Intellectual Property Rights and Agriculture: Interests of Developing Countries

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DRAFT FOR DISCUSSION

Intellectual property rights (IPRs) can be loosely defined as legal rights governing the use of creations of the human mind¹. This term covers a bundle of rights, each with not only different scope and duration but with a different purpose and effect. All IPRs generally exclude third persons from commercially exploiting protected subject matter without the explicit authorization of the right holder for a specified duration of time¹. This enables IPR owners to use or disclose their creations without fear of loss of control over their use, thus helping in their dissemination. It is generally believed that IPRs help encourage creative and inventive activity and make for orderly marketing of proprietary goods and services. Protection against unfair competition is the underlying philosophy for all IPRs, although there are some specific rules in international IP law targeted towards this. IPRs are limited to a defined territory and have historically been attuned to the circumstances and needs of different iurisdictions

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1. Introduction

Intellectual property rights (IPRs) can be loosely defined as legal rights governing the use of creations of the human mind¹. This term covers a bundle of rights, each with not only different scope and duration but with a different purpose and effect. All IPRs generally exclude third persons from commercially exploiting protected subject matter without the explicit authorization of the right holder for a specified duration of time². This enables IPR owners to use or disclose their creations without fear of loss of control over their use, thus helping in their dissemination. It is generally believed that IPRs help encourage creative and inventive activity and make for orderly marketing of proprietary goods and services. Protection against unfair competition is the underlying philosophy for all IPRs, although there are some specific rules in international IP law targeted towards this. IPRs are limited to a defined territory and have historically been attuned to the circumstances and needs of different jurisdictions.

The IPRs that raise quite distinctive issues for the agricultural sector are patents and plant breeders' rights³. Geographical indications are another form of IP relevant to this sector in that they are mostly,

though not solely, applied on agricultural products and are briefly dealt with later in this paper.

Patents are granted for novel, non-obvious and useful inventions and generally give the legal right to exclude others from making, using or selling that invention for a limited period, usually, 20 years from the date of application. All patent laws allow some exceptions. For instance, almost all jurisdictions exclude from patenting inventions that are contrary to morality, public order or public health. Again, not all jurisdictions allow the patenting of inventions on living material such as plants and animals or even of biotechnological processes resulting in such products. Similarly, use by others is allowed in limited circumstances, such as for purposes of research, or through compulsory licenses authorized for specific purposes by the government or courts.

Plant breeders' rights (PBRs) were developed to reward conventional breeding methods used to develop new plant varieties. Such sui generis protection is weaker than patent protection in that right holders cannot exclude other breeders from using the protected variety to develop other varieties and cannot prevent farmers from re-using the seed obtained from the new variety. The protection lasts usually for 15-20 years depending upon the type of plant. The criteria used to grant such protection is also somewhat weaker than that used for patents. New plant varieties have to follow three criteria known as DUS: they have to be distinct (D) from earlier known ones, uniform (U) or homogeneous i.e. display the same essential characteristics in every plant and stable (S) i.e. retain the same essential characteristics upon reproduction⁴. With the development of hybrids, plant breeders have also resorted to trade secret protection to prevent the misappropriation of the undisclosed parent lines. Typically, seed produced by hybrid plants do not produce the same quality plant in further generations and hence farmers have to re-

^{*} This paper has drawn heavily from the author's forthcoming book: "*Intellectual Property Rights in the World Trade Organization: The Way Forward for Developing Countries*", Oxford University Press, India (2000). Views, interpretations, conclusions and errors that remain are solely attributable to the author.

¹ See definition given by WTO available at <u>http://www.wto.org</u>. The term 'ideas' is not used as copyright protects the specific expression of ideas and not the idea itself. ² In the case of trademarks, geographical indications and trade secrets this may mean an unlimited time, under certain circumstances.

³ Other IPRs like trademarks and trade secrets are also relevant but do not raise distinctive issues when applied to the agricultural sector.

⁴ Traditional land races, developed by farmers in their fields, usually do not meet the criteria of uniformity or stability. This has raised the issue of recognizing "farmers' rights" over such landraces, an issue being discussed in the FAO and in UNEP.

purchase seed for every crop season in order to maintain yield or other characteristics of the new plant variety. This is also known as "biological protection" as distinct from legal protection⁵.

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), 1995, when fully implemented, will unambiguously strengthen protection of intellectual property rights (IPRs) almost worldwide, a feat not achieved by any other single international treaty ever before. In particular, it will bring important standards of patents, PBRs and geographical indications in major developing WTO member countries closer to those in major developed countries⁶. TRIPS, however, does not harmonize IP laws and procedures but only sets minimum standards that can be implemented differently in different legal systems. The agreement also permits certain widely recognized limits to these IPRs. Nevertheless, future methods of doing business, including in the agricultural sector, may inevitably change in developing countries not only on account of TRIPS implementation but also because of increased awareness and changing attitudes towards IPRs amongst domestic innovators. Developed countries were obliged to be in compliance with TRIPS provisions by January 1996, while economies in transition had time up to end of 1998 to do so. Developing countries were given time up to end of 1999 to

implement almost all these provisions while least developed countries can do so by 2006.

TRIPS has engendered considerable academic debate on the economic implications of strengthened intellectual property protection in developing countries. However, notwithstanding the recent spate of theoretical and empirical studies on the effects of strengthened IPR protection on foreign investment, international trade, and transfer of technology, there remains considerable uncertainty on the precise nature and dimension of these 'positive' effects⁷. Nevertheless, under certain circumstances and for certain sectors more than others, the strength of patent protection has been shown to be related to trade. Weak patent protection in large, industrializing countries has been shown to be a significant barrier to manufacturing exports from OECD countries. There is also some evidence to show that under specific conditions weak patent and other IP protection could diminish flows of foreign direct investments. It is not possible to make a clear statement on the effects of strengthened IP protection on the transfer of technology as there is no clear measure of the quality of technology transferred. Much of the uncertainty of recent econometric studies also arises on account of the lack of an accurate measure of the strength of IPR protection and reliable data over a period of time for different countries.

More importantly, there is hardly any study that shows the effect of strengthened patent protection on domestic inventive activity in developing countries. For developing countries, we could still be fairly close to the situation described by Fritz Machlup in the context of the patent system in the US in 1958^8 :

"If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its

⁵ Recently, a newly patented genetic technology to prevent unauthorized reproduction of seed or of the desired characteristic, dubbed as the "terminator", caused widespread fears that such biological protection could be applied to any plant variety and could, when commercialized, eliminate the need for IPR protection altogether. In the wake of the debate on this issue, some countries, like India, have already banned the use of this technology, and some organizations like the CGIAR and the Rockefeller Foundation have pledged not to use it. It is, at the present time, not clear when such technology would be commercialized and what form it would eventually take. See CBD SBSTTA Report for more information on this technology. ⁶ Throughout this paper, the terms 'developed countries' and 'developing countries' are loosely used to define the crucial difference between those who demanded rules on strengthened IPR protection in the global trading system and those who opposed them. The picture is complicated as national interests differ with particular sectors and particular IPRs. These complications influenced the positions of different countries during these negotiations.

⁷ See Maskus (1999), Chapter III for an update of the literature in economics on this subject.

⁸ See Study of the Sub-Committee on Patents, Trademarks and Copyrights of the Committee on the Judiciary, US Senate, (1958), p. 79.

economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it."

Since Machlup's time there have been many studies that show that patents are not necessarily the most important economic instrument for generating innovation, except in certain industries such as pharmaceuticals or specialized chemicals⁹. In the present context, patents have proved to be important also to the biotechnology industry. However, an evaluation of the "all or nothing" option is not very meaningful and it is important to study the effect of varying the ingredients of the patent system. For instance, Scherer, after a detailed study¹⁰, was persuaded that technical progress would not grind to a halt if a uniform and enlightened policy of compulsory licensing at "reasonable royalties" were implemented. Others, like Nelson, recommend patents with narrow scope so that further inventive activity is not blocked¹¹. There is, however, need for more studies that show the economic effects of limiting patent rights and the scope of protection, particularly since these are going to be the main differences amongst countries in a post-TRIPS world. Such differences can impact on national and global strategies for agriculture and the environment 12 .

IPRs for agricultural goods in developing countries raise more particular problems and policy issues. Even ignoring the moral, ethical or biosafety dimensions of agricultural biotechnology, these problems can be grouped under three separate though not mutually exclusive headings as those related to:

• Equity: farmer's privilege to save seed, farmers' rights to obtain remuneration for landraces or for rural innovations incorporating traditional knowledge;

- Public domain or public interest: such as those raised by the patenting of research tools, oligopolistic control of food supply or food security, role of the public sector, encouraging follow-on inventions and lastly
- Environmental concerns on maintaining biodiversity and biosafety.

It would be beyond the scope of this paper to discuss all these issues, particularly those relating to the environment. However, many of these questions have been raised in the proposals made by developing countries in the preparations for the new WTO round of negotiations and will be elaborated in that context as well as in the context of the experience of developing countries with transgenic crop varieties.

Section 2 of this paper briefly sets out the current relevant standards of TRIPS on patents and plant breeders' rights. Section 3 explains the ambiguities present in this text and the differing interpretations made so far, including as reflected in the laws of select WTO members. Section 4 reviews the experience of developing countries with transgenic crops and the issues raised by this. Section 5 gives a brief introduction to another relevant IPR, viz. geographical indications, including the relevant provisions of TRIPS and the scope for their revision. Section 6 assesses the prospects for the review of the TRIPS provisions on biotechnological inventions and PBRs in the WTO and makes a normative assessment of where the interests of developing countries would lie in possible negotiations on this issue. Lastly, section 7 presents some concluding remarks and identifies the areas of further research needed for a fuller understanding of this subject.

2. Protection of Biotechnological Inventions and Plant Varieties under TRIPS:

TRIPS obliges, with a few exceptions, that patents be available in all fields of technology for inventions that are new, involve an inventive step (or equivalently, are not obvious to persons of ordinary skill in

⁹ See Levin et al (1997).

¹⁰ See Scherer (1977), pp.84-88.

¹¹ See Merges and Nelson (1990) and Mazzoleni and Nelson (1998).

¹² See Sachs (1999).

that field) and are industrially applicable (or equivalently, are useful). Again, with limited exceptions, TRIPS lays down that patent owners must be given the right to exclude others from making, using, selling or offering for sale the patented invention, including products directly obtained through patented processes. It, however, allows limited exceptions to patent rights, including the grant of compulsory licenses under certain conditions.

TRIPS also explicitly allows exclusions of patentable inventions that are contrary to public order or morality, including those that are prejudicial to the health or life of humans, animals or plants or to the environment in general. However, inventions excluded on these grounds, must also be prohibited from commercial exploitation in that jurisdiction. Further, such inventions cannot be excluded merely because their use is prohibited by domestic law. In other words, these inventions have to be determined to be prejudicial on a case-by-case basis before they can be excluded from patent grant.

The provisions of most relevance to the agricultural sector is Article 27.3(b) of TRIPS, which allows the exclusion from patenting of plants and animals and essentially biological processes for their production, even if such inventions are otherwise eligible for patents. It does, however, require the patenting of eligible inventions covering 'microorganisms' and 'microbiological' or 'non-biological' processes and products thereof. These terms are not defined, leaving considerable scope for interpretation. TRIPS also requires the institution of an 'effective' sui generis law for the protection of plant varieties. Unlike in the case of other IPRs, TRIPS does not oblige compliance with the pre-existing international treaty on the protection of plant varieties, UPOV¹³, nor does it lay down in any further detail the scope or duration of such protection. TRIPS, however, requires this sub-section, 27.3 (b), to be revisited in 1999 and such a review is currently underway in the TRIPS Council of the WTO.

3. Differing Interpretations of Article 27.3(b) of TRIPS:

Clearly, at the time of the negotiations on TRIPS, the US and the EU differed on their approaches to patenting of biotechnological inventions. While the US believed that 'anything under the sun made by man', except for human beings, was patentable, the EU was grappling with strong internal resistance to patents on living organisms. The US had been granting patents on living materials since the landmark decision on the patentability of micro-organisms in 1980¹⁴. It granted its first plant patent in 1986 in *Ex parte Hibberd* and its first animal patent on the famous Harvard oncomouse in 1988. However, since the debate had not yet been settled in Europe, it was agreed to retain a minimal agreement while committing to revisit this provision within four years from the entry into force of TRIPS i.e. by 1999. It was expected that with the passing of the European Biotechnology Directive, under discussion at the time of the negotiations, there would be scope to push for accepting the patentability of all eligible biotechnological inventions, including of genes, plants and animals. With the rapid adoption of transgenic plants in many countries in the last few years, the small number of successful multinational agricultural biotechnology companies, originating mostly in the US, are particularly interested in the worldwide adoption of plant patents. They argue that Plant Breeders' Rights (PBRs), with breeders' exemption and farmers' privilege, are not sufficient to recoup their huge investments on R&D to develop these innovative products. Indeed, there is evidence that private sector investments in the development of new plant varieties has, in the absence of adequate IPR protection, mostly taken place in crops amenable to the production of hybrids and even PBRs are not sufficient to ensure appropriability 15 .

¹³ Union Internationale pour la Protection des Obtentions Végétales or the International Union for the Protection of New Varieties of Plants.

 ¹⁴ Diamond, Commissioner of Patents and Trademarks v. Chakrabarty, 447 US 303, 206 U.S.P.Q. 193 excerpted in Adelman et al (1998), pp. 153-156.

¹⁵ See, for example, the results of detailed survey on agricultural research of private seed companies in India in Pray and Basant (1999).

In the period since the finalization of the TRIPS draft text, some legal scholars have ventured to grapple with the intricacies of interpreting the provisions of the TRIPS Agreement and have suggested differing ways of implementing them in developing countries¹⁶. The reason for these diverse views may lie, in part, in the fact that TRIPS was the result of bitter North-South negotiations, reflecting strong economic interests on the part of the right owners as well as those benefiting from weaker levels of protection for Intellectual Property Rights (IPRs). This conflict of interests was resolved through 'constructive ambiguity', which each side interpreted according to their convenience. Interpretation of ambiguous clauses in certain ways may be one means of 'clawing' back much of what was lost in the negotiating battles in TRIPS. More so as the TRIPS negotiations have no official record and there are areas where the text is unclear and liable to differing interpretations. These differing interpretations will have to be finally resolved in the dispute settlement mechanism of the WTO. Disputes have not yet arisen in the WTO on many of these controversial areas, in part because developing countries have time up to the end of 1999 to implement most of the provisions of TRIPS. Unfortunately, few questions were raised on the implementation of Article 27.3 (b) in the recent reviews of legislation in the TRIPS Council and hence there is little guidance on this issue from within the WTO. The results of the on-going review in the TRIPS Council should throw more light on this issue, when the results are made public.

Some commentators on TRIPS opine that since the term 'invention' has not been defined, there is some scope for making further exclusions¹⁷. For instance, in the context of biological or genetic

materials, substances as found in nature are excluded in almost all jurisdictions as these are discoveries and not inventions. The disagreement arises over whether WTO members can exclude naturally occurring biochemical substances, such as sequences of nucleotides (DNA) where these have been isolated through technical processes. Can the lack of definition of the term 'invention' permit these to be excluded or will the limitation to exclude only 'essentially biological processes' mean than all other technical processes and products thereof have to be patented, if otherwise eligible? Some believe that TRIPS calls for allowing product patents on gene sequences and other such products of nature, when isolated through technical processes, even if the final product merely reproduces what is found in nature¹⁸. The new European directive now clarifies that inventions that consist or contain biological material shall be patentable, if otherwise eligible. Even if such biological material has previously occurred in nature, it must be patentable if it is isolated by means of a technical process, and of course, if new and non-obvious. Thus, genes, including human genes, are unambiguously patentable in Europe, if these can be shown to be non-obvious and industrially applicable.

Others even argue that 'microbiological' processes could be defined restrictively under TRIPS¹⁹. It is also not clear how 'microbiological' processes differ from 'essentially biological' ones. The recent EU Biotechnology directive throws some light on this when it restricts 'essentially biological' processes to natural phenomena such as crossing and selection. Further, what if only one of several steps in a process is microbiological and the remaining are essentially biological? The recent European directive would consider this to be an essentially microbiological process. Microbiological or other technical processes²⁰ and products thereof continue to be patentable under this directive as they were under the EPC. However, it is not

¹⁶ One of the first comprehensive works in this genre is the Max Planck Institute's study Beier and Schricker, Eds. (1996). This represents a step forward from the past work which merely reproduced the provisions of TRIPS. There are now two more such analyses available: Gervais (1998) and Correa and Yusuf, Eds. (1998). In addition, there are numerous papers published in law journals on different aspects of the TRIPS Agreement.

¹⁷ See UNCTAD (1997), p.34, wherein the exclusion is specifically stated to include cells and subcellular components such as genes.

¹⁸ See Straus (1998), pp. 109-110. Ossorio (1999) presents legal and ethical arguments on both sides on patenting of DNA sequences in the US context.

¹⁹ See Correa and Yusuf Eds. (1998), p.196.

²⁰ Note that the Directive does not use the TRIPS term 'non-biological'.

clear that the European interpretations have to be accepted by all WTO members.

The exclusion of 'plants and animals' in Article 27.3 (b) of TRIPS is clearly broader than that of 'plant and animal varieties' given under the EPC (and reiterated in the new EU directive) or in many other national patent laws. In the TRIPS negotiations, developing countries were aware of the confusion caused by the EPC wherein the exclusion of plant varieties was interpreted as not excluding plants as such. The broader term used in TRIPS thus excludes both plants and animals and plant varieties and animal breeds²¹. However, it is yet unclear whether the extension of the rights of the process patentee over the product directly obtained, including through patented genetic engineering processes, would override the exclusions of plants and animals. In other words, if a patentable process of genetic engineering leads to a product that is a plant or an animal, would these products benefit from the extended protection or would they be excluded as no product patents can be granted on these? In Europe, such an extension was allowed even before the new biotechnology directive of July 1998. If TRIPS were to be interpreted in this way, the protection given to biotechnological inventions under TRIPS is stronger than would appear by a simple reading of these exclusion provisions, at least for patentable processes.

Significantly, in the new EU directive, farmers' privilege to re-use farm-saved seed has been included as an exception to the rights granted by plant patents²². Parallel to the exception for farm-saved seed, a farmer may use patented livestock or other animal reproductive material for pursuing his agricultural activity but not for sale. It is not clear if this is a significant concession to farmers and

should be adopted as a model by developing countries in the event of the introduction of patents for plant and animal inventions. Given the high investment involved in the new reproductive and genetic technologies in crop and livestock improvement, it is likely that this kind of exception will lead to very high initial price of innovative products, if and when commercialized, thus benefiting only the more well-to-do farmers. On the other hand, widespread use of this exception could lead to more innovators resorting to trade secret and technological protection, thus depriving society of the disclosure requirements entailed by patents and PBRs.

Interestingly, some developing countries that have implemented TRIPS so far have taken advantage of the ambiguities in the text to exclude substances found in nature, even if these are isolated or transformed through technical processes. Both Brazil and Argentina have formulated fairly broad exceptions in their implementing legislation. In Brazil's Law No. 9.279 of May 1996 to Regulate Rights and Obligations Relating to Industrial Property²³, Article 10.IX excludes from patentability:

"All or part of natural living beings and biological materials found in nature or isolated therefrom, including the genome or the germ plasm of any natural living being, and any natural biological processes."

Similarly Argentina in its new law no. 24.481 'Invention Patents and Utility Models Act²⁴, in Article 7 (b) excludes from patentability:

"All biological and genetical material existing in nature or its replica, in the biological processes implicit in animal, plant and human reproduction, including the genetic processes

²¹ See Straus (1996), p. 184-185 and Correa and Yusuf, Eds. (1998), p.195.

²² While this is an acceptable exception under plant variety protection law, it is unlikely to be an exception allowed under TRIPS if a WTO member accepts to grant patents for plants since this exception does harm the legitimate interests of right holders and thus violates Article 30 of TRIPS. This situation in Europe parallels that of the US in not allowing infringement cases to be brought for patents on methods of medical treatment.

²³ Reproduced in WIPO, *Industrial Property and Copyright*, November 1996, [hereinafter the new Brazilian patent law].

²⁴ Reproduced in *World Patent Law & Practice*, Vol. 2B Rel 75-7/97, (and as translated by Thomas Banzhaf, Esq., Buenos Aires and referred to hereinafter as the new Argentine patent law).

relating to material capable of conducting its own duplication under normal and free conditions, such as they occur in nature".

The Andean Group also adopted a similar exception in its 1993 decision no. 344. Interestingly, Mexico allowed the patenting of plant varieties in its patent law of 1991 but excluded this in amendments made in 1994 upon accession to NAFTA²⁵. Clearly, these provisions do not go as far as the new European Directive as genes as found naturally in plants, humans or animals, cannot be patented even if technical processes were utilized to isolate them²⁶. Mexico, however, excludes the patenting of only human genes in this way. Some feel these laws are incompatible with the requirements of TRIPS²⁷.

There are other developing countries that have voluntarily gone further in protecting biotechnological inventions than required under TRIPS. In its latest patent law of 1994, Singapore significantly departed from its traditional policy of following the UK, when it removed any specific bar to the patentability of plants and animal varieties. It even goes farther than Australia, which bars the patentability of human beings. However, Section 13(5) of its Patents Act, 1994 permits the Minister to vary these provisions "for the purposes of maintaining them in conformity with developments in science and technology", a loophole left to undo any possible blocks to research²⁸.

The Korean Industrial Property Office has recently revised Examination Guidelines for Biotechnology Inventions that allows patents on animals (excluding humans), parts of an animal, a process for creating an animal and a use thereof, confining exclusions to those that are liable to contravene public order and morality. An invented animal is said to have met the inventive step requirement when it has a distinctive characteristic or provides a useful effect which could not easily be anticipated from the known species to which it belongs and is reproducible. Inventions relating to genes whose utility is not described or cannot be inferred are deemed to lack industrial applicability. A genetically engineered method of diagnosing or treating human beings is deemed to lack industrial applicability, by definition, as also all methods of such treatment²⁹.

In its recently adopted patent law, Trinidad and Tobago allows no exclusions to plants and animals or to their varieties, thus going beyond TRIPS requirements to allow for their patenting as well as for essentially biological processes for their production. Under this law, the only exception allowed is on grounds of public order or morality.

Table 1 shows the current implementation of the patent provisions of Article 27.3 (b) of TRIPS for selected developed and developing countries³⁰. If on a scale of 1 to 10, the US could be regarded to have the strongest protection of patent for biotechnological inventions, Australia, Japan, Korea, Singapore, Switzerland and Trinidad and Tobago, which have recently adopted standards close to those in the US in this area, can be placed at 9. The EC could be placed at 8, assuming that the recent biotechnology directive will be

²⁵ See Correa (1999), p. 12, FN 28, available at <u>http://www.fao.org</u>. Article 16 of the Mexican industrial property law excludes essentially biological processes for obtaining plants and animals; biological and genetic material as found in nature; plant and animal varieties; the human body and all living matter constituting it.

²⁶ Sigrid Sterckx asks the question: "Why would the mere fact of isolating a substance from its natural environment, or purifying it, by means of technical processes, turn the substance from a 'discovery' to an 'invention'?". See Sterckx (ed.) (1997), p. 25. This de-emphasises the application of the inventive step as a criterion for deciding patent eligibility.

²⁷ See Straus (1999).

²⁸ See Long (1996), pp. 26-40.

²⁹ See "KIPO Revamps Guideline for Biotech Inventions" in *World Intellectual Property Reporter*, vol. 12, No. 2, 15 February 1998.

³⁰ This table has been prepared from a reading of the current patent law, supplemented by commentaries in some cases. An attempt has been made to cover major developed country and developing country jurisdictions where TRIPS has been implemented, either wholly or partly.

implemented. Canada³¹ and Norway can be placed at 5, as can the other developing countries like Argentina, Brazil, Colombia, Chile, Malaysia and South Africa.

On plant variety protection the level of ambiguity in TRIPS is even greater as TRIPS does not lay down any criteria on scope of duration of such protection. Most developing countries and many developed countries did not have any form of protection for plant varieties until very recently. No official guidance is available so far from the WTO as to how the word 'effective' would be interpreted in this context. There was a proposal by the US in late 1998, in the context of the built-in agenda to be discussed at the next WTO Ministerial Conference, to consider the desirability of incorporating key provisions of UPOV, presumably of the 1991 version, in to TRIPS. This gives an indication that at least one major *demandeur* country would like to see UPOV standards in the implementation of TRIPS.

The US has had a law on plant variety protection for some kinds of asexually reproduced plants since 1930 and on sexually reproduced plant varieties since 1970. Since 1994, it has considerably weakened the farmers' privilege and breeders' exemption in its plant variety protection law. Some European countries like Germany and Netherlands had instituted such protection for plant breeders since the '40's and '50's. The UPOV came into being in 1968 but has had a very limited membership until recently. The main thrust towards worldwide protection of plant varieties came only with the TRIPS Agreement. With TRIPS there has been a rush to join UPOV, although this is not required. Most developing country members preferred to join the 1978 version. There are crucial differences between the 1978 version of UPOV and the revised one of 1991, which entered into force in April 1998. The extension of time given to join UPOV 1978 ended in April 1999. Only UPOV, 1991 is open to membership now.

³¹ However, the issue of patents for multi-cellular organisms is presently before the Federal Court of Appeals in Canada.

Clearly, WTO developing country members do not need to model their sui generis legislation on UPOV at all. However, the UPOV is the only international model available so far on PBRs and given the uncertainty on how the term "effective" will be interpreted, following UPOV, 1978 seems clearly a preferred option for many. Since it was UPOV 1978 that existed at the time of the TRIPS negotiations, this version could be considered as a model for developing countries to frame their legislation, provided that it is otherwise TRIPS-compatible³². Such a law may contain provisions for the 'breeders' exemption', allowing the use of the protected variety for breeding purposes and may also contain the 'farmers' privilege', allowing farmers to retain seed for their own use or for across-the-fence non-commercial exchange or sales of seeds³³. UPOV 1991, on the other hand, disallows some of this flexibility in that the exchange or sale of seeds by farmers is disallowed as it obliges an exclusive right of reproduction of the protected variety. Both versions allow restrictions on the free use of exclusive rights for reasons of public interest and subject to the payment of an equitable remuneration to the right holder. The differences are illustrated in Table 2, showing why developing countries prefer joining the 1978 version, although some have laws that are close to the 1991 version:

Today, many countries have such *sui generis* laws for the protection of new plant varieties as evidenced by the 43 current members of UPOV of which thirteen are developing countries, the latter bound

³² Reciprocity built into UPOV would have to be replaced by national treatment required under TRIPS if the definition of IPRs given in TRIPS is determined to cover plant variety protection. This is not so clear at this point.

³³ See Otten (1994), where the author has argued that it would not be reasonable to interpret the international community as requiring adherence to the standards of UPOV, 1991 under TRIPS. However, UPOV 1978 may not always be compatible with TRIPS. Although the 1978 Act permits protection for a limited number of species of plants, it would not be possible to incorporate clauses based on reciprocity of protection on foreign nationals, as this would violate the national treatment required under Article 3 of TRIPS.

only to the 1978 version³⁴. Significantly none of the Asian developing countries, other than China, are members of UPOV, although many allowed the patenting of microorganisms and microbiological processes even before this was a TRIPS requirement³⁵. Other developed countries also became members in the period from 1993: Austria, Finland, Norway and Portugal. Greece and Luxembourg are the only two EU members yet to join the UPOV. It is expected that membership of UPOV will climb from the present 43 to at least 60-70 by early 2000's in part on account of TRIPS.

Many developing countries have adopted plant variety protection laws conforming to UPOV, 1991. Developing country exporters of cut flowers and ornamental plants like Kenya and Chile see effective PBR protection to be in their long-term interest as it facilitates access to new and better plant varieties. For instance, Bolivia, Colombia and Ecuador have PBR laws conforming substantially to UPOV, 1991 as do other developing countries such as Morocco, Costa Rica, Venezuela. Members of the OAPI in francophone Africa are to adopt similar laws soon. Argentina, Chile and Mexico protect all genera and species even though they follow UPOV, 1978. Given the national treatment requirement under TRIPS it may work in the interest of developing countries to protect all genera and species as reciprocity cannot be applied. Further, "all" will mean, in practice, applications for a few hundred at best, of which the top few ornamental plants will cover the majority. Developing countries that already have some capabilities in plant biotechnology and wish to

encourage such research further, whether in private or in the public sector, need to seriously consider instituting stronger protection through the UPOV, 1991 model and perhaps, additionally through patent protection.

Table 3 shows the level of plant variety protection accorded currently by selected developed and developing countries. The US, Japan and EC could be placed at the level of 10 in a scale of 0 to 10. Australia, Korea and South Africa can be placed at 8, as they have equivalent protection to the first group but allow compulsory licensing. Colombia and other countries of the Andean group can also be placed at 8, as they allow universal coverage, restrict the breeders' exemption and do not provide for compulsory licenses but have a shorter term of protection. Argentina, Brazil, Canada, Chile, Norway and Switzerland can be placed at 5 since they follow UPOV, 1978 and do not confine breeders' exemption to those varieties that are not essentially derived from the protected one. Switzerland, however, does not allow compulsory licenses and is going to shortly replace its law with one compatible with UPOV, 1991.

Clearly, different countries see their national interests as differing and have accordingly varied the scope of protection afforded to biotechnological inventions and to PBRs, even while possibly complying technically with TRIPS.

4. Experience with Transgenic Crops in Developing Countries and the Way Forward³⁶:

Transgenic or genetically modified crops are a very recent phenomenon globally. Between 1996 to 1998, the global area under such crops has increased fifteen times, from 4.3 million acres to 69.5 million acres, reflecting exceptionally high adoption rates by farmers by standards of new technologies in the agricultural sector. The main break-through has come in improvements to herbicide tolerance and insect resistance of crops. The five principal transgenic crops in 1998

TRIPS-implementing legislation.

³⁴ These are, in the order that they joined during the period 1994-1997: Uruguay, Argentina, Chile, Colombia, Paraguay, Ecuador, Mexico Trinidad and Tobago, Brazil, China, Kenya and Panama. South Africa had joined as early as 1977 and has not elected to be a developing country in the WTO. All developing countries adhere to the 1978 version of UPOV.

³⁵ For instance, this was the case in the patent laws of Malaysia, Singapore, Philippines, and Republic of Korea. Others like China, Indonesia and Thailand have also allowed such patenting as a part of their

³⁶ The statistics cited in this section is largely drawn from James (1998).

were, in descending order of importance, soybean, corn/maize, cotton, canola/rapeseed and potato. Soybean and corn alone account for 82% of the global area under transgenic crops. 74% of the global area is in the US, with 15% in Argentina, 10% in Canada and the remainder in Australia, Mexico, Spain, France and South Africa.

Thus this technology has been as readily adopted in some developing countries as it has in some developed countries. Indeed, China was the first country to commercialize transgenics in the early 1990's and by 1996, the global area under such crops was almost split equally between developed and developing countries. Argentina's area under transgenic crops increased three-fold from 1.4 million hectares in 1997 to 4.3 million hectares in 1998, mostly due to the increase in herbicide-tolerant soybean, which now constitutes over 60% of the total area under that crop. China introduced Bt cotton only in 1998 but of the 63,000 hectares, about 10,000 hectares was of a product developed locally by the Chinese.

The economic benefits of transgenic crops to developing countries would depend upon a number of factors such as need for the particular crop, for instance, level of infestation of the targeted pest or weed density, crop performance under local agro-climatic conditions etc. So far, transgenic crops have reduced the use of herbicides or insecticides and have increased average yields. For the US, a study³⁷ indicates that of the \$240 million of total economic surplus, 53% went to US farmers, 26% to the seed company, 12% to consumers and the balance 9% to the rest of the world. The farmer/company benefit ratio of 2:1 is similar to that for conventional agriculture in the US.

Similar studies need to be done in developing countries that have adopted these new technologies. For studies done on the economic benefits of hybrid crops in developing countries, the benefits to farmers seem to be of similar magnitudes. For instance, for hybrid sorghum in India, seed companies captured 18.5% of the benefit while farmers captured 81.5% (Pray and Ramaswami, 1999). These studies also show that the seed prices were considerably higher for hybrids developed in the private sector than those developed in the public sector. However, the value of increases in farmers' yields outweighed the increase in the cost of seeds. Indeed, farmers in developing countries are no more under any obligation to buy newly developed seeds than are farmers in developed countries. In both cases, farmers make the decision to buy improved varieties after taking into account the economic benefits. However, it is true that poorer farmers in developing countries who depend on external finances, usually at usurious rates of interest, and are usually without crop insurance, are less capable of sustaining losses and are thus, more risk averse. Solutions to these generic problems must be found and should not detract from the benefits of the new generation of agricultural biotechnologies.

The potential for the benefits of agricultural biotechnology for developing countries go beyond the adaption to local conditions of the present generation of transgenic crops developed in other markets to solve problems of pest attacks or weeds. This technology has the potential to solve some of the problems of malnutrition, disease and low agricultural productivity that are particular to developing and least developed countries. For example, it was recently announced that genetically modified rice may help reduce iron deficiency anemia or vitamin A deficiency³⁸. Similarly drought-resistant plants or those that tolerate high levels of soil toxicity could help improve yields and lead to greater food security. It is clear that this potential must be fully tapped and this technology further developed for the benefit of humanity. While strong IPR protection, combined with other appropriate policies, may help develop such a potential, there are fears that the resulting products may not be available or may be far too expensive for most consumers in these countries. These fears are exarcebated by the recent trend on mergers and acquisitions in the seed and life sciences sectors. The ten largest global seed firms

³⁷ Falck-Zepeda et al, 1998 cited in James (1998).

³⁸ See press release of August 3, 1999 cited at

www.rockfound.org/news/072699_rice.html.

control 30% of the seed sales in the world (Herdt, 1999). Increasingly, the new seeds being developed are controlled through IPRs that belong to these top companies³⁹. On the other hand, so far agricultural research and seed distribution in developing countries has been overwhelmingly in the hands of the public sector. However, public sector research is suffering from an acute shortage of funds in many of these countries. Increasingly, private firms, mostly foreign firms or joint ventures, are stepping up their research efforts in these countries. These firms are reluctant to introduce new varieties that can be appropriated easily by other rival seed companies in the absence of strong IPR protection. Presently, in countries like India, which are yet to adopt even PBRs, these companies confine their research to hybrids. Even here, seed of single cross hybrids of maize are not being marketed because of the still high cost of seed production and the lack of IPR protection (Pray and Basant, 1999).

Changes in IPR regimes, particularly as related to the agricultural sector are particularly relevant to the way international agricultural research is organized through the centres of the Consultative Group on International Agricultural Research (CGIAR) and the National Agricultural Research Organizations (NAROs). Developing countries have been dependent on the CGIAR system for the free exchange of germ plasm and scientific knowledge. Roughly 15% of the research budget of the CGIAR centres is devoted to genetic engineering and these centres have become key players in agricultural biotechnology. Yet few patents have yet been applied for by these centres and in many cases proprietary technologies may be used without formal consent. This is mostly because of a historic lack of familiarity with IPRs. There is now increasing agreement that these centres should take out defensive patents in order to stake out their claims and ensure access⁴⁰. There is now a discernible global

trend of increasing collaboration between private and public sector institutions. Initiatives such as the Consortium for Genomics Research in the Public Sector of Cornell University in the US have raised interest in national public sector research organizations in developing countries such as Brazil, China and India as well as in the CGIAR centres (Herdt, 1999). The IPR policies of the CGIAR system should be closely watched by developing countries for emulation in their NAROs and other research institutions.

Given the fact that much of the new, proprietary technologies in the agricultural sector are increasingly in the hands of the private sector companies of developed countries while traditionally, in developing countries, it is the public sector that has, by far, the larger research capabilities, collaboration is an important way of acquiring technologies in developing countries. In the agricultural sector, unlike in industry, research products developed elsewhere have to be adapted to local conditions. Stronger IPR protection may give an incentive to right holders to collaborate in order to disseminate these technologies more widely. More importantly, for countries with the appropriate level of education and skills, increased investment in R&D with strengthened IPR protection may provide the needed incentive for domestic innovations that are required locally and would, at the very least, help create "bargaining chips" that could be used to gain access to desired technologies or promote collaborations⁴¹.

There are issues relating to equity and biodiversity that relate to the sharing of benefits from the commercialization of products incorporating genetic material or traditional knowledge taken from developing countries. These issues are more relevant to industrial biotechnology, especially as related to the pharmaceutical sector, than to agriculture. In the agricultural sector, plants must necessarily be adapted to the agro-climatic conditions of the region in which they are grown. For example, the recent biotechnology revolution in

³⁹ There are further fears that 'terminator' type technologies would help increase control over these proprietary technologies, thus changing age-old practices of using farm-saved seed in developing countries.

⁴⁰ See Briefing Paper No. 39 at

http://www.cgiar.org/isnar/publications/briefing/BP39.htm.

⁴¹ This idea finds place in Barton et al (1999).

agriculture in the US is based, for the most part, on the genetic modification of *in-situ* plant varieties. Similarly, two varieties of wheat *Norin 10* and *Brevor* used in the Green Revolution originally came from Japan and the US⁴². However, there is the issue of rewarding farmers for their farm-grown varieties that may have useful traits that, although not reproducible stably, could form the basis for breeding new varieties susceptible of being protected by PBRs. At the minimum, if the nature and scope of plant variety protection is further elaborated in any future review of TRIPS, developing countries may like to see more transparency in ensuring that right holders disclose the origin of the in-bred lines used to produce new plant varieties. The complex conceptual questions of the nature and scope of such farmers' rights and the way to reward them has to be left to a more specialized forum such as the FAO or WIPO.

5. Geographical Indications:

Another area of IPRs related closely to agriculture that is part of the built-in agenda on TRIPS is geographical indications. Geographical indications are distinctive signs identifying products of several undertakings located in a specified geographical area. No one enterprise or even group of enterprises own this distinctive sign and therefore, unlike trademarks, there is no right conferred on any entity to grant or refuse authorization on use. Instead, all undertakings located in the specified geographical area are allowed to use the geographical indication on the specified products produced by them. All other entities are prohibited from doing so. Well-known geographical indications, particularly in agricultural products, mostly belong to the 'old world', synonymous with Europe, while being used widely in the 'new world', i.e. the Americas and Oceania. These factors have made it very difficult to develop an international agreement in this area. Even the TRIPS Agreement has not completely satisfied the demanders of such protection.

Few countries protect geographical indications and unlike other IPRs, there is rarely a specific law protecting them. There are diverse ways and levels at which geographical indications are protected under the laws of different countries, including through trademark law, in particular certification or collective marks, labeling or other regulations, in particular those relating to alcoholic beverages or laws on unfair competition. In common law jurisdictions geographical indications are also protected through passing-off action. There is presently considerable confusion in the TRIPS Council on what the obligations under TRIPS imply and how they are to be implemented.

The main *demandeurs* in the negotiations on geographical indications were, undoubtedly, the European Community and Switzerland. The main opponents were the US, Australia, Canada, Chile and Argentina and others who wanted to protect their existing use of geographical indications of European origin, particularly in the area of wines and spirits. Some countries, like India, attempted to broaden the scope for additional protection under Article 23 from wines and spirits to beverages, such as tea, with little success during the TRIPS negotiations.

TRIPS provides for two levels of protection: at the basic level, all geographical indications must be protected against use which would mislead the public or constitute an act of unfair competition. This obligation is met with in most countries that permit such geographical indications to be registered as collective marks or certification marks and/or which allow passing-off actions to be instituted in civil courts, as is the case in common law countries. Many civil law jurisdictions accord such protection to geographical indications under unfair competition laws. Had this been the only obligation under TRIPS, most developing countries would have been in compliance.

However, in addition, under Article 23 TRIPS obliges the protection of geographical indications on wines and spirits *per se* or in absolute

⁴² See Watal (2000), Chapter V.

terms, without requiring any test of confusion or likelihood of deception to be met. In the special case of wines and spirits TRIPS Article 23.1 prohibits the use of translations of geographical indications or attachment of expressions such as 'kind', 'type', 'style', 'imitation' to products not originating from the place indicated, even where the true origin is clearly indicated. Thus, if 'Champagne' were such a protected geographical indication the use of a label stating "Champagne style sparkling wine, Made in the USA" would be prohibited. This type of higher protection for wines and spirits was only available in the EU prior to TRIPS⁴³. In implementing this provision, several developed and developing countries have opted to provide a uniformly higher level of protection to all eligible geographical indications, irrespective of sector, subject to certain registration requirements. This is found in the relevant laws of Germany, New Zealand and Brazil. Japan provides the higher level of protection through a notification issued under its Law Concerning Liquor Business Associations and Measures for Securing Revenue from Liquor Tax. Others have sought to implement this higher level of protection for wines and spirits through special laws, following bilateral agreements with the EU, e.g. Australia's Wine and Brandy Corporation Amendment Act, 1993. Yet others, like US and Canada have declared a large number of geographical indications to be 'generic' or 'semi-generic'.

The lack of consensus in this area is reflected in the fact that further negotiations and review was built into the text of TRIPS. Article 23.4 calls for negotiations for the establishment of a multilateral system of notification and registration of geographical indications for wines eligible for protection in those members participating in the system. No time limit was set for the commencement of such negotiations. However, Article 24.2 calls for a continual review of the implementation of this section, with the first review to take place within the first two years of the WTO i.e. by end of 1996. Under the

first such review, conducted in 1996, it was decided to commence preparatory work towards negotiations on the multilateral registration system. This work gained momentum only in 1998 in the TRIPS Council. The EU has placed the resolution of the registration system at top priority, in outlining its goals for the new round of trade talks in the WTO but does not expect to see this happen in this time period. On the limited issue of wines and spirits, it can be expected that the EU would be some link to negotiations on agriculture in the new round, as it did in the Uruguay Round.

During the 1996 review it was decided to also review the scope of protection under this section. These efforts are still continuing in the Council for TRIPS, with the European Union, Switzerland and many Central European countries also having an active interest in such expansion to other products such as cheese, chocolates, beer or embroidery. Developing countries that have expressed an interest so far to include other products are Morocco, India, Egypt, Mexico, Venezuela, Cuba, Turkey and Nigeria⁴⁴. Certainly, the value of exports of agricultural products from some developing countries of certain varieties of tea, rice, fruits, vegetables, meat or other products would be greatly enhanced if there could be an agreement under TRIPS to protect such specific geographical indications at the same level as wines and spirits.

However, it must be recognized that there is strong opposition from other developed and developing countries to any attempt to expand the scope of protection on geographical indications and it is not realistic to expect any movement on this matter in the near future. It is likely that even the major *demandeur* on this issue, the EU, will first seek to implement the agreed provisions in TRIPS before seeking actively to extend them further.

6. Prospects for amendments to TRIPS in the WTO in the immediate future:

⁴³ See Knaak (1996), p.125 and p.132, where he describes that even in the EU, the EU Regulation No. 1576/89 on geographical indications for spirits, based on a list system, does not extend absolute protection to all spirits in general.

⁴⁴ See reports on the TRIPS Council meetings available at http://www.wto.org.

Prospects for any amendments to the TRIPS provisions on biotechnological inventions appear to be quite dim for the moment. For years, environmentalists in Europe stalled the European Commission's proposal for a directive that would harmonize patent laws in the EU for biotechnological inventions. The appellate body of the European Patent Office (EPO)⁴⁵ had, with its most recent judgement, virtually placed a block on patents for plant varieties. Ironically, this issue in being currently adjudicated in US courts too. Further, the stiff opposition by consumers in Europe to the sale and consumption of genetically modified foods has also clouded the debate on patents on biotechnological inventions. The European directive on the patenting of biotechnological inventions was finally passed in mid-1998 and is to come into effect mid-2000 in all the EU countries, bringing Europe closer to the US level of patent protection. However, within three months the Netherlands, the only country to have voted against the directive, had challenged it in the European Court of Justice on several grounds, including morality, and there is, once again, legal uncertainty on the patenting of biological materials in the EU. NGOs based in developed and developing countries have been actively campaigning against patents for biological materials, voicing concerns on morality and ethics as well as on biodiversity. This potential for an emerging coalition between powerful lobbies in developed countries and governments of developing countries may, in part, explain why the international business community and *demandeur* developed country governments do not seem to want to change these TRIPS provisions as yet, despite the 1999 built-in review process. However, some discussions on these IPR issues would be possible if biotechnology is raised in the negotiations on agriculture in the new round.

The international business community and the *demandeur* governments are reluctant to re-open the debate on Article $27.3(b)^{46}$.

One reason could be that the legal uncertainty has not quite ended in Europe and any premature re-opening on the international debate could endanger the advances already made in Europe in this area. There is also a fear that any alliance between powerful environmental lobbies in developed countries and governments of developing countries at this stage could jeopardise chances of obtaining improvements to these provisions of TRIPS at a later date. Others may believe that the wording of TRIPS can be subject to interpretation, drawing upon that given in the recent European Biotechnology directive. For instance, there may be considerable scope even in defining 'microorganism' as some view the term as extending to genes⁴⁷, or in defining the products of 'microbiological processes' as these could include plants and animals. These issues can only be settled in dispute settlement. Moreover, there may be technical solutions available to ensure appropriability on proprietary agricultural biotechnologies as farmers' ability to save seed may, to some extent, be restricted by the use of hybrids or in the future, possibly more effectively by using 'terminator' type technologies, more generally called Genetic Use Restriction Technologies. Lastly, as developing countries have time up to 2000 to change their laws to implement this provision of TRIPS, it may be considered premature to review this so early.

One more reason for such caution could be the preparations being made by developing countries to demand changes in TRIPS. As a response to the US proposal of end 1998 many developing countries from Latin America, Africa and South Asia have proposed revisions to TRIPS as a part of the built-in review process. India made a submission in the Committee of Trade and Environment as early as 1996 to amend TRIPS to oblige patent applicants of biotechnological inventions to disclose the country of origin and information on prior informed consent for biological materials and traditional knowledge, wherever this was relevant. This proposal has been reiterated in the run up to the 1999 Ministerial Conference. Some Latin American

⁴⁵ The EPO has a wider jurisdiction than the EU member countries as it includes Switzerland, Norway and Liechtenstein.

⁴⁶ See the policy statement of the International Chamber of Commerce on the review of TRIPS Article 27.3 at www.iccwbo.org.

⁴⁷ However, others confine this term to viruses, algae, bacteria, fungi and protozoa and exclude genes and gene sequences.

and African countries have suggested that TRIPS give effect to the provisions of the Convention on Biological Diversity, including the protection of traditional knowledge, innovations and practices of indigenous peoples and local communities. Others want a clarification that only genetically modified microorganisms should be patentable.

This inertia to change the TRIPS Agreement seems paradoxical as there are, undoubtedly, many ambiguities and gaps that the *demandeurs* for higher levels of IP protection in both these sectors, pharmaceuticals and biotechnology, would like to see fixed as soon as possible. These include patents for plants and animals, clarification on adherence to UPOV, 1991, prohibition of parallel imports, and possibly, the tightening of compulsory license provisions. However, it is clear that the *demandeurs* want to wait to see whether some of these issues can be sorted out through the shorter and more effective process of dispute settlement before taking the negotiating route, where the outcome is relatively more uncertain⁴⁸.

This is borne out by the proposals made so far in the preparations for the 1999 WTO Ministerial Conference. The US had made preliminary proposals on the built-in agenda on TRIPS in November 1998⁴⁹. These proposals call for the expiry of the moratorium on non-violation in January 2000 and an examination of the desirability of eliminating the exclusion for plants and animals and incorporation of the key provisions of UPOV on plant variety protection. The US has since not pressed for any immediate modification to TRIPS on biotechnological inventions. These initial US proposals were also not supported by the later submissions of Europe and Japan, which seem to want only such modifications on TRIPS as will give them leverage with the US⁵⁰. They want to see TRIPS oblige the first-to-file system for patent applications. The US is now the only country in the world that does not follow such a system. Europe, perhaps, hopes to use this lacuna, as it once did in the Uruguay Round, to secure protection for specific geographical indications on its wines. On the other hand, Japan and the EU have found it necessary to explicitly state in their formal submissions that there should be no attempts at lowering of standards or reducing the current level of protection under TRIPS.

This is because some developing countries are demanding exactly such changes in TRIPS: weakening of the provisions on compulsory licences and longer transitional periods. In addition, they want more technical and financial assistance for implementing TRIPS, including for the promotion of domestic R&D and the transfer of technology; and new provisions related to biodiversity, including the protection of indigenous peoples' rights⁵¹. India has been amongst the first to demand in 1996, in the Committee of Trade and Environment, that TRIPS standards on IPRs include transfer of technology and transparency in patent applications in the context of multilateral environmental agreements. In that year, in the run up to the First WTO Ministerial Conference at Singapore, it also demanded, in the TRIPS Council, the extension of additional protection on geographical indications to other products. These demands have been repeated in the preparations for the 1999 Ministerial Conference⁵². The proposal on additional protection for geographical indications other than for wines and spirits has wide support of some developing and developed countries.

Paradoxically, given the lukewarm response of the *demandeur* governments to any changes in the TRIPS provisions, developing countries may not be successful in re-opening the provision on

⁴⁸ The impasse in the WTO in the first half of 1999 on the selection of the Director General points to a possible departure from earlier days where consensus could be built more easily in WTO bodies. In contrast, the Appellate Body of the WTO is widely seen as accommodative of domestic political concerns, particularly of the more powerful members.

⁴⁹ See WT/GC/W/115 (1998).

⁵⁰ See WT/GC/W/193 (1999) and WT/GC/W/242 (1999).

⁵¹ Articulated in an informal proposal circulated to other WTO Members by Honduras, Cuba, Nicaragua and Dominican Republic at the end of March 1999.
⁵² See "India's Proposals on IPR Issues – Preparations for the 1999 Ministerial Conference" made public in *India and the WTO*, March 1999, available at www.nic.in/commin/wtomar/htm.

Article 27.3(b) to incorporate their interests and *status quo* may well be maintained in the near future. The discussions on biotechnology, in the negotiations on agriculture in the new round, could touch upon IPRs but, for the moment, there is considerable uncertainty about the scope of such discussions. However, none of the substantive issues relating to biotechnology or biodiversity raised by developed and developing countries are likely to disappear from the TRIPS agenda and will probably resurface after the review of developing country implementation of TRIPS has been completed in the next 2 to 3 years. Much will depend on the political strength of environmental NGOs in the developed world at that stage and any interpretations made through dispute settlement.

In the end it appears that a satisfactory solution for all concerned, in the immediate short run, would be to leave TRIPS untouched. This would be satisfactory for developing countries as TRIPS already allows some degree of flexibility. This should also be satisfactory for developed countries who, given the several ambiguities in the TRIPS text, would first like to see how developing countries implement what was agreed to in the Uruguay Round, for which they have time up to the end of 1999. In other words, not only is it unlikely that the WTO Conference at Seattle would result in any programme of further negotiations intended to change the existing TRIPS text but there may be no such move in the near future. However, there is the matter of the built-in agenda and other issues on TRIPS to be dealt with by WTO members at some future date. Article 71.1 calls for a review of the implementation of TRIPS in 2000 and every two years thereafter, including reviews undertaken "in the light of any relevant new developments which might warrant modification or amendment" of TRIPS⁵³.

7. Concluding Remarks and Areas of Further Research:

IPRs for agricultural biotechnological inventions pose complex problems relating to ethics, morality, biosafety and biodiversity. In developing countries there are further perceived problems of unfair exploitation of genetic resources and fair and equitable sharing of the benefits. However, biotechnology is undisputably the revolutionary science of the next millennium that promises to solve many of humanity's most difficult problems relating to food, health and the environment. Developing countries should not lose out on rapid and reasonable access to these technologies and products in their zeal to preserve biodiversity from real or imagined damage, control their genetic resources or gain a share in the benefits, however laudable these objectives are. Although steps are necessary to preserve and enhance the existing biodiversity in these countries, environmental and health threats from genetically engineered crops may often be exaggerated. Certainly, it would be paradoxical if these countries forgo the benefits of biotechnology to solve some of their most pressing problems of poverty, disease and malnutrition on account of such fears. The benefits to be derived from transgenic plants and animals should be dispassionately weighed against any possible disadvantages and governments should attempt to educate the farmers and the public to make informed choices, while keeping strict regulatory controls.

But in all this the more important objective of developing competitive skills in research in biotechnology should not be lost. For this, local firms must be encouraged through the grant of adequate and effective IPR protection up to the level obligatory currently under TRIPS. Yet patents should not permit the blocking of research in these areas through overly broad grants, nor should the global trend towards oligopolisation of the agricultural biotechnology industry be encouraged. Given the existing technological gap between lead developed and developing countries and the capital intensive nature of product development, the best way forward for developing countries seems to be to increase spending on R&D to develop technologies and products of interest to firms in

⁵³ The US interprets this to mean a review of implementation in 2000 and a review leading to possible recommendations or modifications of the agreement in 2002. See *Inside US Trade*, August 6, 1999, pp.

developed countries so that further technological progress can be made through collaborative arrangements, including cross-licensing. To safeguard against the adverse effects of restricting competition, liberal use should be made of the flexibility available under TRIPS to grant compulsory licenses in cases of egregious anti-competitive behaviour by right holders or for gaining access to essential patents.

At present there is no need for most developing countries to go beyond TRIPS and grant patents for plants and animals, but they will need to cover microorganisms and microbiological processes and products directly obtained therefrom. Sui generis plant variety protection can also take advantage of the flexibility currently allowed to include farmers' privilege and breeders' exemption. Indeed, developing countries do have counter demands in order to preserve their obligations at the current level. They have rightly demanded that wherever patent applicants base their inventions on genetic or biological resources or on traditional knowledge, they should be obliged to reveal the country of origin and whether they have obtained prior informed consent, if necessary, as a part of the requirements on patent disclosure. This is a substantive demand linked with the goal of the international community on achieving sustained development and maintaining or enhancing the Earth's biodiversity. This would invariably form part of the discussions on the review of Article 27.3(b) of TRIPS. Developing countries have also demanded inclusion of special forms of protection for traditional knowledge and rural innovations. More work needs to be done urgently in WIPO on this issue so that this issue can also be included in future discussions on the review of Article 27.3 (b) of TRIPS.

However, some developing countries have already seen the wisdom of going on to the next stage of granting patents for plants, genes and animals and many others may do so, once domestic research capabilities in DNA technology improve. Since much of the research in agricultural biotechnology is made by the public sector in these countries, collaborative arrangements should be encouraged by the governments with other publicly funded research bodies as well as with the private sector in lead countries. Private industry should also be encouraged to invest in biotechnology. The fruits of such research could benefit from jointly owned IPRs with the terms of enjoyment clearly laid down by mutual agreement. Grant of IPRs does not necessarily preclude the dissemination of these technologies or products by these institutions to certain groups or areas either free or at reasonable prices.

Multilateral developmental institutions should also be encouraged to help developing countries make this transition to a higher level of capabilities in biotechnology through both financial and technical assistance for R&D projects, mapping of genetic resources, documenting traditional knowledge and local innovations as well as for training in related fields, including the legal one. Such institutions could even consider the establishment of "technology rights' banks" that purchase core privately-developed IPR-covered technologies in essential areas, such as important food crops, in order to ensure their widest dissemination, including adaptation to local conditions, at reasonable costs. This could help resolve the conflict between rewarding private innovations through IPRs for generating such useful technologies and ensuring their widest possible use in and benefit to poorer developing countries. For the private IPR holder the trade-off between volumes and value should make such open licensing beneficial⁵⁴. These are just some of the avenues open for exploration on how to reconcile IPRs in biotechnology with the needs of developing countries and much more research is required to fully explore all options. In the end, however, private and public sector institutions in the more advanced developing countries should

⁵⁴ There are parallels in the industrial sector where IPR holders voluntarily submit their IPRs to open licensing at reasonable terms in order to benefit from incorporation of their proprietary technologies into industry-wide standards set by industry associations, governments or international bodies. In a recent article Jeffrey Sachs and Michael Kremer suggest that rich governments pledge to purchase at a realistic price unprofitable vaccines, such as for malaria, for mass distribution in order to encourage the pharmaceutical industry to invest in R&D in such products. This is again an attempt to reconcile incentives for R&D with public interest. See "A Cure for Indifference" in *Financial Times*, 5 May 1999, p. 14.

envision themselves as future generators of IPRs and as competitors in biotechnology to firms in developed countries, rather than as perpetual users. The time frame to achieve this vision would certainly differ from country to country but the direction of the effort should be clear.

Clearly more research is required to understand the role and effects of IPRs, on the economy as a whole and in the agricultural sector in particular, in developing countries. A deeper understanding of the problems and possible solutions can be gained by studying *inter alia*

- the current market structure for seeds viz. the proportion of farmsaved seed to purchased seed; the proportion of seed, including new varieties, commercialized by the public sector as against the local/multinational private sector;
- the R&D expenditures of local/multinational private sector seed companies and public sector agricultural research organizations;
- market prospects for improved/transgenic animal breeds and their costs and benefits;
- PBRs/patents filed by and granted to private and public sector organizations in domestic market/ other countries;
- effects of PBRs/patents on availability, costs, productivity, returns to farmers;
- effects of PBRs/patents on prices for and welfare of consumers;
- implications for future research by public sector agricultural research organizations;
- evidence of abuses of IPRs and effect of corrective measures such as the application of compulsory licenses or competition law;
- evidence of broad patent claims and effects on further R&D or follow-on innovation;
- number and nature of public-private collaborations/joint ventures and terms negotiated on transfer of technology;
- costs and benefits of improved global protection for geographical indications for agricultural products of interest to developing countries.

On many of these issues, data is already available for some developing countries while on many others data will have to be generated some time after IPR laws are established. There is an urgent need to put into place a mechanism for generating such data so that analysis of these questions could be based on firmer ground than has been the case so far.

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TABLE 1:COMPARISON OF IMPLEMENTATION OF TRIPS PROVISIONS ON PATENTS FOR

Subject	US	JP	EC	SW	AU	CA	NW	KR	SA	TT	AR	BR	CO/ CA	СН	SI	MY
1. Product patents on microorganisms, if otherwise patentable	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
2. Process patents on : (a) Essentially biological processes	N	Y	N	N	Y	N	N	N	N	N	N	N	N	N	N	N
(b) Microbiological Processes	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
(c) Non-biological processes	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
3. Product patents on biological or genetic material as found in nature i.e. discoveries	N	N	N	N	N	N	N	N	N	?	N	N	N	N	N	N
4. Patents on plants and animals per se, if otherwise patentable	Y	Y	Y	Y	Y	N	N	Y	Y	Y	N	N	N	N	Y	N
5. Patents on plant and animal varieties	Y	Y	N	N	Y	N	N	Y	Ν	Y	Ν	Ν	N	N	Y	N
6. Exclusion on grounds of morality or public order	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
7. Patents on human body	Ν	Y	Ν	N	Ν	Ν	Ν	Ν	Ν	Y	N	Ν	N	Ν	Y	?
8. Patents on human genes	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Ν	N	N	Y	Y
9. Breeders' exemption for patents	N	N	N	N	N	N	N	N	N	N	Y	Y	N	Y	N	N

BIOTECHNOLOGICAL INVENTIONS IN SELECT WTO MEMBERS

Table 2:Differences between UPOV versions 1978 and 1991

Subject	UPOV, 1978	UPOV, 1991
1. Minimum	5-24 genera or species from	15 to all genera and species from the time of
Scope of	time of accession to eight years	accession to 5-10 years, the lower term being
coverage		applicable to those already members of UPOV,

		1978
2. Breeders' exemption	Breeders free to use protected variety to develop a new one	Exploitation of a subsequent variety that is essentially derived from the protected variety requires right holder's authorisation. Essential derivation criteria met when essential characteristics of first plant are replicated in the second as for e.g. when whole genetic structure replicated
3. Farmers' privilege to save seed for replanting	Implicitly allowed under the definition of minimum rights but countries may opt not to do so.	Allowed at the option of the member country within reasonable limits and subject to safeguarding the legitimate interests of the right holder.
4. Minimum exclusive rights on propagating material	Production for purposes of commercial marketing; offering for sale; marketing; repeated use for the commercial production of another variety and the commercial use of ornamental plants or part thereof to produce the plants or cut flowers.	Production or multiplication; conditioning for the purposes of propagation; offering for sale; selling or other marketing; exporting; importing or stocking for any of these purposes.
5. Exclusive rights on harvested material	No such obligation	Same acts as under 4 if harvested material obtained through unauthorized use of propagating material and if breeder had no reasonable opportunity to exercise his right in relation to the propagating material.
6. Exception to exclusive rights	Farmers' privilege implicit and breeders' exemption expressly required. See also 3 above.	Acts done privately and for non-commercial purposes; acts done for experimental purposes and acts done for breeding and exploiting other varieties, not essentially derived. See also 3 above.
7. Minimum term of protection	18 years for grapevines and trees and 15 years for all other plants	25 years for grapevines and trees and 20 years for all other plants
8. National treatment	May limit national treatment and scope of protection to those members which also protect the genera and species chosen for protection or implement the same scope of protection (although TRIPS makes this obligatory for all WTO members)	National treatment without exception

Source: Compiled by the author from http://www.upov.int

TABLE 3

COMPARISON OF IMPLEMENTATION OF TRIPS PROVISIONS ON AN EFFECTIVE SUI GENERIS SYSTEM FOR THE PROTECTION OF PLANT VARIETIES IN SELECT WTO

								110								
Subject	US	J P	EC	SW	AU	CA	NW	KR	SA	TT	AR	BR	CO/ CA	СН	SI	MY
1. Meets																
standards of	Y	Y	Y	Y *	Y	Y*	Y *	Y	Y	n	Y*	Y*	Y	Y*	n	n
UPOV, 1991																
(*=1978)																
2.Following																
permitted :																
(a) Breeders'	Y	Y	Y	Y	Y	Y	Y	Y	Y	n	Y	Y	Y	Y	n	n
exemption			_	_												
(B.E.)																
(b) Farmers'	Y	Y	Y	Y	Y	Y	Y	Y	Y	n	Y	Y	n	Y	n	n
privilege	-	-	-	-	-	-	-	-	-		-	-		-		
(c) B.E. not for	Y	Y	Y	Ν	Y	Ν	Ν	Y	Y	n	Ν	Y	Y	Ν	n	n
essentially	-	-	-	- 1	-	- 1		-	-		- 1	-	-	- 1		
derived																
variety																
3. Criteria of																
distinctness,																
uniformity and	Y	Y	Y	Y	Y	Y	Y	Y	Y	n	Y	Y	Y	Y	n	n
stability	-	-	-	-	-	-	-	-	-		-	-	-	-		
4. Criteria of																
novelty i.e. not																
commercialized	Y	Y	Y	Y	Y	Y	Y	Y	Y	n	Y	Y	Y	Y	n	n
5. Duration of	-	-	-	-	-	-	-	-	-		-	-	-	-		
15/18 years or	Ν	Ν	Ν	Ν	Ν	Y	Ν	Ν	Ν	n	Y	Y	Y	Y	n	n
below	11	1	1	1	1	-	1	1	1	11	-	-	-	-		
6. Duration of																
20/25 years or	Y	Y	Y	Y	Y	Ν	Y	Y	Y	n	Ν	Ν	Ν	Ν	n	n
longer	-	-	-	-	-	11	-	-	-		1	1	- 1	11		
7. Universal	Y	Y	Y	Y	Y	Y	Y	Y	Y	n	Y	Ν	Y	Y	n	n
coverage	1	-	•	-	-	-	1		1	11	-	1	-	-	11	11
8. Limited	Ν	Ν	Ν	Ν	Ν	Ν	Ν	Ν	Ν	n	Ν	Y	Ν	Ν	n	n
coverage	1	1	1	1	1	1	1	1	1	11	1	1	1	1	11	11
9. Compulsory																
licensing	Ν	N	Ν	Ν	Y	Y	Y	Y	Y	n	Y	Y	Ν	Y	n	n
provided for	T	TN	TN		I	I	I	I	1	n	I	1	T	I	n	n
provided for	<u> </u>							1			1	1				

MEMBERS

For Table 1 and 3 : Y=Yes; N= No; n= not available; US=United States; JP = Japan; EC = European Communities; SW = Switzerland; AU = Australia; CA = Canada; NW = Norway; KR = Korea; SA = South Africa; TT = Trinidad and Tobago; AR = Argentina; BR = Brazil; CO/CA = Colombia and other members of the Cartagena Agreement; CH = Chile; SI= Singapore; MY= Malaysia.