TRIPS Agreement adopted the minimum standard of terms of protection of 20 years.
- <sup>8</sup> In Western countries patents typically begin by claiming a gene standing alone corresponding to a

sequence, then a vector, which incorporates the sequence, and possibly too the organism transformed by the means of the vector (Correa, 1999: 9).

- <sup>9</sup> In the early 1900s plant breeding evolved to become an activity separate from farming in North America and Europe. Public research institutions and seed companies 'became specialised in crossing and creating new varieties of plants'. After the Second World War the Europeans worked out a *sui generis* (specially tailored) IPR system known as plant breeders' rights (PBRs), which granted exclusive rights to breeders (GRAIN, 1996: 2).
- <sup>10</sup> The USA, on the other hand, would ideally have wanted no exemptions to patentability within TRIPS, given their own domestic law where plants are freely patentable. The majority of the developing countries were reluctant to give into any provision for the protection of plant varieties, and many of them would have preferred to exclude all living things from patentability (GATT, 1989: 4).
- <sup>11</sup> It was initially just signed by six developed countries interested in protecting the exclusive rights of plant breeders.
- <sup>12</sup> Also under the 1978 Convention special protection for farmers is allowed under the farmers' privilege. Small farmers can freely access plant genetic resources and continue to save seeds for the coming seasons and informally exchange them with other farmers.
- <sup>13</sup> The 1991 Convention has expanded the rights of breeders' to include not only the production, offering for sale and marketing of the propagated material of a new variety, but also reproduction, conditioning for propagation, exporting, importing and stocking for such purposes.
- <sup>14</sup> Article 8(j) of the CBD has its limitations. According to the African Group the CBD leaves the protection of traditional knowledge to the discretion of nations through the use of language such as 'subject to its national legislation' (WIPO, 2001: 3). In recognising this, contracting parties to the CBD have established an open-ended inter-sessional working group—comprised of nation states as well as indigenous and local communities—to explore and advance the implementation of Article 8(j).
- <sup>15</sup> It is not clear why this provision was included. It is thought by some that the provision was included at the strong insistence of developing countries who wanted a form of security against the huge risk they had taken in accepting the inclusion of Article 27.3(b) in the first place. Yet others argue that the review provision was included under pressure from the USA in order to change the Article so that any exceptions to the patentability of life forms could be removed.
- <sup>16</sup> Developing countries tabled it as one of the issues that needed to be addressed before they could agree to a new round of trade negotiations. This was a time when developing countries were formally linking the issue of the right to food to the TRIPS treaty. It was quite a remarkable change from the old days of GATT when developing countries were passive players, and largely 'out of the debate'. During the lead up to Seattle and indeed Doha, they were very active in clearly linking their human rights concerns to the WTO agreements. Regardless of the outcome of Doha, this process change in itself is of historical importance within the multilateral trading system. Also, the influence of NGOs on developing countries is clearly reflected in official WTO proposals from these nations. Suffice it to say that the proposal met great resistance from the richer countries who did not want to clarify that life forms could not be patented. Such a clarification would go against their biotech interests. However, what the proposal did achieve was to generate a sizeable amount of momentum in the WTO to keep the issue alive right through to the preparations for the Doha ministerial meeting, where it was covered under the list of the implementation concerns.
- <sup>17</sup> However, this is not the overarching view of all developing countries. South Africa, for instance, takes the position that Article 27.3(b) should not be opened up for renegotiations, but 'is in the process of defining how the country's interests can be best promoted and protected, if the section were to be renegotiated' (Wolson, 2001). Egypt too does not take the position that the Article should be negotiated to include new provisions to protect traditional knowledge or the principle of prior informed consent (WTO, 1999b).
- <sup>18</sup> Even in the OECD countries the term 'novel' is defined differently. In the USA for instance a criterion which determines the novelty of an invention is the requirement that it should not have been 'published or described in a printed publication more than one year prior to the date of application'. Under the European Patent Convention, an invention is novel if has not been made available anywhere in public orally or in written form, or in any other way, before the patent application date. For more information see Leskien and Flitner (1997: 12).
- <sup>19</sup> See for example Tansey (1998).
- <sup>20</sup> India is in the process of enacting legislation to conform to the CBD. The legislation addresses the basic concerns of access to, and collection and utilisation of, biological resources and knowledge by foreigners, and sharing of benefits arising out of such access. The legislation provides for a National Biodiversity Authority, which will grant approvals for access, subject to conditions to ensure equitable sharing of benefits (WTO, 2000a: 6–7).
- <sup>21</sup> For more information, see Correa (1999: 13).

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