FUTURE ISSUES ON IPRs IN THE WTO

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JAYASHREE WATAL

OCTOBER 1999

ICRIER

INDIAN COUNCIL FOR RESEARCH ON INTERNATIONAL ECONOMIC RELATIONS
Core-6A, Fourth Floor, India Habitat Centre,
Lodi Road, New Delhi-110 003
INDIA

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Foreword

The Trade Related Intellectual Property Rights (TRIPs) Agreement under the WTO has been a subject of a great deal of controversy in India. An important question that arises at the present moment before the third WTO Ministerial Conference at Seattle, USA, in end-November 1999, is whether this agreement is likely to be changed in future negotiations in the WTO and, if so, how.

This paper by Ms. Jayashree Watal is an attempt to evaluate the future issues relating to intellectual property rights in the light of the ongoing preparation for Seattle and beyond. She is of the view that the developing countries should exploit the available flexibility in the existing TRIPs regime and not push for changes. Her overall assessment is that the developed countries' appetite for further strengthening of TRIPs is

generally poor at this point in time, and the no change scenario may well suit the interests of developing countries. Ms. Watal, a Fellow at ICRIER, is at present a Visiting Fellow at the Institute for International Economics (IIE), Washington, D.C.

I hope that this paper provides adequate food for thought on the part of all those who are seized with the need to evolve a strategy on this very important issue.

Isher Judge Ahluwalia
Director & Chief Executive
ICRIER

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Executive Summary

The Agreement on Trade-related aspects of Intellectual Property Rights (TRIPS), now part of the World Trade Organization (WTO), when fully implemented, will unambiguously strengthen intellectual property protection globally, including in India. Undoubtedly, the *demandeurs* for strengthened intellectual property protection in the Uruguay Round, notably the US, see gaps in the level of protection accorded by TRIPS. There is also a "built-in agenda" where review of existing provisions is mandated in 1999/2000. What are these future issues on intellectual property rights (IPRs) in the WTO? This question assumes importance because of the forthcoming third WTO Ministerial Conference at Seattle, USA in end-November 1999, where an attempt will be made to launch a new round of multilateral trade negotiations.

This paper is an attempt to evaluate the future issues with respect to IPRs in the light of the preparations for Seattle and beyond being made by developed and developing countries. This paper observes that despite the built-in agenda, the *demandeurs'* appetite for further strengthening TRIPS is generally poor for various reasons. Paradoxically, the demand for change in TRIPS is being led vociferously by developing countries, backed by important developed country NGO interests. The end-result may be that status quo will be maintained on TRIPS for some time to come in the WTO, which, this paper concludes is not a bad outcome for developing countries, given the considerable flexibility already available under TRIPS. Developing countries may only be shooting themselves in the foot if they push for changes in TRIPS to get in hortatory clauses relating to biodiversity or transfer of technology or definitions of currently undefined terms, as they would lose their current freedom and may have to make more serious concessions at Seattle or beyond, in return for this.

Discussion Paper

The Agreement on Trade-related aspects of Intellectual Property Rights (TRIPS), now part of

the World Trade Organization (WTO), when fully implemented, will unambiguously strengthen intellectual property protection globally, including in India. The question is whether this agreement is likely to be changed in future negotiations in the WTO and if so, what is the likely direction of change. Undoubtedly, the *demandeurs* for strengthened intellectual property protection in the Uruguay Round, notably the US, see gaps in the level of protection accorded by TRIPS. There is also a "built-in agenda" where review of existing provisions is mandated in 1999/2000. What are these future issues on intellectual property rights (IPRs) in the WTO? This question assumes importance because of the forthcoming third WTO Ministerial Conference at Seattle, USA in end-November 1999, where an attempt will be made to launch a new round of multilateral trade negotiations. This paper is an attempt to evaluate these future issues of IPRs in the light of the preparations for Seattle and beyond being made by developed and developing countries. This paper observes that despite the built-in agenda, the *demandeurs*' appetite for further strengthening TRIPS is generally poor. Paradoxically, the demand for change in TRIPS is being led vociferously by developing countries, backed by important developed country NGO interests. The end-result may be that status quo will be maintained on TRIPS for some time to come in the WTO, which, this paper concludes is not a bad outcome for developing countries, given the

considerable flexibility already available under TRIPS.

There are eight areas of intellectual property covered by TRIPS, viz. patents, plant variety protection, copyrights, trademarks, geographical indications, industrial designs, layout-designs for integrated circuits and undisclosed information. Of these eight areas, Indian law and jurisprudence is, by and large, already in line with the TRIPS requirements on three areas, viz. copyrights, trademarks and industrial designs. Amendments to existing laws or new laws are required to comply with the provisions on patents, plant variety protection, geographical indications, layout-designs and undisclosed information, particularly test data. The most important changes are to be made in the area of patents. Patents are to be made available for both process and product inventions in all areas of technology, including for product inventions relating to food, chemicals and pharmaceuticals, which were previously excluded. The rights of a process patentee must extend not just to the use of the patented process, as is the case in Indian law, but to exclusive rights over the product directly obtained through the process. In addition, judicial authorities must be given the power to order the reversal of the burden of proof under certain circumstances. It must be noted that since product patents will have to be granted to eligible inventions, the rights of process patentees is of more limited importance than would have been the case otherwise under the current Indian

patent law. The term of patent protection must be 20 years from the date of filing, in lieu of 7/14 years available in the Indian patent law. Biotechnological inventions must be protected in that patents must be granted for eligible microorganisms and for microbiological and other non-biological processes for the production of plants and animals. Plant and animal inventions can however, be excluded from patent grant, as can essentially biological processes for their production. Countries that opt to exclude plants from patenting must make available "effective" *sui generis* plant variety protection or plant breeders' rights. The terms "microorganism", "microbiological processes", "non-biological processes", "essentially biological processes" or "effective" have not been defined in TRIPS. Nor has the term "invention" been defined to distinguish it from the discovery of that which exists in nature. The criteria of patentability of "novelty", "non-obviousness" or of inventive step and "industrial applicability" or usefulness have also not been defined. Some developing countries view this absence of definitions as a gap that should be immediately remedied. Developing countries hope to obtain, by consensus, definitions that would suit their purposes. Instead, the absence of definitions in TRIPS is an opportunity to define these terms within national laws without being constrained by international law. As long as a country can credibly defend itself in any possible dispute in the WTO, there should be no problem. A more important provision in TRIPS that often

escapes attention, is that requiring protection of test data submitted for obtaining marketing approval for new pharmaceutical and agricultural chemical products. This provision applies to new chemical entities and has been interpreted by other developed countries, at the insistence of the US, to mean the grant of at least a five-year period of marketing exclusivity. This would mean the grant of exclusive marketing rights even for products that are not otherwise eligible for patents, a back-door entry for "pipeline protection".

Undoubtedly, the *demandeurs* for strengthened intellectual property protection did not obtain all that they wanted to in the TRIPS negotiations of the Uruguay Round. They should logically attempt to plug the most important gaps in TRIPS, according to their perception. Some of these are part of the built-in agenda: non-extension of the existing moratorium on **non-violation**, which expires by the end of 1999 if not extended further by consensus at the Seattle Ministerial Conference; registration system for **geographical indications for wines and spirits**, already part of the work programme; **patents for plants and animal** inventions or at least reference to **UPOV 1991**, as a part of the built-in review of Article 27.3 (b). Others negotiating goals could be: amending the rules to ensure **effectiveness of enforcement**; narrowing down the grounds for the grant of **compulsory licences**; prohibition on **parallel imports**, at least for patented products; **patent term extension** for pharmaceuticals to compensate

for delays in regulatory approvals; patent grant for **new therapeutic uses for known substances**; fixing a period of market exclusivity in the clause on **test data**; improving intellectual property provisions for **electronic commerce,** including the incorporation of the new WIPO copyright and related right treaties; harmonizing rules for patent applications to **first-to file v. first to invent.** There could also be demands to further tighten the definition of what is "new" under the reversal of burden of proof clause.

However, with the exception of non-violation, the *demandeurs* have made no move to further strengthen the TRIPS Agreement in the preparations for the Seattle Ministerial Conference. On the extension of the moratorium on non-violation, the US is alone in its opposition but this is sufficient to block consensus. The US pharmaceutical industry sees non-violation as an important weapon to use to fill in the gaps in TRIPS. It is not quite clear to others how non-violation can be proved, especially as the rights granted under IPRs are defined negatively as the right to exclude third parties. However, even other developed countries like Canada and the EU, are wary of the use of non-violation by the US, particularly against the use of cultural exceptions. Most WTO delegations believe that in the absence of any decision, the moratorium will automatically cease and non-violation will become applicable to TRIPS. This interpretation can be questioned and the discussion on scope and modalities of non-

violation, as applied to TRIPS, continued to be discussed even post-Seattle. Developing countries will have to take the initiative on this as otherwise they may see some of the flexibility available in TRIPS slipping away. Alternatively, they should be prepared to fight the battle through dispute settlement, even if as third parties, as the first panel on the subject may have to interpret whether non-violation is at all applicable to TRIPS.

On all other matters, the US and indeed other *demandeurs*, seem to have decided that the time is not yet ripe to demand a further strengthening of TRIPS. The focus is to remain on implementation "and we would suggest deferring any negotiations in the WTO to improve the TRIPs agreement until we all digest what needs to be implemented for now" (Joseph Papovich, Assistant US Trade Representative as reported in *Inside US Trade*, July 16, 1999). Indeed, the US interprets the biennial review called for under Article 71 of TRIPS from 2000 onwards to be a review of implementation in the year 2000 and review of the TRIPS text thereafter (in *Inside US Trade*, August 6, 1999). On the revision of the provisions on biotechnological inventions, the International Chamber of Commerce "supports maintaining, at this stage, the existing wording of Article 27.3(b), without change" (document no. 450/869 of 1 July 1998 available at http://www.iccwbo.org). ASSINSEL, the leading world association of seeds companies "does not consider it necessary to make substantial change in the scope of the exemptions

from patentability under Article 27.3. However, it might be useful to make the article clearer by specifically referring to UPOV as an effective *sui generis* system" (excerpted from ASSINSEL brief on review of TRIPS 27.3b available at www.worldseeds.org). Note that there is no strong demand for a reference to UPOV. Clearly, the *demandeurs* appetite for further strengthening TRIPS is poor, even on the built-in agenda. It may be recalled that during the TRIPS negotiations, the clause for review of the patenting of biotechnological inventions in four years' time was put in due to lack of agreement between the US and the EU. The EU had not yet passed its biotechnology directive at the time and was facing strong opposition to it from not only some green groups but also from some of its members. Although the European biotechnology directive has now been passed in July 1998 and has cleared the way for the patenting of plants and animals, this directive has been challenged in the European Court of Justice by the Netherlands, once again creating legal uncertainty. More importantly, the directive allows farmers' privilege to save seeds even while allowing plant patents and some see this as lower than the optimal level of protection. Utility patents for plants are also presently under challenge in the US courts[1]. Additionally, the wide

[1] Decision on an appeal filed in the US Court of Appeals for the Federal Circuit in *Pioneer Hi-Bred International v, JEM AG Supply, Inc.*, 33 F. Supp. 2d. 794 (D. Iowa 1999) is eagerly awaited by the agricultural biotechnology industry which holds a number of such plant patents.

spread fears on genetically modified foods, particularly in Europe, has further muddied the waters on the issue of patent protection for transgenic plants. The successful campaign by some NGOs last year against the so-called "terminator" technology that can produce sterile plants, thus giving strong "technological" protection over proprietary genes, led to Monsanto, US the multinational, life sciences company, retracing its steps and promising not to use this technology. However, other Genetic Use Restriction Technologies that control the expression of the proprietary trait in future generations of plants have not been abandoned. With these and the existing hybrids, owners of proprietary new plants have more effective "technological" protection as farmers are forced to re-purchase seed every crop season if they want to have the new improvements. Thus, the legal clause on farmers' privilege, will remain ineffective and, like the forsaking of the "terminator", is only a political sop thrown at opponents. For the moment, not only is the environment not ripe to demand further negotiations to strengthen intellectual property protection for plants and animals, there may soon be little need for such legal protection.

It is not just the environmental NGOs that have been successful in their campaign against further strengthening of IPRs. In the US, aids activists have been assisted by consumer groups in successfully painting the USTR black for preventing South Africa from using measures like

compulsory licensing or parallel imports, both of which are allowed under TRIPS, to reduce the prices of AIDS drugs. Given the sensitivities in the run up to presidential elections, the USTR was forced to withdraw its case against South Africa for this reason (see www.cptech.org for a chronology of events in this case). The EU and Japan have raised the issue of first-to-file as a negotiating tactic against the US. The EU is keen only in pursuing its interests on geographical indications for wines and spirits. None of the *demandeurs* want to see any dilution of the existing level of IPR protection under TRIPS. This is directed against the developing countries as they have made many such proposals so far.

Paradoxically, it is the developing countries who are demanding amendments to TRIPS, not just to tactically counter any possible demands from developed countries, but to incorporate their own interests. Their proposals range from the extension of transitional periods, protection of traditional knowledge, access to genetic resources, transfer of technology to the extension of higher level of protection to geographical indications other than wines and spirits. There is a deep and pervasive feeling amongst many developing countries that the results of the Uruguay Round were unbalanced as they gained far less than developed countries. This is because they have not seen much benefit from the agreements on textiles and agriculture, while made substantive concessions on market access in goods, services

and most of all, on intellectual property. The natural corollary of this is that they want to balance the WTO agreements now by demanding changes, especially to counter what they see as protectionist demands of developed countries on labour and environmental standards. There are also other factors: these countries are far more experienced at playing the negotiating game in the WTO since their Uruguay Round days, have been emboldened by the success they had on the election process of the DG, WTO recently and are far less prepared to take a back seat in the WTO.

On TRIPS, one of the major demands of developing countries is the reconciliation of the **Convention on Biological Diversity** (CBD) with TRIPS. It has been argued, with the support of many developed country environmental groups, that TRIPS ignores the obligations of parties to the CBD to share the benefits fairly and equitably from the commercialization of inventions based on biological resources obtained from developing countries or to transfer relevant technology. They also want to develop an internationally recognized system for the protection of traditional knowledge and rural innovations, which they believe are being pirated with impunity by multinational corporations. One of the earliest and most coherent proposals so far on the subject was made by India in the WTO Committee on Trade and Environment (CTE) in 1996. India demanded an amendment to TRIPS to oblige countries to require patent applicants to disclose the country of origin for

biological materials and traditional knowledge, wherever relevant. India has now gone further to demand that patent applicants obtain prior informed consent from the relevant countries before the filing of such applications. This proposal was echoed by the European Parliament when it proposed such an amendment in the discussions on the European biotechnology directive. Of the 66 amendments proposed by the parliament, the European Commission accepted 65 and the 66th one that was rejected was this one! The Commission argued that this went beyond the international obligations of the EU in international treaties, obviously the CBD and TRIPS. However, the EU clearly does not want to take on this international obligation given its opposition in the WTO to date on this issue.

India and some other developing countries from Latin America and Africa are also demanding obligations in TRIPS on the provision of incentives for the transfer of technology by developed country governments to their enterprises. The origin of this demand can be traced again to the CTE when, in 1996, India juxtaposed the demand of the EU for amending Article XX of GATT to allow trade measures in Multilateral Environmental Agreements (MEAs) with its own demand to incorporate an obligation on developed country governments to grant incentives to their enterprises to allow access to patented environmentally sound technologies and products (EST&Ps) required in the implementation

of MEAs on fair and reasonable terms. This served the tactical negotiating purpose of stalling the demand for amending GATT as well as highlighted the need to view MEAs as a package implemented through punitive trade measures as well as positive financial and technology transfer incentives. In the run up to Seattle, developing countries have gone as far as to demand a separate working group on the transfer of technology. There are many amongst them who are worried that with strengthened IPR protection obligatory under TRIPS, access to technologies may become more limited or costly. To counter the fear of higher prices of medicines, some have demanded that the WHO list of essential drugs be excluded from patent grant under TRIPS. Others want an extension of the transitional period allowed to implement TRIPS by at least a further five years i.e. up to 2005 instead of by 2000. Many developed and developing countries have proposed the extension of the higher level of protection on geographical indications, accorded to for wines and spirits only in TRIPS, to other products. For instance India has an interest in protecting Basmati rice and Darjeeling tea worldwide.

How credible are these proposals and how much should developing countries concede in order to obtain these amendments to TRIPS? Taking the CBD set of issues first, calculations made of the economic benefits of fair and equitable sharing of benefits for such pharmaceutical inventions commercialized so far

reveal very small sums (see www.rff.org). It is not at all evident that developing countries should accept demands in other areas of the WTO negotiations on further market access or on a multilateral agreement on investment in exchange for what might turn out to be fairly insignificant economic benefits, even ignoring all the practical difficulties of actually ensuring the effective working of such provisions at the national level. Similarly, in the past, obligatory clauses on transfer of technology (as present in some MEAs) have not proved effective. At best, the obligation could be confined to government-funded R&D or the provision of subsidies to private R&D. There is no willingness on the part of developed country governments to even discuss these matters in the limited context of R&D for under-researched tropical diseases (as proposed in Sachs, 1999). Certainly, discussions on the provision of research funds or the sharing of the results of public R&D are valid in the limited contexts of endemic under researched tropical diseases or MEAs dealing with transboundary environmental problems. The possibilities of reaching agreements by consensus, which go beyond hortatory statements made so far, have to be carefully weighed by developing country negotiators against the concessions being demanded of them. Also, when demanding the exclusion of essential medicines from patenting, the obvious counterpoint would be that there would then be no R&D forthcoming on finding solutions to diseases likely to be targeted by this list. It is for this reason that WHO has struck a

careful balance and mostly placed drugs already off-patent on its list of essential medicines. Besides, national governments can already use the quite liberal provisions on compulsory licensing, where, following the Indian initiative in the TRIPS negotiations in 1990, there is no bar on the grounds on which such licences can be issued. Paradoxically, some developing countries are now demanding a listing of the grounds on which such licences would be allowed under TRIPS. Such a move can only be counter productive, narrowing down the options now available to these countries. It is only in the case where technologies are difficult to copy (the case with, for instance, the substitutes for CFCs to be phased out under an MEA, the Montreal Protocol[2]), that there may be a problem in using compulsory licences. Governments can also use price controls, competition policy or parallel imports, permitted under the TRIPS agreement, to tackle the problem of unreasonably high prices.

[2] This was subsequently documented in Watal, Jayashree (1997): 'Issues relating to the Transfer of Technology, including the Role of Intellectual Property Rights in the Implementation of the Montreal Protocol in India', Report submitted to UNCTAD, April, being reproduced in Jha, Veena, Ed. (forthcoming): *Trade and Positive Measures in Multilateral Environmental Agreements*, Chapter on India by Watal, J. and Shipra Das.

On biotechnological inventions, developing countries do have the support of some European countries like Norway, Netherlands and Italy, apart from a host of developed country NGO organizations, to make a restrictive interpretation of the undefined terms in TRIPS. Thus, there is no obligation to patent plants, animals or parts thereof, or to patent substances as found in nature, such as gene sequences. Microorganisms can also be defined restrictively as unicellular organisms as Canada has done. There is similarly no obligation to follow UPOV 1991 and each country can define its own sui generis system of breeders' rights. The real danger comes from "technological" protection already available to breeders of hybrids. Here each country will have to evaluate the benefits to its farmers and consumers from such new technologies. The important issue may revolve around access to these new and important technologies at reasonable terms rather than any blanket prohibition on their commercialization.

On geographical indications, the Europeans are keen to move forward with the negotiation on the registration of wines and spirits, which is already a part of the built-in agenda. Although Europe also has interest in extending the scope of the negotiations to cover other products, it does not want to jeopardise its case for wines and spirits.

The US, Australia, New Zealand and many Latin American countries are stiffly opposed to any expansion of the scope as they have swallowed the bitter pill on wines and spirits itself with some difficulty in the TRIPS negotiations. There is thus, little chance of developing countries succeeding in widening the scope of the negotiations on geographicals at this stage. Since countries like India are really interested in a few specific products, the better route is to conclude bilateral negotiations with its important trading partners. With Europe there is a good chance of getting this higher level of protection on a reciprocal basis and work on this as initiated by India in 1996/7.

The demand for the extension of transition period is relevant for very few developing countries as many have already put in place legislation to implement TRIPS. Even India has legislated to accept patent applications for pharmaceutical and agricultural chemical products and grant exclusive marketing rights (EMRs) for a period of five years. Such legislation has the same practical effect as the grant of product patents for these most sensitive products. Not much purpose would be served in delaying the implementation of other less sensitive provisions of TRIPS. Least developed countries already have time up to 2006 and further extensions can also be granted on a case-by-case basis. It is for this reason that developed countries may like to consider granting such extension at the forthcoming Seattle Ministerial Conference, as a political sop to

developing and least developed countries in exchange for other concessions. Developing countries would have to guard against making any such inequitable exchanges.

To conclude, there is surprisingly no demand on the part of industrialized countries to further strengthen IPR protection under the TRIPS negotiations in the run up to Seattle. For the *demandeurs*, TRIPS appears to have fallen off the negotiating table. The reason for this can be traced to the vastly successful NGO campaign portraying the WTO as a forum for big business and against labour and environmental interests, which denied the US government fast track authority to conduct further trade negotiations. In preparation for next year's presidential elections, the US administration is further constrained in pushing business interests. Europe is equally constrained by environmental NGO campaigns and consumer sentiment against genetically modified organisms and cannot forcefully push for the patenting of plants and animals, despite the built-in review on this issue. Academics, international organizations (WHO, UNDP) and even competition authorities have begun to question the dominance of multinationals and address public policy issues on research on under-researched tropical diseases, prices of essential medicines and the increasing technological gap between developed and developing countries. This widespread sentiment against big business, and the questioning of IPRs in this context, does not provide the most propitious environment for the further

strengthening of TRIPS. The *demandeurs* have, therefore, decided to lie low for the time being and review the gains made by them so far by closely reviewing the implementation of TRIPS. The focus on TRIPS will, for developing countries, shortly shift to dispute settlement in the WTO. Developing countries would be making a serious mistake to re-open TRIPS to seek definitions of undefined terms as this would restrict their own current flexibility and freedom. To seek the inclusion of clauses that may, in the end, be only hortatory and unoperational may prove costly in terms of concessions given in the WTO. For the time being, it may well be in their interest to leave TRIPS untouched at the forthcoming Seattle Ministerial Conference and not to accept hortatory language in return for other more serious concessions.

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