

TRIPs and Public Health: What needs to be done in human rights perspective?

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Abstract

The Trade Related Intellectual Property Rights (TRIPs) Agreement of the World Trade Organization (WTO) has generated both opportunities and apprehensions for the rich and the poor respectively. The opportunities under TRIPs agreement have largely benefited multinational corporations (MNCs) and those who got patents in the North. The apprehensions are high in the South amid developments that are directed towards regulating trade and intellectual property rights, thus threatening farming communities and agriculture sector as a whole. Furthermore, TRIPs agreement has been pushing up developing countries in terms of patent regime in the pharmaceutical sector, thus hindering access of populations in these countries to essential drugs.

At one hand, TRIPs agreement allows patents to MNCs that control quality and prices of drugs in world market; on the other hand, it gives opportunity to state governments to exploit the flexibilities provided in certain articles of the TRIPs agreement to ensure access of their people to essential medicines. The access to healthcare is a fundamental human right and has been protected under various human rights covenants and conventions besides the UN Declaration of Human Rights (UDHR).

This paper discusses TRIPs agreement and its impacts on the public health and argues that state governments can intervene in health and pharmaceutical sector to guarantee people's equal access to pharmaceutical products by utilizing flexibilities provided in the TRIPs agreements.

1. Impact of Globalization on Public Health

The fundamental concept of “globalization” seems deviating from its assumed role of ensuring free flow of trade, finance and information while liberalizing markets to achieve the goal of economic development as the developed countries continue to limit breathing space for the developing and least developed countries owing to their heavily subsidized agriculture sector and over protected trade. This uneven globalization has been largely expanding the gap between the winners and losers (the rich and the poor).

“Globalization has its winners and its losers. With the expansion of trade and foreign investment, developing countries have seen the gaps among themselves widen.... Poor countries often lose out because the rules of the game are biased against them, particularly those relating to international trade. The Uruguay Round hardly changed the picture”²

Globalization has gradually been curtailing the role of state in developing countries as the imperative to liberalize has led to reduced state involvement in social sectors and the

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² United Nations Development Programme. Human development report 1997, Oxford, New York, Oxford University Press, 1997.82

markets. It has serious implications for states, as market liberalization has made it difficult for governments to subsidize health services for the poor. Privatization process weakened many states and have increased their vulnerability as they do not have sufficient strength to oppose powerful international groups. Structural adjustment programmes of the Breton woods institutions together with globalization have doubled this vulnerability to weaken state influence. The third element has been recently added to this phenomenon when the United States attacked Iraq after selling a theory that weak and soft states being danger to world peace should be overpowered. These world trends demand stronger states to protect people's rights, specially their right of access to the social sector, particularly to health services and drugs.

1.2 Drug patents under TRIPS agreement of WTO

Among WTO agreements, the Agreement on Trade-Related Intellectual Property Rights (TRIPS) links intellectual property and trade issues for the first time and provides a multilateral mechanism for settling disputes between states on intellectual property. This Agreement is the most comprehensive ever reached on intellectual property. It establishes minimum universal standards for almost all rights in this field (such as copyrights, patents, and trademarks) including patent protection for pharmaceutical products, which may have a significant impact on access to drugs in developing countries.³

For all practical purposes, intellectual property laws are to protect and reward inventors. The inventors who file patent applications in a particular state are asking that state to recognize their exclusive right to inventions within the state's territorial boundaries, and therefore to exclude others from the use of the inventions without the inventors' authorization and the payment of compensation (such as royalties). Because knowledge, unlike consumer goods, can be shared by any number of persons without being diminished, inventors are dependent on such legal protection against direct copying or use of the products or processes they have invented. The adoption of new international rules on the matter has been actively promoted by most industrialized countries to obtain worldwide protection for the innovations they generate.

The TRIPS agreement provides minimum standards for the protection of intellectual property, and each Member State of WTO is required to incorporate these into its own laws before specified transitional periods have elapsed. Provisions in the TRIPS agreement regarding patents, trademarks, health registration data and other items set the basic framework that virtually all countries are expected to follow, or they may be claimed before the WTO dispute settlement body. Some provisions of the TRIPS agreement are controversial in the area of health care and pharmaceuticals, especially for developing countries. Under the TRIPS agreement, all WTO Member States have to make patent protection available for at least 20 years to any invention of a pharmaceutical product or process which fulfils the criteria of novelty, inventiveness and usefulness. This provision only applies to inventions for which a patent application was filed after 01 January 1995, and consequently is entirely prospective, excluding products in the pipeline. (The protection of products in the pipeline would include patent protection for any patent applications made abroad prior to the date of the introduction of product patent protection in the patent law.) However, because some countries did not previously have

³ German Velasquez and Pascale Boulet, Bulletin of the World Health Organization, 1999, 77 (3)

any patent protection system for pharmaceuticals, the TRIPS agreement allows them a 10-year transitional period in which to amend their patent legislation in compliance with the new rules. Countries that choose to delay the introduction of TRIPS-related patent laws and currently do not offer product patent protection therefore have to provide a mechanism to store patent applications for products invented after 01 January 1995. Such applications will remain unprocessed in a “mailbox” until the countries introduce new patent laws giving product patent protection. They are required to do this by 2005 at the latest.

Prior to the TRIPS agreement, many developing countries did not make patent protection available for pharmaceuticals, to permit manufacture of copies and generic equivalents of drugs at reduced prices. In the past it was considered the right of each nation to determine such laws.

According to a study commissioned by UNIDO on pharmaceuticals, “the contrasts between industrialized and developing countries are sharpest in the case of patents. Almost all industrialized countries grant patents on both products and processes typically for a period of 20 years. In developing countries, only 45% studied grant product patents and these are usually valid for a shorter period of time than in industrialized countries. Patents on production processes are more common in developing countries, although, again, the period of validity is comparatively brief”. Such non-patent regulation for pharmaceuticals helped some developing countries to build an indigenous pharmaceutical industry based on imitative cheaper drugs. Some developed countries used to have the same kind of approach and thus managed to create powerful pharmaceutical industries.

Another UNIDO statement said, “the TRIPS agreement may have a severe impact, especially in the high technology sectors such as pharmaceuticals, working to the disadvantage of developing countries in two main respects: domestic manufacturers wishing to produce and commercialize products covered by patents will be forced into licensing agreements involving royalty payments to patent-holders; while research and development activities may be hindered since the TRIPS agreement is likely to inhibit reverse engineering, the process by which research-based industry products are copied and adapted for developing country usage.”

1.3 Compulsory licensing

Article 31 of the TRIPS agreement allows “other use without authorization of the right-holder”. This refers to use by governments or third parties authorized by governments and is known as compulsory licensing. The TRIPS agreement establishes a number of conditions for granting licences by public authorities, notably the need for case-by-case evaluation and decision, which means that the patent law cannot indicate in advance the specific cases in which compulsory licenses will be granted. However, the law may provide a basis for granting such licences, for instance on the grounds of public health, abuse of patent rights or the refusal of a voluntary licence from the patent-holder. Such reasoning should be based on Articles 7 and 8 of the TRIPS agreement, which provide for “the promotion of technological innovation and the transfer and dissemination of technology”, as well as “measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socioeconomic and technological development”.

1.4 Careful handling of biotechnology related issues

States should also be aware of another critical current trend: the move towards monopoly control over a wide range of plants, animals, microorganisms and even genes, including human genes. While the biotechnology industry is based in the North, 80% of the world's remaining biodiversity lies in the tropical and subtropical regions of the South. The new global trade rules give this industry easier access to critical bioresources. Yet it has been argued that the patenting of human life, genes and biochemical processes will artificially increase the price of delivering health care to people. The phenomenon of biopiracy of the biological resources of developing countries is increasing in importance: Western multinational firms are patenting a variety of indigenous plants and seeds that have been grown and used for centuries by farmers in these countries.

The TRIPS Agreement requires Member States to provide patent protection for microorganisms and for "non-biological and microbiological processes", "on the doubtful premise", says UNCTAD, "that the patenting of microorganisms and microbiological processes does not entail the protection of life forms". However, "the lack of consensus concerning biological patents allows countries considerable leeway in fashioning their policy options... States may limit the availability of patents for biological inventions by insisting on strict standards of novelty, utility, non-obviousness, and disclosure... despite tendencies to honour broad claims in some developed countries" (8).

2. Building upon Doha declaration on patents and public health

The last WTO ministerial conference specifically addressed the issue of access to medicines in the context of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This was in response to the growing controversy concerning the impact of TRIPS in the health sector for most developing countries, and in particular the HIV/AIDS tragedy in sub-Saharan Africa.

The TRIPS Agreement requires among other things that all WTO member-states introduce product and process patents in all fields of technology. Exceptions in fields related to the fulfilment of basic needs such as health are not granted. This is in contradiction to the Patents Act, 1970, which provided specific exceptions to patentability in the fields of health and food. The provisions of the 1970 act and similar legal regimes in other developing countries have been the source of significant complaints by the private sector pharmaceuticals industry in developed countries. The US pharmaceuticals lobby estimates that it currently loses more \$1.7 billion annually because of India's insufficient intellectual property protection.

Following the WTO ministerial conference, the joint parliamentary committee on the Patents (Second Amendment) Bill, 1999 finalised its report in December and submitted an amended version of the amendments to parliament. The recently passed legislation must therefore be analysed in the context of the declaration on the TRIPS Agreement and public health (Doha Declaration) and other relevant factors.

The Doha Declaration is a direct consequence of the multiple controversies concerning patents in the health sector, in particular in the context of the HIV/AIDS epidemics. Its importance is linked to the recognition that the existence of patent rights in the health sector does not stop states from taking measures to protect public health. More specifically, it affirms that TRIPS should be "interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all". This strengthens the position of countries that want to take advantage of the existing flexibility within TRIPS. In other words, the declaration does not open new avenues within TRIPS but confirms the legitimacy of measures seeking to use to the largest extent possible the in-built flexibility found in TRIPS.

The declaration focuses mainly on questions related to the implementation of patents, such as compulsory licensing. Compulsory licensing has long been used as a tool to regulate the exclusive rights conferred by patents. In the case of health, the rationale is to make sure that the existence of a patent does not create a situation where a protected medicine is not available to the public because of non-health related factors. The Patents Act, 1970 provided an elaborate regime that included both compulsory licences and licences of right. The TRIPS Agreement has not done away with the notion of compulsory licences but provides a more restrictive framework than the current regime in force in India. The recognition in the Doha Declaration that TRIPS member-states can use the flexibility provided in the agreement and can, for instance, determine the grounds on which compulsory licences are granted must thus be understood in the context of a generally increasingly restrictive international patent regime.

The declaration has been hailed as a major step forward in the quest for making the TRIPS Agreement more responsive to the needs of developing countries and more specifically all individuals unable to afford the cost of patented drugs. In fact, it addresses a number of important issues related to the implementation of medical patents. However, it fails to take up the much more fundamental questions of the scope of patentability and the duration of patents in the health sector. The Doha Declaration remains an important instrument in India for two main reasons. Firstly, at a political level, India was among the most vocal developing countries at the ministerial conference in putting forward developing countries' interests. Secondly, the declaration was adopted while the joint committee was finalising its report.

*Doha Declaration in November 2001 on TRIPs agreement and public health has largely been seen as a big step forward in the struggle to ensure essential drugs in affordable prices. The huge profile given to the issue changes the political climate, building on the victories in the South Africa and Brazil cases. It will now be much harder for the US and the drug companies to bully poor countries over their patent policies. We would have liked to see a stronger declaration but there is a clear political statement that the agreement must be implemented in a way that promotes access to medicines. The next step is to ensure that next year's scheduled review of the TRIPS agreement takes a hard look at the length and scope of pharmaceutical patents in developing countries, which remains the heart of the problem.

Cecilia Oh, Third World Network while commenting on the Doha Declaration said, “The declaration (as it stands) is a good first step. The developed countries, in agreeing to the declaration, have committed themselves to this process. We want to see a commitment on their part, and their pharmaceutical lobbies, to stop pressures on developing countries. The developing countries can get down to the work of implementing and enacting domestic measures, with the guarantee that there will not be pressures or legal threats.”

Zafar Mirza, Health Action International and TheNetwork for Consumer

Protection of Pakistan described the Declaration as a definite step forward though it could be stronger. The declaration explicitly recognizes the issues as well as sovereignty of the governments to take appropriate measures to get around to the issues. A lot depends upon the countries now how they live up to the expectations of the poor patients. The declaration also recognizes the problems of countries with insufficient or no pharmaceutical manufacturing capacity and also the limitation of the compulsory license as solution to these problems. We hope General Counsel comes up with a clear solution to this issue next year. Our challenge now is to get this declaration translated into action, which can save lives.

The Doha declaration on TRIPS is the strongest and most important international statement yet on the need to refashion national patent laws to protect public health interests. It is a road map for using the flexibility of the TRIPS to protect the public health, and sets a standard to measure any new bilateral or regional trade agreement. The declaration is a political statement that did not modify in any way the TRIPS agreement, and the decision to settle for a political statement was controversial in the negotiations. The developing countries had asked for legally binding interpretations of the agreement, including a solution to the single most obvious problem with the TRIPS, the Article 31.f limitations on exports of medicines manufactured under a compulsory license. We were disappointed the European and American negotiators blocked agreement to use Article 30 of the TRIPS to export medicines to countries that do not have domestic capacity for manufacturing, but pleased this issue will be examined by the TRIPS council in 2002. The negotiation over the export of medicines provisions in the TRIPS will be the next battleground in term of trade policy.

Since Seattle there has been a seismic shift. Two years ago many developing countries felt they were powerless against the will of the wealthy countries and their drug companies. Here in Doha more than 80 countries came together and negotiated in mass. It was this solidarity that led to a strong affirmation that TRIPS “can and should be interpreted and implemented in a manner ...to protect public health.” In practical terms it means that countries are not at the mercy of multinationals when they practice price gouging. The threat of punitive action against a country that attempts to address its health needs has been dramatically reduced. With this declaration it is doubtful that a wealthy country would dare file a dispute against a developing country for using one of the safeguards such as compulsory licensing. Now patent holders either offer prices that make their drugs accessible or risk losing their monopoly rights. The victory in Doha is really for people who need or will need access to life-saving or extending medicines.

Like at the Health Ministerial in May 2001, The EC and the EU again fell into this apparently spontaneous good cop/bad cop mode, with the US opposing everything and

the EU claiming to have no position of its own on the issues and to only want to help the opposed parties find a middle ground, while in truth intensively watering down the developing countries' proposals. Then the political need to come back from Doha with some semblance of success made the Brazilian delegates cave in to the rich countries' position and agree to forget legally binding wording as well as clarification of exports for generic versions of patented drugs. India and the Africa group resisted a bit, but were not imparted with enough political commitment to the issue to make this a deal-breaker. The Africa group representative, and the African delegates, did not realize the role and value of press work for negotiation purposes, both in terms of contradicting rich countries' propaganda and of holding North public opinions ransom for North government's predictable efforts to renege on the spirit and/or letter of the Doha Declaration. They waited until the last day to talk to the press, instead of crying foul at the first immoral positions insisted upon by developing countries. The chairman of the Africa Group did not answer when asked in press conference whether it should be expected that the hard-won right to effectively use compulsory licensing provisions would be exercised by African countries in the short term, in the context of the health crises currently obtaining on the continent, and after the US and Pharma had told the press in the morning that the Declaration didn't mean anything in the sense that it was purely political, and that it did not really say anything about how WTO would react should patents broken. Where relation with the media is concerned, developing countries seem to show surprising naivens about the influence of the pharmaceutical industry over richest country governments and their duplicity with regard to international agreements. They should be briefed about negotiation techniques and the role of the press therein.

This declaration is a major step forwards in the quest to ensure access to medicines for all. The text that has been agreed upon now was unthinkable 6 months, 6 weeks, even 6 days ago. It states clearly that there are serious conflicts between the obligations under the TRIPS Agreement and countries need to protect public health including providing access to medicines, it states that countries have the right to take measures to overcome patent barriers to public health and the statement outlines clearly how countries can do this. It is a missed opportunity that this ministerial conference did not offer a solution for countries without production capacity that want to make use of compulsory licensing. But we are confident that this issue will be resolved in the next year in the TRIPS Council. Countries can ensure access to medicines without fear of being dragged into a legal battle. Now its up to governments to use this power to bring down the cost of medicines and increase access to life-saving treatments.

3. Access to Medicines and TRIPS agreement in human rights perspective

During recent years, growing HIV/AIDS crisis, the issue of access to affordable medicines in many of the world's poor and developing countries is finally receiving the attention it deserves. There are no two opinions that making medicines accessible to those who need them requires action on many fronts. There is a dire need to look into private patents in pharmaceutical products under TRIPs agreement as these patents keep drugs prices much higher than the affordability of those who need them most.

We have to emphasize on this aspect that TRIPS agreement sets out minimum standards for a global regime of protecting intellectual property, including patents on pharmaceutical products and processes. The current and anticipated impact of the TRIPS agreement on countries' ability to take legislative measures making medicines more accessible to their populations is a matter of ongoing discussion, not only among non-governmental "civil society" organizations and treatment activists, but within governments and at inter-governmental levels.⁴

The issue is now firmly on the agenda of various United Nations bodies and the World Trade Organization (WTO). Within the UN system, bodies ranging from the Commission on Human Rights to the UN Development Program have begun to examine the issue from the perspectives of human rights and human development. Within WTO, Doha Declaration has been dubbed as a step forward in this regard and now there is a need that the member countries move in the right direction and make their legislations using all flexibilities provided in the TRIPS agreement to ensure access and affordability of the people to medicines. Both the General Council and the subsidiary Council for TRIPS are taking up this issue as a matter of human development, generally with little or no reference to the directly relevant body of international law dealing with human rights.

3.1 Public Health as Human Right in International Law

The right to healthcare has been recognized as a "fundamental right" by the international community since the adoption of the Constitution of the World Health Organization in 1946. The United Nations Charter (adopted in 1945), although it makes no specific reference to a right to health, obliges all UN member countries to "take action" to achieve universal respect for, and observance of, human rights, which is one of the four foundational purposes of the United Nations. The Articles 1, 55 and 56 of the UN Charter create a legally binding treaty obligation on states to realize human rights.

The health as a basic human right is covered in other instruments in international law. The Universal Declaration of Human Rights (UDHR) recognizes every person's right to a standard of living adequate for his/her health (Article 25), the right to share in scientific advancement and its benefits (Article 27), and the right to a social and international order in which the Declaration's rights can be fully realized (Article 28). **The UDHR has achieved the status of customary international law, namely those practices recognized, with substantial uniformity, by states as being required by prevailing international law. As such, its norms are legally binding upon all the world's countries.**

Several of the key treaties, declarations and statements by states that have established the UDHR as part of customary international law include, the Helsinki Final Act (1975), the Declaration on the Rights of Disabled Persons (1975), the Declaration on the Use of Scientific and Technological Progress in the Interests of Peace and for the Benefit of Mankind (1975), the Declaration of Alma-Ata on Primary Health Care (1978), the Vienna Declaration and Programme of Action (1993) from the UN's World Conference

⁴ Richard Elliott, LL.B. - Director, Policy & Research - Canadian HIV/AIDS Legal Network, November 2001; --- www.aidslaw.ca

on Human Rights, and the UN General Assembly's recent Millennium Declaration (2000).

As confirmed by the International Court of Justice in the 1970 *Barcelona Traction* case, human rights obligations are *erga omnes*, meaning that they are incumbent upon every state in relation to the international community as a whole. Furthermore, the centrality and importance of human rights in the body of international law is highlighted by the fact that at least some of the norms set out in the UDHR amount to *jus cogens*, meaning they are peremptory norms not subject to any derogation and unquestionably superseding all other rules of international law.⁵

Even those human rights norms which have not yet achieved the status of *jus cogens* (because some derogation may be permitted if justified) may nonetheless still enjoy primacy over norms of international law, including States' obligations under trade treaties. Treaties are also a principle source of a legally binding right to health in international law. The key provisions of regional instruments creating a legally binding right to health in the Inter-American, European and African human rights systems are also canvassed. Finally, there is a need to look at the significance of the provisions of the *International Covenant on Economic, Social and Cultural Rights* (ICESCR) that create a legally binding right to health (Article 12) on states which are parties, as well as imposing legal obligations on all states parties to co-operate internationally to realize this right (Article 2). Of particular importance are the expert observations of the UN's Committee on Economic, Social and Cultural Rights. In particular, its General Comment 3 on the nature of States' obligations under the ICESCR to fulfill the rights it sets out, and its General Comment 14 specifically on the right to health, provide useful guidance in filling in the content of the human right.

3.2 Trade and Primacy of Human Rights in International Law

In this Part, the paper sets out a legal argument for the conclusion that States' obligations under the international law of human rights take precedence over other obligations under international law (including trade agreements). It was noted in Part I that Articles 1, 55 and 56 of the UN Charter create legally binding treaty obligations on all UN member countries to realize human rights. Article 103 of the UN Charter expressly states that in the event of a conflict between States' obligations under the UN Charter and their obligations under "any other international agreement," their obligations under the UN Charter shall prevail. Furthermore, the International Court of Justice has confirmed this hierarchy in international law in its 1992 ruling in the *Aerial Incident over Lockerbie Case*. States' practice also indicates that, legally speaking, the UN Charter enjoys primacy in international law. From the entry into force of the *Vienna Convention on the Law of Treaties*, to many resolutions by the UN General Assembly, the countries of the world have affirmed the "paramount importance" of the UN Charter and the obligation on all States to fulfill its obligations under the Charter. In its 1970 advisory opinion in the *Namibia Case*, the International Court of Justice has ruled that States which deny fundamental human rights are in "flagrant violation" of the UN Charter. The combination of the supremacy of the UN Charter in international law, plus the elaboration of the human rights referenced in the Charter in an instrument such as the UDHR that has

⁵ *ibid*

achieved the status of customary international law, provides a solid basis for the proposition that basic human rights norms enjoy primacy over States' obligations under trade treaties. Beyond treaties, customary international law and the decisions of the International Court of Justice, State practice also provides evidence of their recognition of the primacy of human rights in international law. Examples include the Charter of Economic Rights and Duties of States (1975), adopted by an overwhelming majority of the UN General Assembly, as well as the UN's Declaration on the Right and Responsibility of Individuals, Groups and Organs of Society to Promote and Protect Universally Recognized Human Rights and Fundamental Freedoms (1998), and the resolution adopted at the UN General Assembly's Special Session on Social Development (2000).

Commentary from learned jurists with expertise in the field also directly conclude that human rights, including the right to health, must take priority over other obligations under international law. The "Maastricht Guidelines" explain how states may breach rights protected by the ICESCR through failing to take such obligations into account when entering into treaties with other States, including trade agreements, and that States must ensure that the programmes and policies of organizations to which they belong must not result in violations of human rights.

Furthermore, the UN Committee on Economic, Social and Cultural Rights has reminded States that they must give due attention to the right to health in international agreements, and that measures restricting another States's supply of adequate medicines "should never be used as an instrument of political or economic pressure." In addition, the UN Sub-Commission on the Promotion and Protection of Human Rights has repeatedly reminded all governments of "the primacy of human rights obligations under international law over economic policies and agreements," and has specifically called on governments to ensure the implementation of the TRIPS Agreement does not negatively affect human rights.

3.3. Correctly interpreting TRIPs agreement under International Law

Amid multiple health hazards in a larger part of the world due to endemics such as HIV/AIDS and environmental degradation and rising costs of medicines due to patents on drugs by MNCs, there is a need to correctly interpret and to implement TRIPs agreement. It directly impacts millions of individual people and their families across the globe and the world community's collective efforts to respond to these crises.

International and national laws require states to take all appropriate measures, including legislative measures, to realize each person's right to enjoy the highest standard of healthcare. Many countries and commentators have claimed that the necessary flexibility is already there in the TRIPS agreement, though it is still a question whether or not it is sufficient.

This part examines how the TRIPS Agreement should be correctly interpreted under international law, in accordance with established rules of treaty interpretation. In doing so, reference is also made to existing WTO jurisprudence relevant to the interpretation of the WTO's agreements, including the TRIPS Agreement. This part outlines the reasons why a correct interpretation of the TRIPS Agreement is one that is consistent with the

States' superseding obligations under international law to respect, protect and fulfil human rights, including the right to health. The rules of treaty interpretation applied are those set out in Articles 31 and 32 of the 1969 *Vienna Convention on the Law of Treaties*, now accepted (including within the WTO jurisprudence) as representing a codification of the customary international law rules.

Article 31 of the *Vienna Convention* requires that a treaty be interpreted "in good faith" in accordance with the "ordinary meaning" to be given to the terms of the treaty "in their context" and "in the light of [the treaty's] object and purpose." The text of the treaty (including its preamble and annexes) must be considered as the principal source for interpretation. Other aspects of the "context" for interpreting treaty terms include any agreements relating to the treaty that were made in connection with concluding the treaty, or any instruments related to the treaty made in connection with its conclusion and accepted by the treaty parties. In addition, the interpretation of the treaty must also consider any subsequent agreement regarding its interpretation, any subsequent practice establishing this kind of agreement, and "any relevant rules of international law."

There are numerous elements in the TRIPS Agreement that lend support to an approach of interpreting the Agreement in a manner allowing States to satisfy their legal obligations to realize human rights. In particular, the Preamble and Articles 1, 8, 27, 30, 31 & 40 all indicate that the treaty's provisions must be interpreted so as to allow countries' maximum flexibility in balancing their obligations to accord exclusive patent rights in medical inventions against their obligations to protect and improve individuals' and public health.

For example, Article 8 ("Principles") allows WTO member countries to adopt measures necessary to protect public health and promote the public interest in sectors vital to their development, as well as to prevent the abuse of patent rights and practices that unreasonably restrain trade and the international transfer of technology. In a case such as *Canada - Generic Medicines* (2001), WTO jurisprudence acknowledges that Article 8 must be considered in interpreting other terms of the TRIPS Agreement.

Similarly, Article 27 ("Patentable subject matter") allows countries to exclude inventions from patentability if preventing their commercial exploitation is necessary to protect *ordre public* or morality, including to protect health. The protection and promotion of internationally-recognized human rights, including the right to health, must surely be considered a "fundamental interest" of society that would fall within the rubric of *ordre public* or morality as a basis for limiting the scope of claims to private patent rights. In the parallel context of the General Agreement on Tariffs and Trade (GATT), a GATT dispute panel and the WTO Appellate Body have ruled that WTO member countries must have a "large measure of autonomy" to determine their own policies for expressing important public interests, including the protection of human health (eg, *Thai - Cigarettes* case, 1990; *US - Gasoline* case, 1996).

Outside the text of the TRIPS Agreement, the main Agreement Establishing the World Trade Organization sets out the framework for the entire WTO system, and states that countries' trade and economic relations should be aimed at raising standards of living and sustainable development. These provisions further reinforce the basis for interpreting terms of the TRIPS Agreement in a fashion that achieves these objectives, rather than strictly enforcing exclusive, extensive private patent rights where to do so is at the expense of these objectives. In addition, from the outset of the WTO's existence,

Ministers of its member countries have agreed in a *Decision on Measures in Favour of Least-Developed Countries* least-developed countries of the WTO, “while complying with the general rules set out in the aforesaid instruments, will only be required to undertake commitments and concessions to the extent consistent with their individual development, financial and trade needs, or their administrative and institutional capacities.”

Furthermore, the WTO Ministers agreed that the rules set out in WTO agreements “should be applied in a flexible and supportive manner for the least-developed countries” and therefore, “sympathetic consideration shall be given to specific and motivated concerns raised by the least developed countries in the appropriate Councils and Committees.” These provisions provide a further legal basis, under the accepted rules of treaty interpretation in international law, for interpretation and application of the TRIPS Agreement, and any negotiations regarding the Agreement such as ongoing discussions regarding its “clarification,” to be informed by a recognition that least-developed countries may have particular difficulty satisfying their binding legal obligation to realize the right to health of their populations, especially if private patent rights are strictly interpreted and enforced at a time of great need for affordable medicines for widespread illness.

In applying the customary rules of treaty interpretation to the TRIPS Agreement, of particular significance is the requirement to consider “any relevant rules of international law.” For obvious reasons in the case of a treaty imposing minimum intellectual property standards on medicines, the body of international law establishing States’ obligations regarding the right to health is “relevant” to the interpretation of TRIPS.

WTO jurisprudence has affirmed that WTO agreements cannot be read “in clinical isolation from public international law” (eg, *Japan - Alcoholic Beverages*, 1996; *US - Gasoline*, 1996; *US - Shrimp/Turtles*, 1998), and this is consistent the International Court of Justice’s ruling that an international treaty must be interpreted and applied in the framework of the entire legal system prevailing at the time of interpretation (*Namibia Case Advisory Opinion*, 1971). Therefore, the full range of States’ human rights obligations under the UN Charter, the Universal Declaration of Human Rights as customary international law, and various human rights treaties are relevant to the correct interpretation of terms of the TRIPS Agreement.

It must also be remembered that States have a legal obligation to act in good faith to fulfil their treaty obligations, and this obviously applies to their obligations under human rights conventions and the UN Charter (the latter expressly taking precedence over all international agreements in the event of a conflict). Given this obligation of good faith, the interpretation of treaties such as the TRIPS Agreement must proceed on the assumption that States already bound by international legal obligations to protect and promote human rights would not enter into other treaties (such as the WTO agreements) with the intent of violating those existing obligations which are of the highest order, derived as they are from the UN Charter and the UDHR.

Indeed, as the UN Committee on Economic, Social & Cultural Rights has observed in its General Comment 14 on the right to health, “there is a strong presumption that retrogressive measures taken in relation to the right to health are not permissible” by virtue of States’ legally binding obligations under the *International Covenant on Economic, Social and Cultural Rights*.

Alternatively, to draw the conclusion that States intend to breach their human rights obligations through the interpretation and application of the TRIPS Agreement, at the very least some express statement or indication of such an intent to violate pre-existing human rights obligations under treaty or customary law would surely be required.

Although failing to use the language of human rights law, WTO jurisprudence has recognized that obligations under trade agreements may need to give way to more important public interests in protecting health (eg, *Thai - Cigarettes*, 1990; *EC - Asbestos*, 2001). By way of a non-limiting example, surely the need for affordable medicines in the context of widespread illness such as the HIV/AIDS pandemic is a clearcut example of a case in which States' obligations to act to protect and promote the human right to health is unquestionably of a higher legal (as well as ethical) order than the protection of private patent rights.

As the UN Committee on Economic, Social and Cultural Rights reminded WTO member countries before the 3rd Ministerial Conference (Seattle, 1999): "Human rights norms must shape the process of international economic policy formulation so that the benefits for human development of the evolving international trading regime will be shared equitably by all, in particular the most vulnerable sectors. ... Trade liberalization must be understood as a means, not an end. The end which trade liberalization should serve is the objective of human well-being to which the international human rights instruments give legal expression."

4. Africa: Options for SADC Countries

Signatories to TRIPs have flexibility in how they implement the Agreement, as TRIPs only defines the *minimum* requirements.

SADC countries are now studying how to formulate or adapt their legislation to widen their options to access essential drugs. This means using the provisions in TRIPS Article 30 to provide for limited exceptions to the exclusive rights conferred by a patent, provided that they are limited, justified, and do not unreasonably affect the patent owner. The exceptions enable countries to parallel import the drugs or to compulsorily license them, provided their national laws provide for this.

The strongest grounds for such exceptions are in the interests of public health, given that TRIPs enables members to give the highest possible priority to protecting the public interest.⁸ SADC countries

are thus challenged to define an acceptable and evidence-based definition of public health interests that can justify the exceptions they seek to impose on patent owners.

In SADC countries that currently do not have patent laws, or in cases where drug companies have not sought patent protection, generic copies of drugs can be imported.

TRIPS allows certain public health safeguards for patented drugs:

i When a patented product is marketed at a lower cost in another

India: Amended Patents Act and Access to Medicines after Doha (Economic&PoliticalWeekly_TRIPS_June2002)

Patents (Amendment) Act, 2002

The Patents (Amendment) Act, 2002 must be analysed with the 1970 patent regime in mind. The adoption of the Patents Act, 1970 was based on a lengthy legislative process and careful consideration of the socio-economic impacts of patents in sensitive fields such as health. As a result, the Patents Act drastically restricted the rights of patent holders in fields linked to basic needs. In the pharmaceuticals sector, the Patents Act and associated measures such as price control have had a number of positive impacts. Firstly, relative drug prices have decreased significantly since the 1960s compared with those in other countries. Secondly, India now has a vibrant local generic pharmaceuticals industry. Thirdly, some of the local companies have developed sufficient expertise to produce their own new medicines. The TRIPS Agreement requires fundamental changes to the current legal regime. This constitutes an important reason for the initial reluctance of the government to accept TRIPS in the context of the Uruguay Round and parliament's reluctance to adopt the first amendment bill.

The first version of the amendments as drafted in 1999 did not reflect this genesis. In fact, they were noteworthy for sticking quite closely to the letter of the TRIPS Agreement. The result of the 1999 draft would have clearly been to remove most of the specificities of the Patents Act, 1970, in particular in the field of health. It would have drastically altered the balance between the interests of patent holders and the interests of society at large, in favour of the former. This included raising the duration of patents in the health sector from seven to 20 years. The 1999 draft also proposed the deletion of an important provision of the act seeking to oblige patent holders to manufacture their inventions in India. It made use of some of the exceptions and flexibilities provided in TRIPS but only at a superficial level. In other words, while the bill incorporated exceptions such as those provided in Article 27.2 in TRIPS, it did not attempt a broader reading of TRIPS in the light of Articles 7 and 8.2, which provide the objectives and principles that should guide the interpretation and implementation of the whole treaty.

The 2002 amendments adopted by parliament substantially follow the first draft of 1999. In particular, they do not seek to provide an exception to the 20-year duration for pharmaceutical patents in the light of the broader interpretative framework proposed by the Doha Declaration. However, it is significant that the three dissenting opinions

appended to the joint committee report lamented the fact that the committee did not propose any modifications to the 20-year rule in the health context. There are, however, a number of new elements in the 2002 amendments. One noteworthy addition is at Section 3 of the act, where it is suggested that traditional knowledge be excluded from patentability. This clause has the potential to be significant in practice given the existence of various indigenous systems of medicine in India. This provision, however, only restates the uncontroversial position that knowledge in the public domain cannot be patented. The real issue is whether inventions based on traditional medicines can also be denied patentability. This refers to a broader problem concerning the definition of patentable inventions. In fact, TRIPS does not impose on member-states a specific definition of what constitutes non-obviousness and parliament could choose to provide an extensive definition which restricts not only the patentability of ayurvedic medicines but also derived medicines, which are essentially laboratory copies of the original.

The 2002 amendments are also substantially different from the 1999 draft with regard to compulsory licensing. Section 83, which provides a general framework to guide the issuance of compulsory licences is particularly noteworthy. It constitutes a broader endeavour to incorporate some of TRIPS' in-built flexibility into the Patents Act. Interestingly, Section 83 specifically mentions that patents granted should not "impede protection of public health", should not prohibit the central government from taking measures to protect public health and that patents should be granted to make the benefits of the patented invention available to the public at reasonably affordable prices.

The new compulsory licensing regime deserves further comments. Firstly, this is the only place in the act where a specific attempt has been made to make TRIPS responsive to domestic needs and priorities. Secondly, the emphasis put on the compulsory licence regime is indicative of the regressive nature of the debate concerning patentability in health and other basic need-related sectors. Chapter XVI on compulsory licensing makes a real attempt to use TRIPS flexibility. However, what is noteworthy is that the amended act stops short of proposing similar clauses as guiding principles for the whole Patents Act. If a similar section to Section 83 were inserted at the beginning of the act, this would allow the Patent Office to use similar criteria in examining patent applications. The Patents (Amendment) Act, 2002 only proposes to apply flexibility at the level of the implementation of already granted patents and thereby dramatically restricts the potential effectiveness of the proposed clauses. Thirdly, the 'progressive' nature of the amended act must be judged against the regime inherited from the 1970s. If the 1970 Patent Act is taken as a benchmark, the 2002 amendments provide a more restrictive regime and noticeably do away with licences of right. Fourthly, it is doubtful whether focusing on compulsory licensing as the main tool to redress the perceived inequities of the international patent system constitutes an appropriate strategy. In the TRIPS era, it is not very likely that developing countries will have the liberty to widely use compulsory licensing provisions. They may be useful as bargaining tools in negotiations with specific companies as highlighted in the case of Brazil, but they should only be complementary measures. The adoption of a strong compulsory licensing regime cannot be a substitute for strong health-related provisions in the main part of the act.

Forthcoming WTO Negotiations

The Doha Declaration constitutes a major step forward insofar as it acknowledges in the WTO context that the introduction of patents in the health sector has significant impact on access to drugs. However, the declaration neither amends the TRIPS Agreement nor provides a basis for developing countries to link their patent and health legislations. In this regard, the Patents Act as adopted in 1970 was one of the most interesting attempts to link the fundamental right to health and the introduction of patents in the health sector. At this juncture, the WTO is far from providing a comprehensive response to the needs of developing countries in the field of health in general. At the most, the Doha Declaration provides a temporary respite in some limited areas. The declaration does not even indicate that negotiations in the new round of trade negotiations will necessarily go towards a relaxation of the TRIPS requirements in this field. In fact, the recent aggressive posturing of the US pharmaceuticals industry seems to suggest that significant lobbying for further strengthening of patent rules is likely to take place in the future.

On the whole, the Patents (Amendment) Act, 2002 closely follows TRIPS and in the process does away with provisions of the 1970 Act that constituted India's own response to the challenge of providing exclusive commercial rights in a field concerned with the fulfilment of basic health needs. This is unexpected for several reasons. Firstly, there has been no official change in the policy underlying the Patents Act to justify such drastic changes. Secondly, India's domestic and international commitments regarding the fundamental right to health of all individuals have not changed in the past decade. Thirdly, it appears likely that the introduction of product patents in 2005 will adversely affect access to medicines for crores of people. One factor pushing the government in this direction may have been the desire to favour its own private sector pharmaceuticals industry. However, it is striking that there is no unanimity on the part of the industry, which remains today completely or mainly domestic. Some large companies that produce mainly generic drugs have been completely opposed to changes in the 1970 Patents Act, some large companies that have developed significant R and D facilities feel that the new regime may provide them an opportunity to grow overseas while small companies generally seem to have understood that they are not important enough to influence policy-making significantly and must concentrate on surviving either independently or by linking up with bigger domestic or foreign companies.

Overall, the likely negative impacts of the new patent regime for patients who purchase medicines should sway the balance in favour of maintaining the status quo in all areas that do not absolutely have to be amended for compliance with the TRIPS Agreement. This includes using the Doha Declaration to maintain the reduced duration of patents on medicines and taking into account the fact that the revision of an important provision like Article 27.3.b of TRIPS is yet to be completed, offering good ground for not implementing it before an agreement is found among all TRIPS member-states. Indeed, it appears inconceivable that such major changes should be introduced without a full-fledged rethinking of the policy underlying the patent system.

Given the importance of the issues at stake, the debate concerning the impact of medical patents on access to drugs is unlikely to subside in the near future even though the Patents (Amendment) Act, 2002 has just been adopted. One more crucial moment will come in 2005, when the Patents Act will have to be again amended to allow product patents on medicines. This still leaves several years for further open debate concerning the final response to be given to TRIPS in the health sector.

Himal, March 2001: Patents, Private Charity and Public Health

The diseases are in the developing South, but the money and the patents are locked in the post-industrial North. The world's poor are in a free fall.

-by Rajashri Dasgupta

Patently unfair

The effect of patenting on the availability and price of drugs will be devastating, taking critically-needed medications beyond the reach of most patients in South Asia, for example. Without patent obligations, local drug firms in India and Bangladesh, for example, are presently able to provide quality drugs at a tenth to a hundredth of the prices charged by the Western MNCs. "India, which has a strong indigenous drug industry, will now be forced to impose patents on all newly invented drugs," says Professor Sudip Chaudhury of the Indian Institute of Management, Calcutta. "It means Indian companies will be confined to producing patent-expired drugs in the future."

The reason consumer groups and health activists find the 20-year rule so patently unfair is that modern drugs have short life spans because of constant and accelerating innovations in pharmaceutical research. Hardly any drug at the end of the 20-year moratorium period will be worth manufacturing because better ones will have been introduced, and so the wait for a patent to expire will be in vain.

There would be no reason to rail against the 20-year stipulation if the patented drugs were available to all and sundry at affordable prices. But that is not the case, for the price of patented drugs are fixed by drug MNCs with an eye on the Western clientele, supported as they are by social safety nets, health insurance and strong currencies. The result is a fast-emerging ethical violation of mind-boggling proportions, in which the drugs are being produced, but the price barrier erected by a patent regime thrust upon the supine governments of the Third World denies treatment to people who are poor.

"The drug industry is instigating the United States to use its power to force unworkable arrangements on poor countries which cannot afford US-priced medicines. This is bound to lead to millions of needless deaths over the years," says Amitav Guha, of the Medical Representative Association of India. The emerging scenario is such that even in emergency situations involving mass-trauma, such as in earthquakes, epidemics or floods, the supply of drugs will at some point be under the control of the MNCs.

The patent regime will have the developing countries held to ransom by the pharmaceutical multinationals, which have the resources, know-how and research capability to produce vital new drugs. Look at the data: Northern countries today hold 97 percent of the patents and the multinationals 90 percent of all technology and product patents. On the flip side, Third World countries where TB, HIV and malaria wreak havoc, never developed a pharmaceutical research base and have little to gain from the TRIPs Agreement. Even the economics does not seem to be in favour of drug development in the South. On average, R&D of a new drug costs approximately

USD 150-200 million in the West. Even considering the lower costs of development in a developing country, the fact is that the total costs can rarely be offset from sales.

The fear of the Third World poor being denied access to critically necessary drugs is real and proximate. Medicine for HIV, for example, could have been manufactured at one tenth of today's price if it were not for patent restrictions. As a result, 90 percent of HIV patients in poor countries, including all over South Asia, cannot afford the drugs which can cost more than USD 10,000 for a year's treatment.

One does not even have to refer to the Third World to study the impact of TRIPs patent regulations — a United States study estimated that just by increasing the patent moratorium by just three years from 17 to 20 (as per the TRIPs Agreement), American patients would have to pay USD 6 billion extra due to delays in the introduction of generic drugs. If this is true for the US, the scenario is nearly homicidal for the poor countries.

Though the pharmaceutical companies have assumed an international character, the industry is far from global in terms of ownership. Dr K Balasubramaniam of Consumers International, who has extensively researched the drug industry, points out that the industry severely lacks "competition", which is ironically the main plank on which the United States and other developed countries are pushing the globalisation agenda.

Dr. Balasubramaniam says the multinational pharmaceuticals are concentrated in ten countries, and a mere 50 of them account for more than two-thirds of the world's production and exports. The annual sales of pharmaceuticals worldwide add up to USD 320 billion, and in 1995 the sales of the top 50 MNCs stood at USD 273 billion. In fact, the sales of the top ten MNC drug firms amounted to USD 130 billion, or 40 percent of the global production.

The GDP of the 76 poorest developing countries put together is less than the annual sales of the top ten drug firms, each of whom sell upwards USD 10 billion to USD 19 billion each year. This financial clout gives the multinational giants power over the agenda-setting function in both the developed and developing countries. With the weakening of international commitment to stand behind public health—with agencies like the WHO losing clout and a backing away by others such as Unicef from the critical socio-political arena—the defence of the poor in the poor countries is left to the governments, which have themselves shown how little they care.

Their financial robustness also helps the MNCs to set drug prices without bothering too much about the Third World market, which is seen merely as a bonus to the larger takings in the developed world. In fact, there is even sometimes a topsy turvy situation in which the patients in the poorer countries pay more than those in the richer ones. Based on a survey of retail prices of selected drugs in some representative countries, the organisation Health Action International (HAI) charges that the pharmaceutical multinationals practice price discrimination. For example, HAI reports, 100 tablets of 150 mg Zantac (Zinetac in India) produced and marketed by the same manufacturer varied from USD 2 to USD 196 across the world market. And the prices in the two of the least developed countries, Mongolia and Tanzania, were much higher than in the advanced countries.

The drug giants have their allies in medical professions all over the world, in a line that extends from great hospitals of the United States to the roadside clinic in Calcutta. The habit of prescribing expensive, patented drugs, despite the availability of generic substitutes, after all, is universal. "The trend is to prescribe newer but not always effective and efficient drugs. Drug companies in developing countries tend to encourage doctors through various mechanisms to prescribe particular drugs," says Dr Zafar Mirza, Association for the Rational Use of Medication in Pakistan.

Pakistan To Tighten Laws On Intellectual Property Rights

By Muddassir Rizvi

ISLAMABAD (IPS) - Pakistan plans to tighten intellectual property rights laws that many fear may give total control of the country's lucrative drug and seeds markets to transnational corporations (TNCs).

Developing countries like Pakistan are facing the deadline of January 1, 2000 to comply with the provisions of the Agreement on Trade Related Intellectual Property Rights (TRIPs).

The agreement requires intellectual property rights protection in seven areas -- copyrights, trademarks, industrial designs, geographical indications, patents, integrated circuits and undisclosed information.

The country has already introduced adequate changes to its copyrights and trademarks laws, but its compliance with the most controversial TRIPs section dealing with patents is still awaited.

"The government is giving final touches to Patent Act 1999 and Plant Breeders Rights Act 1999," said Bashir Ahmed, who is deputy chief at the Ministry of Commerce' International Trade Wing. " These draft laws would be forwarded to the cabinet for approval and subsequent promulgation as ordinances soon."

While health advocacy NGOs raise concerns over the impact of patents on people's access to medicines, those working in the area of food security say the law on plant breeders' rights would alter traditional farming practices and seriously jeopardize the interests of small farmers.

Currently, Pakistan is offering patents only on processes under a 1911 law, enabling the local pharmaceutical industries to provide alternatives of patented drugs to people at affordable rates.

The local companies hold 60 percent by volume of the country's 80 billion dollar drug market and 40 percent in sales, showing they sell more drugs at lesser prices.

The new law will extend patent protection to products as well, and that too for a period of 20 years, as required by the TRIPs agreement and fulfill one of the longstanding demand of pharmaceutical TNCs.

"We believe that product patents will seriously erode people's accessibility to medicines and the proposed changes will push the drug prices beyond the reach of the common man and also result in non-availability of medicines for tropical diseases," said The Network, an Islamabad health advocacy group.

"In a letter to the country's Minister of Commerce and Industries Abdul Razak Dawood, who at the recent WTO meeting at Seattle demanded exclusion of the World Health Organization's Essential Drugs List from patenting.

The Network fears that the patent law would seriously jeopardize the capability of local pharmaceutical industry, which lags behind in research and development, to provide cheaper alternatives to people for common diseases.

"We suggest that the government delay this law for a period of five years under Article 65.4 of the TRIPs agreement, which allows this concession to countries that offer process patents," said The Network's letter.

According to a UN report, more than 50 percent of people have no access to medicines in Pakistan. Another World Bank report said that the cost of medicines form 90 per cent of medical bills in Pakistan, a country where more than 80 per cent of drug purchases are made out-of-pocket.

However, Anwar Khan, who is a senior research officer at the Ministry of Industries and is also coordinating the revision of the patent law, said the government is considering proposals sent by various stakeholders with a view to finalizing the draft soon.

Although the government may avail the in-built concessions under the TRIPs agreement to delay product patents, it has no option but to extend protection to plant varieties either through patents or a sui generis system.

Pakistan has opted for the latter or a locally devised system in order to provide maximum protection to farmers against seed TNCs that are now eyeing the lucrative seed markets in developing countries.

Officials at the Ministry of Food and Agriculture said that they are aware of the requirements and practices of the local farmers, whose interest would be protected by the new law.

"The new law would allow the farmers to save, retain and share seeds, but bar them from marketing seeds on a commercial basis," said Dr Akhlaq Hussain, Director General of the Federal Seed Certification and Registration Department.

But activists question the law on the grounds that it does not recognise the rights of the communities on plant varieties as is being done in India and Bangladesh, which is a requirement of the Convention of Biological Diversity (CBD) to which Pakistan is a signatory.

The CBD gives nations state sovereign public rights over their biological resources, while TRIPs considers biological resources private intellectual property said Mushtaq Gadi who works with the Sungi Development Foundation an organisation engaged in civil rights advocacy.

"The CBD says access to biological resources requires prior informed consent of the country of origin and approval and involvement of local communities, so that there could mutual sharing of benefits from commercial exploitation," said Gadi.

Officials in the agricultural ministry said that the main beneficiary of the new law would not be companies but the public sector research institutions that account for more than 90 percent of new plant varieties in the country.

"Under the new law, 70 percent of royalty would go to the research institutions and 30 percent to scientists giving them an incentive to develop commercially lucrative plant varieties," said an official. (END/IPS).

Pakistan

Price Controls and Forced Price Reductions

While the Government of Pakistan has committed itself to allowing annual price increases utilizing a formula which considered currency devaluation and local inflation, the last price increase was allowed in November 1996. Even when price increases were allowed, they were substantially below the indexed figure which represented the true cost increases that the industry had to bear. It is now two years since the last increase. PhRMA seeks the support for the U.S. Government to ensure that the Government of Pakistan allows price increases immediately, and at a level which will be sufficient to stem the dramatically declining profitability of the research-based pharmaceutical industry during recent years.

This dramatic decline in profitability is driven by:

A cost increase of 90% over the last five years generated by three factors - an inflation of 76%, a devaluation of Pakistani currency by 85% in relation to the U.S. Dollar, and an introduction of duties of 10% beginning June 1996.

Insufficient price increases which do not compensate for the cost increases:

For "Controlled" drugs, the price increase was only 21% in the last five years

For "Decontrolled" drugs, the price increase was only 29% in the last five years

Government imposed compulsory price reductions on targeted products which were based on an unjustified price comparison with India.

There are three other recent developments that have harmed the industry significantly and have had enormous impact on pricing decisions. These include:

Show Cause Notices: with political pressure for cost containment, many multinational companies received Notices with orders to reduce prices of products by 30%. After negotiation, the industry agreed on reductions ranging from 5-28% on 21 packs of 17 products. (Double that number were on the original list). The drive behind this move is political and the reason given is the prices which prevail, for the same products, in India. Utilization of prices applicable to the Indian market are inappropriate when applied to pricing of pharmaceuticals in the Pakistani market. India has a significantly lower cost base for all materials, utilities and employee costs; and the purchasing power of the average Indian is significantly below a Pakistani citizen. In addition, all prices have, in any case, been approved by the Ministry of Health (MoH). Furthermore, they ignore all those products where there is a much lower price in Pakistan than in India.

119 High Price Products: Apparently the MOH has a list of 119 packs of 56 products, including those already targeted, they consider to have high prices (again the rationale is the price of these particular products in India). The likely outcome is that when prices are increased, these 119 presentations will not be allowed any increase.

Alleged Illegal Price Increases: There has been much recent coverage in the Pakistani media alleging that companies have been illegally raising prices. Such claims are untrue because of requirements that all price increases have to be notified to, and authorized by, the Ministry of Health. The MOH has the legal ability and right to take appropriate action to withdraw any increases made illegally. In fact, research-based companies have complied with the Government's controls on prices in good faith during the financial turmoil in Pakistan, only to find that the Government is renegeing on its legal obligation to allow for annual price adjustments.

These data clearly demonstrate the serious difficulty facing the pharmaceutical industry. No other industry in Pakistan has been put under such stringent price control; and no other industry has been forced to reduce prices. Given the significant level of foreign investment and international quality of locally produced products, it is only fair that the Government of Pakistan seriously consider the negative impacts of the current economic environment upon the industry when making decisions regarding the price increases which are now due.

In order to return to the profitability level of four years ago (i.e. 1993) the Government-allowed price increase should be of over 50% according to the SRO 1038(I)94 formula. However, the industry understands that such a large increase cannot be approved by the government for political reasons. Furthermore, the industry would not wish to burden the people for humanitarian reasons.

In order to return to an acceptable minimum profitability level, PhRMA supports the efforts of the research-based pharmaceutical industry in Pakistan to achieve:

Immediate implementation of upward adjustments for prices for "controlled" products recognizing that the adjustment due now is for a two year period from November 1996 to

November 1998. A figure in excess of 20% will in no way compensate for the historical shortfall but will allow the industry to maintain supply of quality products.

The Government must commit to honoring annual price adjustments for controlled products in the future, according to an acceptable formula that will enable the industry to plan for the future with some confidence.

Either remove Customs Duty or allow a compensation in price adjustment. Note that the adjustment must be to maintain margin not simply to pay the duty. Hence, since approximately 65% of industry cost base is imported material, the extra increase must be 6.5%.

Withdraw all notion of a high priced group of products on which no upward adjustments will be allowed.

Introduce the concept of market driven pricing for the "decontrolled" products (i.e. abolish any control over these prices).

Intellectual Property Barriers

Pakistan has a law for the protection of intellectual property. In Pakistan, patents are registered under the Patents & Designs Act of 1911 and trademarks are registered under the Trademarks Act of 1940. Protection for patents is for processes only, and the duration of protection normally is 16 years.

The Patents & Designs Act, 1911 (PDA) confers on the patentee exclusive privilege for making, selling and using his invention throughout Pakistan and of authorizing others so to do. The primary purpose of the PDA is to protect new invention and to encourage the growth of industry in the country.

In case the patentee is inadequately remunerated for his patent during currency of the patent period, he may apply to the Federal Government for patent extension at least six months before the expiry of the patent period. The Pakistan Government may refer the application to the High Court which may, after hearing, grant an extension for a period of five years.

The PDA covers "manners of new manufacture" i.e., process patent as registered in Pakistan. In the event the same item is manufactured from another process, it would not be construed as patent infringement. As a consequence there are only few litigations of patent infringements cases registered in Pakistan. Moreover, there is always the chance that someone with a slightly different process can reproduce the same product/formula and market it at on an equal footing.

There are several specific problems with the Pakistan law in addition to its lack of product patent protection for pharmaceuticals. These include the following:

The right of the patentee is not adequately protected in the law, with the result that the infringer continues to freely manufacture counterfeit products.

Numerous pending cases in High Courts result in delay of justice. Due to the delay in the court proceedings, the patentee cannot immediately obtain injunction orders against infringer.

The patent-owner only can file a suit against the infringer. The law does not allow a licensee of a pharmaceutical product to institute a legal proceeding against the infringer.

There is always a threat of revocation of the patent through compulsory licensing. An application in the High Court can be filed claiming that the patented article in Pakistan is

not being met to an adequate extent and on reasonable terms and can thus force a compulsory license to be issued.

In sum, the two basic issues are that: (a) more active legal enforcement should take place, and (b) product patents should be allowed as well. The existing law needs to be amended and clarified in terms of providing clear protection to genuine original patent holders, whose process patents are infringed upon by others who have a slightly different process. The law should provide protection in "letter and spirit" and there should be no lacunae in the law.

In addition, the penalties for infringement should be more severe, and there should be a dedicated Government Office, as well as a separate panel of well-trained judges who fully understand the laws and are competent exclusively to try intellectual property infringement cases. This could result in the formation of an effective deterrent to potential infringers.

PhRMA does applaud the fact that, in 1996, Pakistan's Government moved expeditiously to provide a form of interim protection for certain qualifying pharmaceutical products through a "Mailbox" provision in its law, as per its obligations under TRIPS.

Other Barriers

Product

The regulations to obtain a sales permit for a given pharmaceutical product require that the dossier of supporting data be accompanied by Certificates of Free Sale, confirming the approval for sale of the product in developed countries of the world, such as the U.S., Europe and Japan. The research-based industry has understood and accustomed itself to this requirement.

Now, however, it seems that the Pakistan Ministry of Health is unilaterally adopting a discriminatory policy against multinational pharmaceutical companies by insisting that they can only register products which are on sale in the country of incorporation of the respective company. Local companies, however, can register products from any source. This policy discriminates, therefore, against the research-based companies operating in Pakistan, many of which have registered in Pakistan as Pakistani companies.

Moreover, the general experience of many multinational pharmaceutical companies in Pakistan is that the time required for the registration process often is two years and sometimes longer. For the benefit of patients in Pakistan, and in view of increasing costs of pharmaceutical research and development and limited patent life of drugs, it is vital to keep the procedure of registration as brief as possible. PhRMA believes it necessary that the Government of Pakistan enhance the capacity of its equipment and manpower sufficiently to complete a registration process within a maximum period of twelve months.

There is a related issue in this area which also concerns the research-based pharmaceutical industry in Pakistan, and that is the proposed amendments in the form of a revised application for the Renewal of Product Registration Form. There are several proposed amendments that are cumbersome, not really necessary, and, in some cases, irrational. The Technical/Regulatory Affairs Subcommittee of the Pharma Bureau in Pakistan (i.e., the local equivalent of PhRMA) is examining these amendments with a view to filing formal objections to those clauses which they believe are not required, or

Registration

discriminatory. However, it is still too early to paint a clear picture of where this issue stands and how far it has progressed.

Drug	Labeling	Rules
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By a Pakistan Government notification dated August 24, 1994, the generic name of the substance has to be printed "with at least equal prominence as that of the brand name." This has now been carried forward as policy by the Pakistan Government.

The addition of the generic name in equal prominence to the trademark constitutes an infringement of the proprietary rights of the originator. This is intended to dilute existing differences in quality, efficacy and safety, and incorrectly implies total interchangeability and equality of two different products. PhRMA asks the U.S. Government to note that these laws also appear to place Pakistan in violation of WTO TRIPS rules protecting trademarks, and therefore should be amended to comply with TRIPS.

Potential Exports/Foreign Sales

Pakistan remains an "Outsider" in the global community of nations providing some form of intellectual property protection for pharmaceutical products. At present, there is no product patent protection in Pakistan, but only protection for processes. It is incumbent upon the patent holder in Pakistan to prove that the "pirate" is using the same process as the inventor, which is practically impossible in the current Pakistan legal environment. One of the most important current issues for our industry in Pakistan is that this piracy continues to inflict losses on the research-based pharmaceutical industry, now estimated at \$15 million to \$20 million per year. While these "losses" are not as significant as those that we incur in India, they still represent a threat to the industry's ability to utilize its resources for the discovery of new medicines to address problems of morbidity and mortality, and uncured diseases worldwide.

Recommendations

Means of ensuring equitable access to essential drugs

Developing and least-developed countries have been granted a period of grace of 5, 10 or 11 years, depending on their level of development, in which to amend their intellectual property laws in accordance with the standards of the TRIPS Agreement. Some of them (such as Argentina, Brazil, Mexico and Thailand), have already modified their patent laws; others still have to do so. However, in implementing the TRIPS provisions at national level there are some options for ensuring that the poorest populations have access to essential drugs. Two types of provision in the TRIPS Agreement may be used to protect public health goals: exceptions to exclusive rights and compulsory licensing.

Exceptions to exclusive rights (Go at recommendation part)

Article 30 of the TRIPS Agreement allows Member States to include in their patent laws some limited exceptions to the exclusive rights of patent-holders.

This means that countries can decide on some specific cases or situations where the use of a patent without the consent of the patent-holder would not constitute an infringement. The following examples can be found in several existing laws at national and global level.

It is important to provide for exceptions relating to research and experimentation on inventions, for scientific and commercial purposes, so as to facilitate innovation based on the improvement of protected inventions (6). Another type of exception relates to the price advantage of generic products. Some countries allow tests to establish the bioequivalency of generic products before patents expire, thus helping generic manufacturers to put their products on the market as soon as expiry occurs. The so-called US "Bolar exemption" contained in the 1984 Waxman-Hatch Act allows a generic manufacturer to reference an innovator's safety and efficacy data in its application, and to manufacture a small amount of the product before patent expiry to demonstrate bioavailability.

In addition, generic companies in Canada can also stockpile their drugs for marketing six months before the innovator's patent expires. Moreover, an amendment to the Israeli patent law goes far beyond giving Israeli companies the right to carry out research and development in order to file for regulatory approval in countries with similar legislation (Canada, Hungary, and the USA), even during the life of the Israeli patent (which typically lasts a year longer than the USA patent). This amendment allows manufacturers of generic drugs to supply raw materials to generic companies abroad for the purpose of registering drugs with different health ministries. This kind of regulation makes it possible for generics to gain faster access to the market and therefore gives populations increased access to cheaper drugs. Such exceptions to the exclusive rights of patent-owners are very important, given that brand-name firms "evergreen" their products by continually adding patents for minor variations to the list of patents still in force, thus extending the period of protection. Additional patents may, for example, relate to coatings, manufacturing processes, delivery systems and crystalline forms.

Parallel imports, permissible under the principle of exhaustion of rights, may also be listed in patent law as an exception to exclusive rights. For example, if a patented product is sold in country A for US\$ 100 and in country B for \$80, the principle of exhaustion of rights allows any interested party in country A to import the product from country B without the consent of the patent's owner (7). This arises because once a product has been legally put on the market the rights of the patentee are exhausted, since he/she has already exercised his/her rights in the matter. Imports of such patented products by a party without the authorization of the title-holder are generally known as parallel imports. This issue is of particular importance for developing countries wishing to ensure access to products on a competitive basis and therefore at a lower price.

Conclusions (GO to recommendation part)

Ultimately, the TRIPS Agreement appears to request Member States to treat pharmaceuticals like any other technological products in so far as the granting of patent protection is concerned. But drugs are not ordinary consumer products (9): they save lives, and if patients want to be cured they have to buy them.

Moreover, it is often the prescriber rather than the consumer who decides which pharmaceuticals should be purchased. Patents may well have stimulated the discovery of new cost-effective drugs, although it does not follow that these have been affordable to all people. However, research and development in the pharmaceutical industry are subject to market imperatives, and consequently new drugs that come on to the market do not always meet the most pressing therapeutic needs of the majority of the population.

The patent system in the private sector should not be seen as the only source of finance for pharmaceutical research. WHO should also encourage other sources, such as the public sector, to finance research and development in pharmaceuticals and to provide incentives for innovation in vital fields, for instance that of tropical diseases. Therefore, is it not time to consider the idea of an "Action Programme on Essential Research"?

As we have stated elsewhere, "the differences between the health/drugs and other markets (informational imbalance, limited competition, externalities and non-profit objectives) justify government/ state intervention in the health and pharmaceutical market" (2). It is essential that all involved in the health sector be aware of the stakes and issues and that they play a role in the continuing process.

The new international economic and social context is likely to have an important effect on the equitable access of populations to health and drugs, especially in developing countries. The new rules on intellectual property could increase these countries' dependence. Each country's strategy regarding globalization in the field of the production and distribution of drugs should be incorporated into a national pharmaceutical policy within national health policy (10).

OBJECTIVE OF THIS PAPER

The goal of this document is to set out the basis, in international law, for the following conclusions:

- (a) States' binding legal obligations to realize human rights have primacy in international law;
- (b) therefore, the TRIPS Agreement must be interpreted in a fashion consistent with States' superseding obligations under international law to respect, protect and fulfil human rights; and
- (c) where this is not possible, States' obligations under the TRIPS Agreement must be recognized as not binding to the extent there is a conflict with their human rights obligations under international law.

Our hope is that this document will assist heads of state, trade ministers and other government policy-makers, and human rights advocates in recognizing and articulating the fundamental principle that international treaties, including international trade agreements, must be interpreted in a fashion that is consistent with States' legal obligations under international law to respect, promote and fulfil human rights, including the right to health.

Conclusions (Go to recommendation part)

Based on the analysis in the preceding three sections, Part IV concludes the document by presenting several steps that should be taken to comply with these requirements of international law. The paper concludes that:

1. States should formally recognize, in the context of the WTO and its legal instruments, the primacy of their legal obligations to respect, protect and fulfil human rights in international law, whether conventional or customary. This should be done through a variety of mechanisms, as set out in the following conclusions.

2. To this end, the next WTO Ministerial Conference should adopt a Ministerial Declaration stating that:

(1) in the event of a conflict between States' obligations under current or future WTO agreements and their obligations under the international law of human rights, the

latter obligation(s) shall take precedence;

(2) specifically, nothing in the TRIPS Agreement shall prevent a WTO member state from taking measures to respect, protect and fulfill the human right to health of its people;

(3) all provisions in the TRIPS Agreement must be interpreted in the light of its Articles 7 and 8, as well as the relevant obligations of WTO members under international human rights law, both customary and conventional.

3. When interpreting the TRIPS Agreement (or any other WTO agreement), the Dispute Settlement Body (including Panels and the Appellate Body) must prefer any reasonable interpretation of the agreement that is consistent with States' obligations under international human rights (including their obligations to realize the right to health) over any alternative interpretation that is inconsistent with those obligations.

4. The TRIPS Agreement should be amended to include express reference to States' obligations under international human rights law, and to include a clause which recognizes the non-binding status of their obligations under the Agreement when these require States to act (or refrain from acting) in breach of their obligations under international human rights law.