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# Intellectual Property; Emerging Issues for Sri Lanka

LAW & SOCIETY TRUST

## Editor's Note .....

Article 12 of the International Covenant on Economic, Social and Cultural Rights imposes a duty on the Sri Lankan State to recognise the right of everyone to the enjoyment of the highest attainable standard of physical and mental health and requires the State to take necessary steps, *inter alia*, for the prevention, treatment and control of all forms of disease and for the creation of conditions that would assure medical service and medical attention to all in the event of sickness.

Balancing consumer rights to medicine, nutrition and health is, in this respect a primary duty of the State when passing legislation in Sri Lanka. This issue of the Review questions whether this duty has been satisfied in respect of the new law on Intellectual Property, which was passed by Parliament in the month of July, 2003.

Towards this end, it publishes the Supreme Court Determination relating to the Intellectual Property Bill, which was challenged in the Court as a matter of public interest by three petitioners in May, 2003.

The Court declared particular clauses of the Bill as inconsistent with Article 12(1) of the Constitution and directed that the Bill was required to be passed with the special majority stipulated in terms of the provisions of paragraph 2 of Article 84 of the Constitution.

It is particularly relevant that the Court, in its Determination, made it plain that producers of patented products and processes and their agents in developed nations and consumers of such products in developing countries such as Sri Lanka cannot be taken as parties that are similarly circumstanced.

Therefore, the Court reasoned that there is ample justification to treat them differently as they cannot be put on an equal footing. On the other hand, if they are to be treated differently, such decision should be justified by relevant criteria, which the Court concluded was lacking in the instant case.

Two contributors in this issue examine emerging issues arising from the new Intellectual Property Law in the context of Sri Lanka's obligations under international conventions that we are a party to and in respect of patients' rights and health care needs.

An important question meanwhile remains unanswered, regarding the manner in which the Bill was brought before Parliament and indeed, the circumstances in which it was ultimately passed into law following amendments necessitated by the Determination of the Supreme Court.

In the first instance, one primary grievance of the petitioners before Court concerned the fact that the Sri Lankan public had not been afforded sufficient time to study the Bill and all its ramifications since it was unavailable to the public. The Bill was placed on the Order Paper of Parliament on or about 21st May, 2003 but was unavailable to the public until 26th May, 2003, leaving very little time for citizens to take the Bill before Court within the obligatory one week period within which Bills must be challenged in law.

Even more seriously, as the contributors to this issue have specifically noted, the amended Bill was also not made available to the public before its passing by Parliament. The exact contents of the new law are still not known even though it is now one and a half months since it was passed by Parliament. All efforts by the *Law and Society Trust* to obtain a copy of the new Act have not been successful.

This negative experience with one of the most consumer crucial laws to enter our statute books is only the most recent of a number of such instances in the past where important Bills have been hurried through the legislative process with scant regard for the fundamental principles of good governance.

It is therefore hoped that Sri Lanka's pending Freedom of Information Law would provide specifically for a period of public consultation in respect of Bills and in respect of amendments brought to Bills prior to being passed by Parliament. In the alternative, we would only be engaging in a farcical exercise in representative democracy.

# In the Supreme Court of the Democratic Socialist Republic of Sri Lanka

A Bill bearing the title "Intellectual Property"

In the matter of petitions under Article 121(1) of the Constitution

**Present** :

Sarath N. Silva - Chief Justice

Shirani A. Bandaranayake - Judge of the Supreme Court

J.A.N. de Silva - Judge of the Supreme Court

**S.C. Special Determination No. 14/2003**

Dr. Kamalika Abeyratne,
No. 91A, Fifth Lane,
Colombo 3

**Petitioner**

**Counsel** :

Ms. I.R. Rajapakse with Ms. S. Daluwatte

Saleem Marsoof, PC, Additional Solicitor-General with Shavindra Fernando, Senior State Counsel and N. Wigneswaran, State Counsel for Attorney-General.

**S.C. Special Determination No. 15/2003**

Centre for Policy Alternatives (Guarantee) Ltd.,
No. 24/2, 28th Lane,
Sir Ernest de Silva Mawatha,
Colombo 7

**Petitioner**

**Counsel** :

M.A. Sumanthiran with Buddhika Illangatillake, S. Anthony and S. Kanag-Iswaran.
Saleem Marsoof, PC, Additional Solicitor- General with Shavindra Fernando, Senior State Counsel and N. Wigneswaran, State Counsel for Attorney-General.

**S.C. Special Determination No. 16/2003**

Nihal Fernando,
No. 18, Skelton Road,
Colombo 5

**Petitioner**

**Counsel** : Jagath Gunawardane with Ms. Lilanthi de Silva.

Saleem Marsoof, PC, Additional Solicitor-General with Shavindra Fernando, Senior State Counsel and N. Wigneswaran, State Counsel for Attorney-General.

The Court assembled at 10.00 a.m. on 6th June, 2003 and at 1.30 p.m. on 09th June, 2003.

A Bill bearing the title "Intellectual Property" was placed on the Order Paper of Parliament for 21st May 2003. Three petitions numbered as above have been presented, invoking the jurisdiction of this Court in terms of Article 121(1) of the Constitution to determine whether the Bill or any provision thereof is inconsistent with the Constitution. Hon. Attorney-General has been given due notice of the petitions.

The Counsel representing the petitioners and the Additional Solicitor-General were heard before this Bench at the sittings held on 06th and 09th June, 2003.

The petitioners contended that Clauses 84, 90, 91, 92, 93 and 94 of the 'Bill' are inconsistent with Articles 3 and/or 4(d), 12(1) and 14(1) g of the Constitution and that if they are to become law, they must be passed by a two-thirds (2/3) majority in Parliament.

The Petitioners also contended that, although they are mainly concerned with the Clauses referred to earlier, which are found in Chapters XIV to XVII, that it would be necessary to refer to other areas, which would include other Clauses. Accordingly the petitioners contended that clauses 62, 83 and 87 of the Bill are also inconsistent with Articles 3 and/or 4(d), 12(1) and 14(1) g of the Constitution.

The Bill seeks to provide for the law relating to Intellectual Property and for efficient procedure for the registration, control and administration and to amend the Customs Ordinance and the High Court of the Provinces (Special Provisions). Act, No. 10 of 1996.

## Clauses 83 and 84

The present Bill consists of eleven parts and forty-three Chapters. Clause 83, which is in Chapter XIV, deals with the Duration of Patent and Clause 84, which is in Chapter XV, provides for the rights of an owner of a Patent. The contention of the petitioners is that these two clauses would make provision for the grant of a Patent for a twenty-year duration in respect of products and processes. The owner of such a Patent, it was contended, would have the exclusive right for a period of twenty years to exploit the patented invention to assign or transmit the patent and to conclude licensing contracts in respect of such inventions. The petitioners further contended that, in accordance with the terms of Patent Chapters read with Articles 3 and 4 of the Trade Related Intellectual Property Rights

(TRIPS) Agreement, the Government of Sri Lanka will not be able to accord to its own citizens or corporate entities, any protection or privileges which are not granted to foreign persons or corporate entities. These provisions, in effect, would allow the foreign patent holders of any product or process, including medicinal drugs and the processes for their manufacture, to control the supply and price of such drugs in the Sri Lankan market. This would result in the increase of the prices of such medicine in the market as the aforementioned provisions will have the effect of removing the power of the Sri Lankan authorities or a Sri Lankan citizen from obtaining medicines for the 'people of Sri Lanka at the cheapest available price and from a source of their choice.

The contention of the petitioners therefore is that these provisions are violative of Article 12(1) of the Constitution. In support of this contention, the petitioners drew our attention to the Report on "TRIPS and Health Section in the South – East Asia Region" published by the World Health Organization (WHO) which sets out the consequences of adherence to the TRIPS agreement on the health of people in the South and East Asian countries, including Sri Lanka.

The Petitioners' contention is chiefly based on the position that the mitigating features, which were incorporated in the TRIPS Agreement, have not been included in the present Bill. The following three (3) examples could be cited as important issues that should have been taken into consideration.

(A) Articles 30 and 31 of the TRIPS Agreement provides for a State to make provision for the use of the subject matter of a patent for the domestic market without the prior authorization of the patent holder in certain situations such as national emergencies.

Article 30 of the TRIPS Agreement is on **Exceptions to Rights** conferred and reads as follows.

> *"Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."*

Article 31 on the other hand deals **with other use without Authorisation of the Right Holder,** and reads as follows:

> *"Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provision shall be respected:*
> *12 provisions are laid down under this Article."*

(B) The Doha Declaration makes provision for compulsory licensing and parallel importing of pharmaceutical drugs to meet national health emergencies. This includes granting of compulsory licenses in respect of pharmaceutical products with regard to public health crisis including those related to HIV/AIDS, tuberculosis, malaria and other epidemics.

(C) The TRIPS Agreement includes several mitigatory measures, which are allowed under the said Agreement.

None of these measures have been incorporated in the Bill on Intellectual Property. The provisions of the TRIPS Agreement clearly specifies that it has incorporated mitigatory provisions, as the Agreement would be applicable for developed countries as well as to the less developed nations. In fact, World Trade Organisation (WTO), has recognized the inequality of nations in respect of the TRIPS Agreement by prescribing a staggered time frame for the implementation of the Agreement among countries of different economic levels. Therefore it is an accepted fact that the provisions of the TRIPS Agreement would be applicable to countries developed as well as developing, which cannot be treated as equals. Article 12(1) of the Sri Lanka Constitution not only guarantees equality before the law, but also provides for the equal protection of the law. It is well settled law that just as much equals should not be placed unequally, at the same time unequals should not be treated as equals.

Equal protection means the right to equal treatment when similar circumstances are prevailing allowing no discrimination between two persons who are similarly circumstanced. Similarly, equal protection in terms of Article 12(1) guarantees protection not only from the executive, but also from the legislature. This Article is in line with Article 7 of the Universal Declaration of Human Rights (1948), which states that, "All are equal before the law and are entitled, without any discrimination, to equal protection of the law."

Article 12(1) of our Constitution is similar in content and effect to the 14th Amendment to the Constitution of the United States of America and to Article 14 of the Constitution of India. As it has been decided by a series of cases in India, the guarantee of equal protection of the laws is an injunction issued by the framers of the Legislature against enactment of discriminatory laws. Although the legislature has a wide choice in articulation of subject matter of its laws, it should not treat unequals as equals and equals as unequals.

For the aforesaid reasons we determine that Clauses 83 and 84 of the Bill are inconsistent with Article 12(1) of the Constitution. The Bill in its present form therefore requires to be passed by the special majority required under the provisions of paragraph 2 of Section 84 of the Constitution.

**Clause 90, 91, 92, 93 and 94**

Clauses 90 to 97 are in Chapter XVII and deals with licence contracts. Clause 90 which is the Interpretation Clause, defines the licence contract and is in the following terms:

*"For the purposes of this part licence contract means any contract by which the owner of a patent (hereinafter referred to as 'the licensor') grants to another person or enterprise (hereinafter referred to as 'the licenser') a licence to do all or any of the acts referred to in paragraph (a) of sub-section (1) and sub-section (3) of Section 84."*

Section 84, as referred to earlier, deals with the rights of an owner of a patent. It was contended on behalf of the petitioners that, a patent, which is a statutory grant of a right to an inventor on his invention from which others are excluded as long as the grant runs, will give the inventor a monopoly to exploit the invention at the exclusion of all others. This will detract any opportunity available for the use of the patented product by any other user. This in effect would be a disincentive and an obstacle to the development of the local pharmaceutical industry, which would in turn be unequal treatment and violation of equal protection for the persons who are engaged in such industry.

We therefore determine that Clauses 90, 91, 92, 93 and 94 are inconsistent with Articles 12(1) of the Constitution.

**Clause 87**

The petitioners contended that Clause 87 of the Bill is inconsistent with Articles 12(1) and 14(1) g of the Constitution for the following reasons.

Clause 87 deals with the rights derived from prior manufacture or use and, reads as follows:

*"Where a person at the filing date or where applicable, the priority date of the patent application –*

*(a) was in good faith making the product or using the process in Sri Lanka which is the subject of the invention claimed in such application.*

*(b) had in good faith made serious preparation in Sri Lanka towards the making of the product or using the process referred to in paragraph (a).*

*he shall have the right, despite the grant of the patent to exploit the patented invention:*

*Provided that the product in question is made or the process in question is used by the said person in Sri Lanka.*

*Provided further, if the invention was disclosed under circumstances referred in paragraphs (a) or (b) of sub section (3) of Section 64, he may prove that his knowledge of the invention was not as a result of such disclosure."*

Clause 64 deals with 'Novelty' and refers to 'Prior art', which is defined in Clause 64(2) in the following terms:

> *"Prior art shall consist of –*
>
> *(a) everything disclosed to the public, anywhere in the world by written publication, oral disclosure, use or in any other way prior to the filling or, where appropriate, priority date of the patent application claiming the invention."*

However, in terms of Clause 87(1) read together with Clause 64, a Sri Lankan, who had been already making a product or using a process in respect of which another party has applied for the patent, may end up only with the right to exploit the patented invention or process. If the purpose of the inclusion of Clause 87 was to protect the Sri Lankan who is already making a product or using the process, where another party had applied for a patent, then the Sri Lankan should be entitled to it and the application made by the other party for the patent should be refused on the ground that the invention has already been anticipated by prior art.

Clause 87 therefore is not granting the equal right or the equal protection to an inventor, who had already made a product or uses a process and thereby is inconsistent with Article 12(1) of the Constitution.

**Clause 62**

Clause 62 deals with definitions and Clause 62(3) b refers to the items, although they are inventions, which are not patentable within the meaning of sub-Clause (1) of Clause 62. These are –

> *"(b) plants and animals, **other than micro-organism** and an essentially biological process for the production of plants and animals other than non-biological and micro-biological processes"*
> *(emphasis added)*

It is clear that this Clause has excluded micro-organism by excluding them from living organisms thus allowing them to patented.

Petitioners contended that in terms of the TRIPS Agreement, although it is necessary for a country to give patents to micro-organisms, there is no definition given to this term. This has created a situation where it is possible to have a broad scope of patent protection, which could in turn be detrimental to the interests of the country. Examples were given of the pure culture of the micro-organism sreptisporangium fragile that is capable of producing the antibiotic complex containing Frajilomycin a which has been found in a paddy field in the village of Anaikota, situated about 5 miles from Jaffna in the Nothern Province of Sri Lanka. Reference was also made to micro-organism known as

'pathogens.' It was submitted that due to the fact that there is no definition for the term 'micro-organism' makes it possible for a variant of a pathogens to be patented. This will pave the way for a patent holder to carry out research for the purpose of diagnosis and finding cures, which in effect will increase the prices of diagnosis and cures. Therefore the petitioners contended that, the non-inclusion of the necessary definition to micro-organism is inconsistent of Article 12(1) of the Constitution which guarantees equal rights and equal protection to person, with which we agree.

It is however, suggested that if the words **"and micro-organism other than transgenic micro-organism"** is added after the word animals in Clause 62(3) (b) thereby amending the said Clause, it would cease to be inconsistent with Article 12(1) of the Constitution.

Accordingly the following paragraph also will have to be added to Clause 213 of the Bill as an Interpretation Clause.

"Transgenic" means an organism that expresses a characteristic, not attainable normally by the species under natural circumstances, but which has been added by means of direct human intervention in this genetic composition."

Learned Additional-Solicitor General, did not concede to the suggested amendments to the present Bill in order for it to be consistent with the provisions of the Constitution. He was also not in agreement to consider the inclusion of proposed Clauses which were included in a previous draft that were deleted from the instant Bill.

Learned Additional Solicitor General's contention was based on the purpose of a Patent and how it could be claimed by another person. He took up the view that a patent is the ownership of intellectual property rights, which would be necessary in order to meaningfully exercise one's fundamental rights, especially those guaranteed under Article 14(1) g. This provision, he contended, is restricted in terms of Article 15(7) of the Constitution in the interests of *inter alia* "securing due recognition and respect for the rights and freedoms of others ..."

According to the learned Additional Solicitor General, in terms of Article 15(5) of the Constitution, fundamental rights may be restricted in the interests of national economy or of meeting the just requirements of the general welfare of a democratic society. This would be the basis whereby the Legislature would strive to achieve the balance between the rights of the individual and the society in general.

Undoubtedly the provisions of Article 14(1) g is restricted in terms of Article 15(5) of the Constitution. However, this does not mean that such provision could override the safeguard and protection given to persons in terms of Article 12(1) of the Constitution. As referred to earlier, the provisions in Article 12(1) guarantees equal rights as well as equal protection and the provision of the TRIPS Agreement cannot be applicable to developed and developing countries equally without

attributing due consideration to such rights with particular reference to the mitigatory provisions in the Agreement.

Producers of patented products and processes and their agents in developed nations and consumers of such products in developing countries such as Sri Lanka cannot be taken as parties that are similarly circumstanced. There is ample justification to treat them differently as they cannot be put on equal footing. If they are to be treated equally such decision should be justified by relevant criteria.

The learned Additional Solicitor General has showed no such justification by a relevant differentiation between the aforementioned parties. Nor has he given any indication as to why the mitigatory provisions suggested by the TRIPS Agreement could not be considered in the enactment of the Bill. In such circumstances we are not in a position to agree with the submissions of the learned Additional Solicitor General when it is visibly clear that the aforementioned Clauses of the Bill are inconsistent with Article 12(1) of the Constitution.

For the aforementioned reasons we determine that clauses 62, 83, 84, 87, 90, 91, 92, 93 and 94 are inconsistent with Article 12(1) of the Constitution. We therefore state that the Bill in the present form is required to be passed by the special majority required under the provisions of paragraph 2 of Article 84 of the Constitution.

We shall place on record our appreciation of the assistance given by the learned Additional Solicitor General and all the other learned Counsel who made submissions in this matter.

Sarath N. Silva,
**Chief Justice**

Shirani A. Bandaranayake,
**Judge of the Supreme Court**

J.A.N. de Silva,
**Judge of the Supreme Court**

# The TRIPS Agreement, the Doha Declaration and the Intellectual Property Bill 2003

*Dr. K. Balasubramaniam*[*]

## Introduction

Sri Lanka and other developing countries today face the complex challenge of implementing various international agreements that were negotiated during the Uruguay Round.[1] In the process, developing countries are becoming aware of the far reaching implications for their development, economies and societies inherent in some of these agreements. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is a case in point. Its implementation is emerging as a major concern for Sri Lanka.

The Final Act embodying the results of the Uruguay Round of Multilateral Trade Negotiations was issued in December 1993 and authenticated by 117 nations on 15 April 1994 at Marrakesh. It came into force upon its signature by member nations and the establishment of the World Trade Organization (WTO) on 1 January 1995. Sri Lanka is a founding member of WTO.

The Final Act is not limited to interborder trade issues but governs the very functioning of national economies and their accessibility to transnational corporations (TNCs) in terms of financing productive infrastructure and market outlets.

The rules are designed to allow maximum freedom for corporate decision making while minimizing the role of national governments in formulating and implementing their economic, commercial and technological development strategies and plans. In other words, the Final Act represents an unprecedented transfer of power over economic functioning from the heads of nation-states to the dominant actors in the market place, namely the transnational corporations.

Industrialized countries forced developing countries to initiate negotiations of an agreement on TRIPS with the clear objective of universalizing the standards of intellectual property rights (IPRs) protection that some of these major industrialized countries had incorporated in their national legislation only after they had attained a high level of technological and industrial capability. For example France, Germany, Italy, Japan, Sweden and Switzerland, homes of some of the most innovative transnational drug companies, persistently resisted providing pharmaceutical product patents until their industries had reached adequate technological and industrial development to compete in the world market.

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[1] The General Agreement on Tariffs and Trade (GATT) set up in the late 1940s was confined to trade in goods. Since its inception, several rounds of multilateral trade negotiations (MTNs) took place; all these were limited to trade in goods. The last round of negotiations began in Uruguay in 1986 and ended in 1994. This was called the Uruguay Round and was quite different from the previous MTNs and for the first time GATT negotiations included services, investment and intellectual property.

France introduced product patents in 1960, Germany in 1968, Japan in 1976, Switzerland in 1977 and Italy and Sweden in 1978.[2]

Developing countries made several concessions in terms of agreeing to higher levels of protection of IPRs demanded by the industrialized countries but in return got very little by way of tariff reductions in agriculture and textiles.[3]

## The Third WTO Ministerial Meeting in November 1999

There were unprecedented and massive protests when the Third WTO Ministerial Conference opened in Seattle, Washington State, USA, in November 1999. Several NGOs planned the protest to voice their serious concerns that the WTO puts profits ahead of human rights, labour safety and environment.

A section of the protestors became violent; the opening ceremonies of the four-day long trade talks were cancelled because of the violence. Unfortunately the mainstream media coverage was corporate led and therefore concentrated on the sensationalism of the violent aspects of the protests without looking into the real issues. Protestors estimated between 50,000 to 1000,000, went to Seattle from all over the world, not just from the developed countries. They ranged from human rights groups, students, environmental groups, religious leaders, labour rights activists etc. wanting fairer trade with less exploitation. The fact that 50,000 to 100,000 people turned up in the pouring rain, despite police crackdowns etc indicates the extent of concern felt by them. Their protests centered on the fact that the WTO rules do not accommodate public health principles and social values. Neither could they be said to address issues of social development and equity essential to human development.

The Seattle WTO Ministerial Conference seems to have been a turning point for developing countries. Since then, there has been an organized and sustained campaign by developing countries supported by NGOs including the Third World Network (TWN) Health Action International (HAI) Consumer Project on Technology (CPT) OXFAM and Medecins sans Frontieres (MSF) to emphasize that the TRIPS Agreement should not prevent governments from taking measures in favour of public health.

## Doha Declaration on the TRIPS Agreement and Public Health

The differing socio-economic and political interests of the WTO Members have resulted in differing interpretations of certain provisions in the TRIPS Agreement. This divergence has been clearly demonstrated in the ongoing debates and controversies on the TRIPS Agreement and Public Health.

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[2] Balasubramaniam K – Heads – TNCs win: Tails – South looses or the GATT/WTO/TRIPS Agreement – Consumers International, Regional Office for Asia and the Pacific, Penang, Malaysia 1998.
Carlos Correa – Intellectual Property Rights, the WTO and Developing Countries, Third World Network, Penang, Malaysia 2000.

[3] Agosin, M & Tussie D; Developing countries and the Uruguay Round.*y la nave va.* An evaluation of the changed intuitional balance, FLASCO, Buenos Aires 1994

To solve the conflicts and controversies developing countries led by the WTO Member States in Africa (referred to as the Africa Group) initiated a process in early 2001 to request the Council for TRIPS to deal specifically with the relationship between the TRIPS Agreement and Public Health.

This process, initiated by the Africa Group of countries with active support from the majority of the developing countries including Sri Lanka, saw the developing countries demanding a common understanding on the TRIPS Agreement. This common understanding was that the Agreement allowed the degree of flexibility necessary to meet public health objectives, particularly in relation to compulsory licenses, parallel importation and exceptions to patent rights. This was thought necessary, not so much because the TRIPS Agreement lacked clarity, but more because of the political obstacles that were put in their way in attempting to put into effect the inherent flexibility of the TRIPS Agreement at the national level. The developing countries were moved to take this action in order to give effect to the conviction that the TRIPS Agreement and its provisions should not prevent WTO Members from adopting measures necessary to protect public health, including measures to ensure access to affordable medicines.

The staff in the Sri Lankan Permanent Mission to the UN and WTO in Geneva were the Sri Lankan negotiators in this process which included the drafting of the proposal to the Council for TRIPS. The Sri Lankan Permanent Mission to the UN sent the Africa Group's proposal to the Director-General of Commerce, Ministry of Commerce and Consumer Affairs Sri Lanka requesting him to send copies of the proposal to all stake-holders to get their concurrence so that Sri Lanka could be a signatory of the Africa Group's proposal to the Council for TRIPS. The proposal was sent to the Director General, Health Services and copied to the Director of the National Intellectual Property Office. The DG Health gave the concurrence of the Ministry of Health supporting the proposal. The Director General Commerce giving the concurrence on behalf of the Ministry of Commerce and Consumer Affairs sent it back to the Sri Lankan Permanent Mission to the UN in Geneva and Sri Lanka became one of the signatories to this historic document which was taken up by the Council for TRIPS at its meeting in Geneva June 2001.[4]

At the Fourth WTO Ministerial Conference (9-14 November 2001) held in Doha, Qatar, WTO Members took the unprecedented step of adopting a special declaration on issues related to the TRIPS Agreement and Public Health[5] Discussions on this Declaration was one of the outstanding issues at the conference. The Director – General of WTO emphasized the importance of this issue on the opening day of the conference indicating that agreement on public health and TRIPS was the 'deal breaker' of the new round. Pascal Lamy, the EU Commissioner for Trade, stated at the Conference that "... we must also find the right mix of trade and other policies – consider the passion surrounding our debate on TRIPS and Access to Medicines, which has risen so dramatically to become a clearly defining issue for us this week."[6]

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[4] Personal Communication from the Sri Lankan Permanent Mission to the UN in Geneva 2001

[5] Doha Ministerial Declaration on TRIPS Agreement and Public Health, WT/MIN (01)/Dec/W/2, 14 November 2001.

[6] Carlos Correa – Implications of the Doha Declaration on the TRIPS Agreement and Public Health. Health Economics and Drugs, EDM Series No 12, World Health Organization, Geneva June 2002

The Doha Declaration thus represents a political victory for developing countries including Sri Lanka. It is a strong political statement which provides a degree of security and acts as a sheet anchor for Sri Lanka and other developing countries in adopting national level measures necessary to meet public health objectives against the fear of very costly legal battles. However, the Declaration was only the first step. The real test of the success of the Declaration rests at the national level, whether or not developing countries will proceed to take the necessary measures at the national level to put into effect public health safeguards provided for in the TRIPS Agreement and reiterated and recognized in the Doha Declaration.

## The Intellectual Property Bill 2003

Let us see the measures taken at the national level in Sri Lanka.

The Intellectual Property Bill 2003 was placed on the order paper of Parliament 21st May 2003. The Supreme Court assembled on 6th June to hear three petitions and to determine whether the Intellectual Property Bill 2003 or any provision thereof was inconsistent with the Constitution of Sri Lanka.

The petitioners' contention was chiefly based on the position that the mitigatory features which were incorporated in the TRIPS Agreement have not been included in the Bill.

The petitioners cited three examples as important issues that should have been taken into consideration.

a. Articles 30 & 31 of the TRIPS Agreement which provide for a State to make provision for the use of the subject matter of a patent for the domestic market without the prior authorization of the patent holder in certain situations such as national emergencies.
b. The Doha Declaration on the TRIPS Agreement and Public Health which makes provisions for compulsory licensing and parallel importing of pharmaceuticals to meet national health emergencies.
c. The TRIPS Agreement includes several other mitigatory measures which are allowed under the agreement.

The judges noted that none of these measures have been incorporated in the Bill. They added that these provisions were specifically included so that TRIPS consistent public health safeguards can be provided for in national intellectual property bills. The judges determined that several clauses in the Intellectual Property Bill 2003 were inconsistent with the Article 12 (1) of the Constitution.[6(1)]

The Bill, therefore, needed to be amended to include public health safeguards provided for in the TRIPS Agreement and underscored in the Doha Declaration. These safeguards include government use, parallel imports and compulsory licensing.

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[6(1)] S.C. Special Determination Nos; 14/2003, 15/2003 and 16/2003. The Bench comprised Chief Justice Sarath Silva, Justice Shirani Bandaranayake, and Justice J.A.N. de Silva-

## National Seminar on the "Trips Agreement, the Intellectual Property Bill 2003 and Public Health

In order to examine and analyze the present scenario relating to Intellectual Property Bill 2003 and to propose appropriate amendments to the Bill, the Ministry of Health, Nutrition and Welfare in collaboration with the Department of Commerce, Ministry of Commerce and Consumer Affairs and Health Action International Asia – Pacific organized a National Seminar on "The TRIPS Agreement, the Intellectual Property Bill and Public Health" on Friday 4th July 2003 at BMICH, Colombo. There were 76 participants representing all stake holders in health and pharmaceuticals.

Reports of the proceedings of the seminar and issues related to the Intellectual Property Bill were carried in the Sri Lankan media.[7]

The objective of the seminar was to propose appropriate policy options & TRIPS consistent safeguards including provisions for government use, parallel imports and compulsory licensing and to present them to the government for consideration by the drafters of the amendments.

## Comments on the Intellectual Property Bill 2003 with an Emphasis on its Impact on Access to Drugs[8]

It is a moot point that the Intellectual Property Bill 2003 should not only be consistent with provisions in the TRIPS Agreement but also may need to be consistent with the "Agreement on Protection and Enforcement of Intellectual Property Rights between the United States of America and the Democratic Socialist Republic of Sri Lanka.
*(Signed on 20th September 1991).*[9]

The Intellectual Property Bill 2003 has some gaps. The most important are: missing provisions on government use, compulsory licensing and parallel importation. Important but less crucial are missing provisions on exceptions to patent rights (Section 86 of the Bill).

The single most important set of issues involves government use and compulsory licensing. Here, there are two considerations: What is ideal TRIPS-compliant policy to promote access to essential medicines? And, what limitations are imposed by the Sri Lanka-U.S. Intellectual Property Agreement. If Sri Lanka still feels bound by this bilateral agreement, then Sri Lanka will not be able to have a general compulsory licensing provision. Instead, it will be necessary to concentrate on government

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[7] Patents Bill: Patents to get priority in new draft – Daily Mirror 4th July 2003
Patent Rights in New Bill by Kishani S Fernando – Daily Mirror 5th July 2003
IP Bill: Narrow Escape from a National Disaster by Dilshani Samaraweera – The Business Standard 11th July 2003

[8] This is based on a paper prepared by Robert Weissman, J D Harvard Law School, Consultant, World Health Organization Co-Director, Essential Action, Washington, DC and circulated as one of the background documents at the National Seminar 4th July 2003

[9] This can be downloaded from:http://www/cptech.org/ip/health/c/agreements/srilanka-1991-ip.html

use and issuance of compulsory licenses only as a remedy for anti-competitive practices. In this regard, it is vital to elaborate specific grounds for issuance of licenses, specific procedures to handle compulsory licensing requests, clear guidelines for compensation, and specific rules for handling appeals.

## Compulsory Licensing and Government Use

Compulsory licensing is a critical policy tool to promote competition and access to medicines. It brings the benefits of generic competition before patent expiration. Even where it is not actually employed, the mere prospect that a compulsory license may be issued, enhances government's and others' negotiating power with patent holders.

Compulsory licensing enables a government to instruct a patent holder to license the right to use its patent to a company, government agency or other party.

Compulsory licensing is completely permissible under the TRIPS Agreement, for all products, under circumstances that are left virtually entirely to national law and determination. The freedom of countries to determine the grounds for compulsory licensing was reiterated in the Doha Declaration. The TRIPS limitations on compulsory licensing are procedural in nature, and the procedures are not overly burdensome.

Government use provisions are a subset of compulsory licensing – a compulsory license issued to a government agency. TRIPS permits government use ("public, non-commercial use" or "crown use") provisions that make it simple and easy for governments to make use of patents, without the authorization of the patent owner. Some of the procedural requirements for general compulsory licensing do not apply to government use. Many rich countries, including the United States United Kingdom have such streamlined government use provisions and The Bill contains no language on compulsory licensing.

A compulsory licensing regime that is intended to facilitate access to medicines should take advantage of the flexibilities available in the TRIPS Agreement. To do so requires:

- Expanding the grounds for issuance of compulsory licenses
- Streamlining procedures for consideration of license requests
- Establishing compensation guidelines for compulsory license
- Establishing appropriate terms of review on appeal

The following grounds for issuance of compulsory licensing may also be considered:

- The patented invention is important for public health or nutrition interests and is being made available to the public in insufficient quantity or quality or at high prices, such that consumers are unable to access it sufficiently.

- A market for the patented invention is not being supplied on reasonable terms in a country, where "reasonable" means the country's consumers who could benefit from the product are not able to afford it.
- When the patented invention is important for public health or nutrition interests, the patent owner has refused to offer non-discriminatory and non-exclusive licenses on reasonable terms and conditions, unless the patent owner can demonstrate that more restrictive licensing practices do not impede access to healthcare or nutrition.
- A license will facilitate the promotion of technological innovation and the transfer and dissemination of technology.
- A license will advance the public interest or public welfare in sectors of importance for socio-economic and technological development.
- Non-working. The patent holder does not manufacture the drug locally.
- A license is needed to make use of another patent (a "dependent patent").
- To remedy anti-competitive practices, including to remedy lack of competition for medical treatments. In cases where economies of scale are significant, such authorizations may include authorization to export products.

In regard to establishing a compulsory licensing regime, Sri Lanka faces a particular difficulty, which is that it is a signatory to the 1991 agreement with the United States on intellectual property rights. There are good reasons to argue that Sri Lanka should not feel bound by this agreement. First, the United States itself violates it, for example with legislative provisions on compulsory licensing of atomic energy technologies that are not compliant with the Sri Lanka-U.S. agreement.

Second, the agreement runs counter to the Doha Declaration affirmation that TRIPS "can and 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" and the reaffirmation of "the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose." By limiting the flexibilities in the subsequently negotiated TRIPS Agreement, the U.S.-Sri Lankan agreement runs counter to the basic premises of the Doha Declaration.

Both Sri Lanka and the United States are now WTO members, and bound by its intellectual property rules. There is no valid reason for continuation of the bilateral agreement, which offers no countervailing benefits to Sri Lanka. The agreement stipulates that it may be terminated by either party with one year's notice, once 10 years have passed, as they now have. The last paragraph in the Agreement states as follows:

> "This Agreement shall enter into force thirty days after it is signed by the Parties. It shall remain in force for a period of ten years and shall continue to be inforce unless terminated in accordance with this Article. Either party may, by giving one year's notice to the other Party, terminate this Agreement at the end of the initial ten year period or at any time thereafter."

The bilateral agreement permits compulsory licensing only in three cases: to remedy anti-competitive practices, to address a national emergency, or for air pollution technologies. It does not contain overt authorization of government use, but contains an enforcement provision (Section 2(f)(5)) which effectively authorizes government use, including the aggressive and heavily used government use statute.

Apart from government use, then, the key compulsory licensing flexibility available to Sri Lanka under bilateral agreement with the United States, is in the area of remedying anti-competitive practices. Thus it is vital to craft provisions that enable Sri Lanka to employ this flexibility.

As with crafting a general compulsory licensing provision, it is important to address the same issues with a focus on competition policy. This will include:

- Expanding the grounds for issuance of compulsory licenses - Streamlining procedures for consideration of license requests - Establishing compensation guidelines for compulsory license – Establishing the terms of review on appeal.

Grounds for issuance of compulsory licenses

The grounds should be fully delineated. Simply saying that compulsory licenses may be available to remedy anti-competitive practices is not enough. Without more direction, potential plaintiffs are unlikely to file cases, and government authorities may feel uncertain about the definition of an anti-competitive practice and will likely be deterred from issuing licenses.

A list of potential anti-competitive practices which may be remedied by issuance of compulsory licenses includes:

- Refusal to deal, where the applicant for the license has unsuccessfully endeavored during a reasonable period of time (90 days) to obtain the patent holder's consent for the use of the patented invention under reasonable terms and conditions.
- Excessive pricing, including where a patented invention is important for public health or nutrition interests and is being made available to the public at excessively high prices, such that consumers are unable to access it sufficiently.
- Non-working. – The patent holder does not manufacture the product locally
- Enabling the use of interdependent patents
- Lack of competition for essential medicines
- Price-fixing, as well as collusive tendering, market or customer allocation arrangements, allocation by quota as to sales and production, collective action to enforce arrangements, e.g. by concerted refusals to deal, concerted refusal of supplies to potential importers, collective denial of access to an arrangement, or association, which is crucial to competition.
- Illegal tying, where a product is made available only if the consumer agrees also to buy a distinct, separate product.

- Predatory behavior.
- Discriminatory (i.e. unjustifiably differentiated) pricing or terms or conditions in the supply or purchase of goods and services, including by means of the use of pricing policies in transactions between affiliated enterprises which overcharge or undercharge for goods or services purchased or supplied as compared with prices for similar or comparable transactions outside the affiliated enterprises.
- Improper use of market power.

## Procedures

Any person should be free to file a case alleging anti-competitive practice with the relevant authority. The authority itself should be able to initiate cases. Typically, authority would rest with a special competition authority (already existing or newly created) or the Ministry of Justice. (An ideal arrangement would lodge authority with a special competition authority, because of its expertise in the area, or with both the competition authority and the Ministry).

The authority should be able to hear cases pursuant to administrative procedures and issue a ruling. It is not necessary to resort to the courts.

The authority must issue rulings on the merits of the individual case before it. But delineation in the law of specific and clear anti-competitive practices will make determinations easier in certain fact patterns, such as refusal to deal. And the anti-competitive practices themselves may establish certain presumptions; that is, the law may specify that committing certain objectively definable acts may presumptively be anti-competitive.

Note that there is no need for the plaintiff in an anti-competitive case to have requested a voluntary license before filing the case. (For most other compulsory licensing requests, TRIPS does require such prior negotiation.) However, prior attempts at negotiation, even if not by the plaintiff, may be needed for some cases, such as those alleging refusal to deal.

## Nature of License

Licenses issued to remedy anti-competitive practices should presumptively be non-exclusive and available to all bona fide users. (This standard should apply for a general compulsory licensing statute as well, if Sri Lanka decides to adopt one after terminating this US-Sri Lanka Agreement on Intellectual Property.)

When economies of scale are important, as will typically be the case for pharmaceuticals, compulsory licenses issued to remedy anti-competitive practices should permit importing, and/or manufacturing for domestic and export markets.

## Compensation Standards

It is important that compensation standards be established in law. The standards and royalty guidelines included in the Third World Network Manual may be useful.[10]

Note, however, that TRIPS permits consideration of anti-competitive behavior in determination of appropriate compensation, and this factor is included in the Third World Network Manual guidelines. Where necessary to remedy anti-competitive practices, royalty rates may be lowered, to as low as 0 percent. Zero percent royalties are not uncommon in the United States in connection with competition cases (on occasion, effective compensation may even be negative, with 0 percent royalties combined with affirmative obligations on patent holders to make certain expenditures to benefit compulsory licensees).

## Recommended approach to Government Use

A well-functioning government use provision is easiest drafted if it is separated from the general compulsory licensing provisions.

Key features to be included are:

- The government may make use of a patent without engaging in prior negotiation with the patent holder for a voluntary license.

- Government use authority is broadly held, not just concentrated with the patent officer, the attorney general or any small group of authorities.

- Government use authority may be transferred to any private contractor doing work for the government. That is, they may make use of any patent, without engaging in prior negotiation with the patent holder for a voluntary license, so long as they are operating on behalf of the government.

- The patent holder may not seek to stop the government use by lawsuit. Patent holders are entitled to reasonable compensation, and the only basis of appeal for a government use is whether the patent holder has received adequate remuneration. Authority to hear such appeals may be lodged in administrative authorities.

[10] Manual on Good Practices in Public Health Sensitive Policy Measures and Patent Laws : Third World Network, Penang, Malaysia, March 2003.

## Parallel Importation

### Background

Parallel importation is the ability of countries to import, without the permission of the patent holder, a patented product once it has been put on the market in another country. This is one of the key flexibilities maintained in the TRIPS agreement.

TRIPS provides that countries have unfettered freedom to determine their "exhaustion" regimes, and the Doha Declaration reiterates this point. When a patent holder has "exhausted" his/hers rights, others then gain the ability to use the product as they see fit, including by exporting it to other countries for resale.

Parallel importation is important in containing prices for a number of reasons, including that brand-name companies price differentiate. They may charge lower prices in one country with a larger market, and higher prices in a smaller or poorer country where they choose to target only the economic elite.

Countries increase their flexibility to contain pharmaceutical prices by allowing parallel importation. The extent of country flexibility depends on the terms of parallel importation rules. For example, permitting parallel importation from a market where the product has been compulsorily licensed will enhance the cost-containment benefit, but will be more controversial in the TRIPS framework. A less far-reaching but not unimportant parallel import rule would permit such importation in any case where the patent holder put the product on the market, or where it was put on the market with the patent holder's consent.

## Exceptions to Patent Rights

### Background

TRIPS Article 30 provides a general exceptions provision to patent rights. It offers a framework within which countries may designate certain actions as not violating patent rights. Article 30 is used to provide the framework for early working or "Bolar" provisions (enabling generic firms to import and use patented substances while on patent for the exclusive purpose of obtaining regulatory approval) and other purposes.

### Draft Language

The draft bill contains a general exceptions provision in Section 86, containing a research exemption (Sec. 86(1)), among other provisions.

**Evaluation**

While some exceptions are included in Section 86, many important and commonly used exceptions are not. These include:

- An early working/Bolar exception
- An exception for individual prescriptions.
- An exception for export of a patented product to meet healthcare needs in a third country in which the product is compulsory licensed or not patented.

## Conclusion

The Doha Declaration was a political victory for developing countries. Sri Lankan trade negotiators in Geneva worked hard with their colleagues from other developing countries and NGOs to get the Declaration unanimously adopted. Very unfortunately for Sri Lankan consumers, the Intellectual Property Bill 2003 was an anticlimax. It ignored the Doha Declaration and the TRIPS consistent safeguards to promote and protect public health. (See annexure to this paper for further elucidation.)

The Supreme Court, which heard three petitions, determined that several clauses in the Bill were inconsistent with article 12 (1) of the Constitution because it did not include the safeguards mentioned in the Declaration.

Consumers want answers for the following:

i. How did the Bill go through legal safety nets in the Intellectual Property Office, Intellectual Property Advisory Commission and the Attorney General's Department and yet was found to be inconsistent with the Constitution?
ii. What would have happened if the three petitioners had not taken the Bill to the Supreme Court?
iii. Based on the experience of the original Bill, why was the amended Bill not made available to the public for their views before it was sent to the Parliament?

The public and NGOs are very much concerned at the non-transparency in the manner in which the original Bill and the amended Bill were drafted and sent to the Parliament. They demand that their representatives and more importantly the Health Ministry should be given an opportunity to review the amended Bill.

Finally they request the Government to review the Agreement on IPRs between the US and Sri Lanka and withdraw from the same due to the fact that this Agreement prevents the provision in Sri Lankan legislation, of TRIPS consistent safeguards to protect public health. Valid reasons for withdrawal from the Agreement are discussed in this paper.

# Annexure

## Model Legal Provisions for:

### A. Parallel importing of patented products and

### B. Compulsory licensing

## Note

The Doha Declaration on the TRIPS Agreement and Public Health makes clear provisions for parallel importing and compulsory licensing. Developing countries like Sri Lanka face a problem of how to maximise the use of the TRIPS consistent safeguards in their national legislation. There is no point in having these safeguards mentioned in the national legislation unless it enables the countries to use them to the maximum and in the best possible way. To enable to use the safeguards very effectively, countries need well-drafted national legislation that conveys them in clear language to government officials.

The following sections describe model provisions for:

a. Parallel importing of patent protected drugs; and
b. Compulsory licensing

These sections are reproduced from the "Manual on Good Practices in Public Health Sensitive Policy Measures" published by the Third World Network (TWN) Penang, Malaysia, March 2003. The Manual was informed by three separate workshops at which there were debates and discussions from intellectual property experts around the world.

It provides some easy to understand guidance in the technical area of drafting national legislation on intellectual property rights.

**PARALLEL IMPORT**

Importation of products placed in other markets

A patent holder shall not have the right to prevent acts of importation of any product covered by a patent that has been put on the market in any country by the patent holder or by any party authorised to use the invention.

EXPLANATORY NOTES

## A1. Effect of model provision

Parallel import is the import and resale in a country, without the consent of the patent holder, of a patented product that has been legitimately put on the market of the exporting country under a parallel patent.[1] Since some patented products are sold at different prices in different markets, the rationale for parallel importation is to enable the import of patented products from countries in which they are sold at lower prices into those countries where the same patented product is being sold at a higher price.

This model provision allows for the parallel importation in any of the following circumstances:

parallel importation of a patented product that has been placed on the market of another country by the patent holder; or
parallel importation of a patented product that has been placed on the market of another country by a (voluntary) licensee or authorised agent of the patent holder; or
parallel importation of a patented product that has been manufactured and placed on the market by a compulsory licensee.

The incorporation of this model provision within a national patent law will enable any party to parallel import patented products into a country in the three cases mentioned above, and to sell the said products.

## A2. Objective and rationale

A patent confers a monopoly for the working of an invention upon the patent holder, in that the patent holder may prevent any other person from using making, selling or importing the patented product in the country in which the patent is in force. Thus, the patent confers not only the exclusive right to manufacture and work the patent in the country, but also the exclusive right to import the patented product into the country.[2]

However, these rights of the patent holder are qualified by the principle of exhaustion of rights. This principle of exhaustion states that once patent holders or other authorized parties have sold a patented product, they cannot prohibit the subsequent re-sale of that product since their rights in respect of that market are exhausted by the act of selling it. The patent holder's rights over a patented product are therefore, "exhausted."

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[1] when an invention is covered by more than one national patent registered by the same person in different countries.
[2] Velasquez, G & Boulet, B (1999) Globalisation and Access to Drugs: Perspectives on the WTO/TRIPS Agreement, DAP Series No 7 Revised, WHO, Switzerland, p. 22

Thus, from the moment the product is marketed, the patent holder can no longer control its subsequent circulation – the patent holder still holds exclusive right to manufacture the product and to put it on the market, but from that moment on, has no further right over the product on the market.[3] On the basis of the exhaustion principle, it would be possible for another party (apart from the patent holder or its authorised agents) to import the patented product from another market where the product is sold.

Parallel importing can be an important tool enabling access to affordable medicines because there are substantial price differences for pharmaceutical products in different markets. The price differences may be due to local market conditions, based on factors such as differences in intellectual property rules, or prevailing income levels, as well as the degree of competition among producers. Where there is little competition among producers, or where the producer has a monopoly within a particular market, a very high price may be charged for a medicine, regardless of the income levels. This has been observed in studies, where patented medicines were priced far higher in developing countries with low levels of income than in developed countries. By permitting some form of parallel imports, countries can "shop around" and get better prices for pharmaceutical products.

The model provision enables parallel importation of three categories of patented products, that is;

patented products that have been placed on the market by the patent holder; or patented products that have been placed on the market by the by the authorised agents of the patent holder; and patented products that have been produced and placed on the market by a compulsory licensee.

Whilst the first two situations are not in question, some doubts have been raised as to whether patented products placed on the market by a compulsory licensee may be parallel imported.

It has been argued that in the case of a patented product produced and marketed under a compulsory licence, the rights of the patent holder have not been exhausted, as there has been no consent given by the patent holder for the production and eventual placing on the market. Proponents of this "consent theory" have thus argued that parallel import in this case is not allowed.

The alternative view, which espouses the "reward theory" in relation to exhaustion of rights, holds that parallel importation of patented products produced and marketed under a compulsory licence are allowed. The reward theory is premised on the fact that since the patent holder has been rewarded through the first sale or distribution of the product, the patent holder has no right to control the use or resale of the product put on the market with the patent holder's consent or in an otherwise authorised form.[4]

Therefore, it is not so much consent (of the patent holder in the placing of the product on the market) but rather whether the patent holder has been rewarded for the use of his patent. In the case of

[3] *Ibid.*, p. 23
[4] Correa (2000), Integrating Public Health Concerns into Patent Legislation in Developing Countries, South Centre, Switzerland, p 72

patented products produced and placed on the market by a compulsory licence, the patent holder would have received compensation from the compulsory licensee (as a condition of the issue of a compulsory licence). Hence, the patent holder would have been duly rewarded for the use of his patent.

### A3. TRIPS - compliance

Parallel imports are allowed under the TRIPS Agreement. Article 6 of the TRIPS Agreement provides that the issue of exhaustion of rights shall not be a matter of dispute settlement. Hence, TRIPS leaves it to Members to decide how the principle should be applied within their national territory. They have three main options:[5]

Members may adopt the principle of international exhaustion of the patent rights. Adoption of this principle in the national patent law would allow any party to import into the national territory a patented product from any other country in which the product was placed on the market by the patent holder or any authorised party.

Members may adopt regional exhaustion of rights, where adoption of this principle would allow the possibility of importing into the national territory a patented product originating from any other Member state of a regional trade agreement.

The third option is that of national exhaustion of rights. This principle limits the circulation of products covered by patent in one country to only those put on the market by the patent owner or its authorised agents in that same country. In this case, there can be no parallel importation.

During the negotiations leading up to the Doha Declaration on the TRIPS Agreement and Public Health, developing countries were keen to clarify that WTO Members have the right, by virtue of Article 6 of the TRIPS Agreement, to adopt an international principle of exhaustion of rights. The Doha Declaration has re-affirmed that Members do have this right. Paragraph 5(d) of the Declaration states that each Member is "free to establish its own regime for such exhaustion without challenge". That this has been clarified in the Doha Declaration is an added reassurance for Members wishing to adopt an international exhaustion principle, that it is legitimate and consistent with the TRIPS Agreement to do so.[6]

Adoption of this principle in the national law would permit the importation of a patented product into a country without the consent of the patent holder where the said patented product has been placed on the market of another country. It is important to note that this "flexibility" allowed in the TRIPS Agreement and confirmed by the Doha Declaration does not automatically translate into the national

[5] Velasquez & Boulet (1999), p.23
[6] Correa (2002), p.18

regimes, and it is necessary and recommended that specific legal provisions be enacted in national laws.[7]

For those countries wishing to avail themselves to the widest scope in terms of parallel imports, it will be important to enact a clear legal provision to that effect. Incorporation of the model provision within the national law will operationalise international exhaustion principle.

Unnecessarily restrictive formulations on parallel imports should be avoided, such as those that require "express consent" of the patent holder before a patented product is imported. If the consent of the patent holder is required for the import of a patented product, the ability to parallel import will be restricted to only those cases where the patent holder has given consent. For instance, though the patent owner may grant voluntary licenses in a foreign country, he may prohibit his licenses to export generally or to some countries or regions.

Parallel importation is permissible under the TRIPS Agreement, and it is an important tool for meeting public health interests, where it enables importation of a patented medicine from a country in which it is sold at a lower price so that more patients may have access to the cheaper medicine.

## COMPULSORY LICENCE

### 1. Grounds for grant of compulsory licence

Any person may request the Competent Authority* for the grant of a compulsory licence on one or more of the following grounds:

that the patented invention is capable of being worked in (country) and it is prevented or hindered from being so worked by the importation of the product;

that the applicant for the licence has unsuccessfully endeavoured during a reasonable period of time (e.g., 90 days) to obtain the patent holder's consent for the use of the patented invention under reasonable terms and conditions;

that the interests of public health and nutrition, including that of ensuring the access to medicines for all, demand the commercial working of the patented invention in (country), where the patented invention is being made available to the public in insufficient quantity or quality or at abnormally high prices;

that public interest demands that the patented invention be exploited;

that there is a need to remedy the abuse of intellectual property rights or anti-competitive practices*;

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[7] *Ibid.*

that there is a national emergency or situation of extreme urgency, including public health crises, which requires the use of the patented invention; and

that a patented invention cannot be used without infringing another patent, where the former patent involves an economically significant technical advance compared to the latter patent, and provided that the owner of the latter patent is offered a cross-licence, and use authorised for the former patent will not be assignable without the assignment of the latter patent.

## 2. Prior negotiation

**a. A licence under this Part shall be granted subject to the condition that the applicant has made efforts to obtain authorization from the patent owner on reasonable commercial terms and conditions, and such efforts have not been successful within ninety (90) days from the request.**

**b. This condition shall not apply where a licence is requested under the grounds (e) and (f) of Section 2 above.**

## 3. Compensation

a. Where a licence under this section has been granted the applicant shall pay to the patent owner an adequate remuneration, the amount of which shall be determined by the Compensation Committee* in the circumstances of each case, in accordance with the Compensation Guidelines.*

b. In the case of a compulsory licence granted on the ground (e) of Section 1 above, the Compensation Committee in determining the amount of adequate remuneration by shall take into account the need to correct anti-competitive practices and may reduce the amount of remuneration accordingly.

## 4. Rights under a compulsory licence

**a. The grant of a licence under this Part shall confer on the licensee the right to make, use, import or keep the patented invention, or sell or offer to sell it.**

**b. A licence granted under this section shall be;**

(i) non-assignable, except for that part of the enterprise or goodwill which enjoys such use;

(ii) valid for the duration of the remaining lifetime of the patent, unless a shorter term is justified in the public interest.

**c. The use of a licence under this section shall be predominantly for the supply of the domestic market. This limitation shall not apply in the case of a licence issued on ground (e) of Section 1 above.**

## 5. Remedies

**a.** The patent holder shall be entitled to appeal the grant of a compulsory licence made pursuant to Section 1 above to the (Court or an administrative body set up to hear such appeals).

**b.** An appeal against the grant of a compulsory shall not stay or suspend the use of the patented invention during the appeal process. The patent holder's sole remedy shall be action for the recovery of compensation, the determination of which shall be made in accordance with the Compensation Guidelines.

EXPLANATORY NOTES

**B1. Effect of model provision**

This provision lays down the grounds and conditions upon which compulsory licences may be granted. A compulsory licence is directed at a specific patent or patents, and is generally applied for, and granted, on a case-by-case basis, after a process of approval. The model provision presumes the establishment or designation of a granting authority - referred to as the Competent Authority in the model provision – that receives and processes the applications for, and determines the grant of, compulsory licences.

Any person may apply for a compulsory licence, provided his application is based on one or more of the seven grounds specified in the provision (Section 1a-1g). The seven grounds, as provided for in the model provision, on which an application and the grant of a compulsory licence may be based, are as follows:

(a) non-working or insufficiency of working – where the patent is granted but not exploited in the territory of the country, or is insufficiently exploited;

(b) refusal to deal – where the patent holder has refused to enter into a voluntary licensing agreement on the reasonable commercial terms offered by the applicant;

(c) public health and nutrition – where the interests of public health and nutrition requires, including to ensure the availability and affordability of medicines;

(d) public interest – as may be defined by the competent authorities;

(e) anti-competitive practices – the need to correct anti-competitive practices is a ground for the issue of a compulsory licence, as provided for in Article 31(k) of TRIPS;

(f) national emergency or situation of extreme urgency – most countries provide for the use of patented inventions without the consent of the patent holder in emergency situations, such as war, famine, natural catastrophe, etc.; and

(g) dependent patents – a compulsory licence is issued, on the basis of certain conditions, where a new invention requires the use of a pre-existing patented invention for working.

The grant of the compulsory licence is subject to the fulfilment of the conditions laid down. Section 2a of the model provision provides for the requirement that prior efforts have been made to obtain a voluntary licence from the patent holder before applying for a compulsory licence. However, this requirement does not apply where the compulsory licence applied for is based on the grounds of anti-competitive practices or in cases of emergency, as stated in Section 2b of the model provision.

Section 3a of the model provision specifies another condition for the grant of a compulsory licence; that of payment of compensation to the patent holder. The model provision also requires the establishment or designation of a body to determine the amount of the compensation to be paid, in accordance with the criteria set out in the Compensation Guidelines (see Part 3, below).

### B2. Rationale and objective

The patent holder is free to exploit the protected invention or to authorize another person to exploit it. However, when reasons of public interest justify it, national public authorities may allow the exploitation of a patent by a third person without the patent holder's consent.

The patent holder is therefore, forced to tolerate the exploitation of his invention by a third person or by the government itself. In these cases, the public interest in ensuring broader access to the patented invention is deemed more important than the private interest of the patent holder to fully exploit his exclusive rights.[8]

The use of a patent without authorization or consent of the patent holder under a compulsory licence is distinguished from the limited exceptions to patent holder's rights under Article 30 of TRIPS, as discussed in Section C above. Whilst an exception under Article 30 is available to any party, a compulsory licence only allows the use of a patent by the person that has been granted the licence. The circumstances justifying an exception under Article 30 are also rather more limited, whilst compulsory licences may be granted on a variety of grounds (see D3 below).

[8] Reichman & Hasenzahl (2002), Non-Voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS and an Overview of the Practice in Canada and the United States of America, UNCTAD/ICTSD Capacity Building Project on Intellectual Property Rights and Sustainable Development, Geneva.

Compulsory licences play a crucial role in ensuring that patent laws are able to meet public health needs and do not prevent or hinder measures needed to protect public health or promote access to affordable medicines. Such licences promote competition and increase the affordability of medicines, at the same time providing compensation to the patent holder for the use of his patent.

**B3. TRIPS-compliance**

Article 31 of TRIPS lays down the conditions governing the issuance of compulsory licences but leaves the decision regarding the grounds on which compulsory licences can be granted to the national governments. A number of compulsory licences are already expressly envisaged by TRIPS, including:

(1) compulsory licences granted in emergency or extreme urgency;

(2) compulsory licences granted to remedy a practice determined after administrative or judicial process to be anti-competitive;

(3) compulsory licences to enable the use of a dependent patent

(4) compulsory licences in the case of public, non-commercial use of patents.

Article 31 also refers to "public, non-commercial use", in the context of use of a patent without authorization of the patent holder. Thus, public, non-commercial use may be incorporated as a specific ground for the grant of a compulsory licence. However, public and non-commercial use of a patent can also be in the form of the government's right to use patents; that is to say, without the need for a compulsory licence. The government use provision allows for the use of patent to be 'fast-tracked' as government rights in terms of public and non-commercial use of patents are often procedurally much simpler (see B above on the government use model provision). Therefore, the model provision does not include public, non-commercial use as a ground for the grant of a compulsory licence.

The TRIPS Agreement does not state that Members are limited in terms of the grounds on which they may decide to grant a compulsory licence. In practice, Members are only limited with regard to the procedure and conditions to be followed in the issue of compulsory licences. This freedom to determine the grounds upon which compulsory licences can be issued was re-affirmed in Paragraph 5(b) of the Doha Declaration which states that "(E)ach Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted."

The clarification in Paragraph 5(b) of the Doha Declaration is therefore to be welcomed as it would appear that WTO Members can now determine which grounds are most appropriate in the effort to protect public health and ensure access to affordable medicines. The grounds listed in the model

provision are those that have been adopted in many countries, including the developed countries (see D4 below for examples of state practice).

However, there may yet still be interpretations put forward by certain developed countries, keen to protect their patent holders' rights that question the validity of compulsory licences issued for the local production of a patented invention is not worked or insufficiently worked (see D3.1 below for a further examination of this issue).

Apart from the non-working issue, strenuous efforts were made during the negotiations of the TRIPS Agreement to limit the powers to grant non-voluntary licences on other grounds, particularly on the broad heading of "public interest", although these proved difficult to sustain in the face of state practices in the leading developed countries, such as those in the US, which provided broad government use powers as well as statutes allowing grant of private compulsory licences on specific public interest grounds.[9]

Article 31 codifies the conditions governing the issuance of compulsory licences, requiring among other things, cases by case authorization, prior negotiations, non-exclusivity, limited scope of licences, adequate remuneration, limitation on exports, judicial review and termination of licence.

Of these, the most troubling is the patent holder's possible claim to terminate a compulsory licence under Article 31(g), "if and when the circumstances which led to it cease to exist and are unlikely to recur". In opening up the possibility of a compulsory licence being terminated as soon as the circumstances which led to its granting cease to exist, the licensee is exposed to the risk of revocation of his licence. This, many experts fear will discourage investors from seeking compulsory licences. It is ironic that "the more efficient the licensee, the greater his chance of losing the right to use the invention."[10]

It is recommended that this provision should be interpreted broadly so as not to frustrate the purpose of Article 31. Therefore, the duration of a compulsory licence should be of a sufficiently long duration to provide adequate incentive and to justify the licensee's investment for production.[11] The model provision provides that the licence be valid for the remaining lifetime of the patent, unless a shorter term is justified.

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[9] Reichman & Hasenzahl (2002), p. 10

[10] Correa C (1999), Intellectual Property Rights and the use of Compulsory Licenses: Options for Developing Countries, Trade Related Agenda, Development and Equity (TRADE) Working Papers No 5, South Centre, Geneva. P. 8

[11] UNCTAD-ICTSD Resource Book on TRIPS and Development: An authoritative and practical guide to the TRIPS Agreement (http://www.ictsd.org/iprsonline/unctadictsd/ResourceBookIndex.htm)

### B3.1 Note on non-working or insufficiency of working

The origin of the compulsory licence is linked to the obligation to work a patented invention locally - a requirement of many national patent laws during the 19th Century.[12] The granting of compulsory licences evolved as a means to mitigate the drastic measure of direct forfeiture of a patent, in the case of failure to work a patent holder.[13] The local working requirement was incorporated into national patent laws as many countries felt that the need to encourage development of national industries by requiring a foreign patent holder to work his invention locally.

The Paris Convention, after the Hague Conference in 1925, recognised the right of member countries to establish compulsory licensing systems within their national patent laws as the main means to ensure the local exploitation of a patent. The TRIPS Agreement incorporates the provisions of the Paris Convention, which recognised the right of countries to grant compulsory licences "to prevent possible abuses," connected with monopoly. As such Article 5A.(2) of the Paris Convention provides that "Union Members shall have the right to take legislative measures providing for the grant of compulsory licences to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work."

The notion of abuse of patent rights is also referred to in Article 8.2 of TRIPS, which states that "appropriate measures ... may be needed to prevent the abuse of intellectual property rights ... or resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology." However, there is no reference to the failure to work a patent.

It could also be argued that the local working of a patented invention contributes to the promotion of socio-economic and technological development of a sector of vital importance, for which Article 8.1 of TRIPS allows Members to adopt necessary measures. Hence, it should be justified for countries to legislate that in sectors of vital importance, if the patent holder does not locally manufacture the product or is still importing after 3 years, a compulsory licence could be granted with a view to improving supply of domestic market or price conditions.

The Paris Convention clearly authorises the grant of compulsory licences for failure to work a patent. On the other hand, the TRIPS Agreement does not incorporate a direct prohibition. The negotiating history of the TRIPS Agreement indicates widely divergent views amongst the Members on the issue of local working. While several delegations during the negotiations pressed for a clear prohibition against local working requirements, the TRIPS Agreement does not include such a prohibition.[14] Indeed, nothing in Article 31 suggests that there is a prohibition.

However, Article 27.1 speaks of non-discrimination between imported and locally produced products. Thus, one argument against local working is that a compulsory licence for this purpose would

[12] Correa (1999), p. 3
[13] See Correa (1999), p. 3 and Reichman & Hasenzahl (2002), p. 4-6
[14] UNCTAD-ICTSD Resource Book on TRIPS and Development: An authoritative and practical guide to the TRIPS Agreement (http://www.ictsd.org/iprsonline/unctadictsd/ResourceBookIndex.htm)

contravene the provisions of Article 27.1 of TRIPS, which states that patent rights shall be "enjoyable without discrimination ... whether the products are imported or locally produced."

The requirement for non-discrimination between imported or locally produced products in Article 27.1 was at the heart of the U.S. initiation of a WTO dispute against Brazil in 2000 over a provision in Brazil's patent law. The Brazilian provision requires all patent owners to manufacture their patented products in Brazil or be subject to the compulsory licensing of their patents. The US contended that the provision was in violation of Article 27.1 of TRIPS. This provision, the US said, prohibits Members of the WTO from requiring the local production of the patented invention as a condition for enjoying exclusive patent rights. The US withdrew its complaint so the dispute was not pursued to its conclusion, with US and Brazil coming to an agreement that Brazil would consult the US if it intended to make use of the local working provision.

Whilst there has been no decision of a WTO dispute settlement on this issue, it was indicated in the Canada-Generics decision that Article 31 is subject to the rule of non-discrimination, as stated in Article 27.1 of TRIPS. However, it is suggested that the dispute panel distinguished between "discrimination", which is the conduct prohibited by Article 27.1 and "differentiation", which is not. Thus, where governments adopt different rules for particular products or locations of production for *bona fide* purposes, this may be permitted. For example, where adoption of a rule for improper purposes, such as to solely confer an economic advantage to local producers would not be permitted, but where compelling public interests exist, differentiation may be allowed.

It is also arguable that Article 8.1 of the TRIPS Agreement allows the granting of compulsory licences on the grounds of lack of local working, when such a lack affects the commercial or industrial development in a country's sectors of vital interest.[15] With the Doha Declaration's exhortation that the principles and objectives of the Agreement should be taken into account in its interpretation, this argument gains more strength.

[15] Correa (1999), p. 9

# Identifying Public Health Priorities; The Debate on Pharmaceutical Patents and Drug Prices

*Kishanie Swaris Fernando*[*]

## Background

The impact of patent laws on pharmaceuticals keeps medicines out of reach for millions of poor people in developing countries and has generated substantial controversy in recent years. Rights created by pharmaceutical patents are believed by some as an essential part of the market system, an essential for a knowledge generation, an incentive for research, the development and the protection of which is often seen as an important factor affecting the investment climate of a country.

Others insist that these rights must be managed in an impartial way protecting the interests of the patent-holders as well as safeguarding public health principles and be monitored to ensure that they actually promote healthcare.

The World Health Organisation (WHO) has recognized that access to essential drugs is a human right to health and affordability of essential drugs is a public health priority. The HIV/AIDs pandemic acted as a spur to recent debate on these issues.

## South Africa's Struggle

On 19 April 2001, thirty-nine drug Trans National Corporations (TNCs) took the South African government to court challenging the Medicines and Related Substances Control (Amendment) Act, which allowed compulsory licensing and parallel importing of drugs including AIDS drugs. Later, the TNC's dropped the law suit unconditionally.

The withdrawal of the law suit was, in no way, altruistic. On the contrary, it was due to intense pressure caused by health activists and groups internationally in a bid to give millions of people access to quality life prolonging AIDS drugs at affordable prices. The South African epic was a victory that boosted the morale of the people of the developing world leading action groups to demand medicines at affordable prices.

## The Sri Lankan Experience

On 17 June 2003, the Sri Lankan Supreme Court delivered Special Determination, striking down several clauses of the Bill bearing the title "The Intellectual Property Act No.... of 2003", as inconsistent with the Constitution of Sri Lanka.[1]

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[1] S.C. Special Determination Nos; 14/2003, 15/2003 and 16/2003.

The Bill was designed *inter alia* to repeal the previous Code of Intellectual Property Act No. 52 of 1979 to meet Sri Lanka's international obligations under Paris Convention on Industrial Property and the Agreement on Trade Related Intellectual Property Rights (TRIPS), which binds all members of the World Trade Organisation (WTO) including Sri Lanka.

Three petitioners,[2] challenged the constitutionality of the Bill invoking the jurisdiction of the Supreme Court in terms of Article 121 (1) of the Constitution.

The Bill deals with many aspects of Intellectual Property Law. The Petitioners were particularly concerned with the provisions relating to patents found in chapters xii to xvii (Clauses 67 –100) of the Bill.

Their main contention was that Clauses 84, 90,91,92,93 and 94 of the Bill were inconsistent with Articles 3 and/or 4(d), 12 (1) and 14(1) (g) of the Constitution. Thus, if they were to become law, they must be passed by a two-thirds (2/3) majority in Parliament.

## Infringement of Article 12(1) – Treating Un-Equals as Equals

The Petitioners contended that Clause 83 and 84 would grant an owner of a patent, exclusive rights for 20 years in respect of products and processes, to exploit a patented invention, to assign or transmit the patent and to conclude licensing contracts. They pointed out that when the patent chapters were read with Articles 3 and 4 of TRIPS, the Government of Sri Lanka would not be able to accord to its citizens or corporate entities, any protection or privilege not granted to foreign persons or corporate entities. As such, due to the vast difference in technological and financial resources between countries like Sri Lanka and countries of the developed world and transnational corporations, these provisions would be gravely prejudicial to Sri Lankan citizens and the development of its industries, particularly in the field of pharmaceutical drugs.

The Petitioners further claimed that certain mitigatory features which were incorporated in the TRIPS Agreement, (more importantly provisions on compulsory licensing and parallel importation and less importantly exceptions to patent rights), had not been incorporated in the Bill. These safeguards would ensure that Sri Lanka has regular access to safe and effective quality drugs at affordable prices.

They argued that Article 30 and 31 of the TRIPS Agreement (providing for a State to make provision for the use of the subject matter of a patent for the domestic market without the prior authorization of the patent holder in certain situations, including national emergency or urgency or in respect of practices deemed to be anti competitive), had not been taken into account.

Further, the Doha Declaration on the TRIPS Agreement and Public Health (November 2001) reaffirmed the rights of the WTO Members to make use of measures like compulsory licensing and

[2] The Centre for Policy Alternatives (CPA), Dr. Kamalika Abeyratne, Chairperson of the AIDs Coalition in Sri Lanka and Nihal Fernando.

parallel importing of pharmaceutical drugs to meet national health emergencies. This too had not been taken into account.

Without any of these mitigatory measures, it was pointed out that the Government would have to treat citizens of Sri Lanka on an equal footing with persons individual and corporate of countries with a higher level of economic development - resulting in the equal treatment of persons unequally situated and thus violating the fundamental rights enshrined in Article 12(1) of the Constitution.

In effect, it would allow the more economically powerful and technologically advanced foreign patent holders, including those who have patents on medicinal drugs and processes, to manufacture and control the supply and price of such drugs in the Sri Lanka market. Further, it may constrain Sri Lankan authorities or a Sri Lankan citizen from making available/obtaining medicines for the people of Sri Lanka at the cheapest available price and from a source of their choice.

These concerns were noted by the Supreme Court. The Court pointed out accordingly that –

> *"In fact, the World Trade Organization (WTO) has recognized the inequality of nations in respect of the TRIPS Agreement by prescribing a staggered time frame for the implementation of the agreement among countries of different economic levels."*

The reasoning of the Supreme Court in this respect proceeded on the following lines. In the first instance, it was reiterated that Article 12 (1) of the Sri Lanka Constitution not only guaranteed equality before the law, but also provided for the equal protection of the law. The Court said that –

> *"It is well settled law that just as much equals should not be placed unequally, at the same time un-equals should not be treated as equals."*

Producers of patented products and processes and their agents in developed nations and consumers of such products in developing countries such as Sri Lanka, could not be taken as parties similarly circumstanced. There was ample justification to treat them differently and if they were to be treated equally, such decision should be justified by relevant criteria.

The Court pointed out that Article 12(1) was in line with Article 7 of the Universal Declaration of Human Rights (1948) which declared that –

> *"All are equal before the law and are entitled, without any discrimination, to equal protection of the law."*

The 14th Amendment to the Constitution of the United States of America and Article 14 of the Constitution of India (which are similar in content and effect to Article 12(1) of the Sri Lankan Constitution), was also referred to.

Comparable jurisprudence in India which had guaranteed equal protection of the law as an injunction issued by the framers of the legislature against enactment of discriminatory laws was noted in this context. Thus, the Court stated;

> *"Although the legislature has a wide choice in articulation of subject matter of its laws, it should not treat un-equals as equals and equals as un-equals"*

## Discrimination Against Sri Lanka's Pharmaceutical Industry

The Petitioners contended that Clauses 90, 91,92,93 and 94 of the Bill which defined and dealt with license contracts (read with Clauses 83 and 84) were inconsistent with Article 12 (1) and 14 (1) (g) of the Constitution. It was contended that the monopoly to exploit at the exclusion of all others would act as a disincentive and be an obstacle to the development of the local pharmaceutical industry.

The Court held that this would be unequal treatment and would violate equal protection for persons engaged in such industry and as such was inconsistent with Article 12 (1) of the Constitution.

## Discrimination against Sri Lankan Inventors

The Petitioners contended that Clause 87 of the Bill, which might at first glance be seen as intending to protect Sri Lankans, was highly discriminatory. According to Clause 87 (1), a Sri Lankan who had been already making a product or using a process in respect of which another party had applied for a patent, might end up only with a right to exploit the patent.

The Court held that if the purpose of Clause 87 was to protect a Sri Lankan inventor, in such a case, the application made by the other party should be refused on the grounds that the invention had already been anticipated by prior art as defined in Clause 64 (2). As such, the Court concluded that Clause 87 read with Clause 64 did not grant an equal right or gave equal protection to an inventor who had already made a product or was using a process and thereby inconsistent with Article 12 (1) and 14 (1) (g) of the Constitution.

The Petitioners also cited Special Determination on the 19th Amendment to the Constitution Bill[3] where the Supreme Court observed that the Government holds and exercises all powers under the Constitution, be it legislative, executive or judicial, as trustees of the people.

## Contention of the Attorney-General

The Learned Additional Solicitor General, appearing on behalf of the State before Court, took the view that a patent was an ownership right which was necessary to exercise one's fundamental rights. Accordingly, Article 14 (1) (g) is restricted in terms of Article 15 (7) of the Constitution in the interests of *inter alia* "securing due recognition and respect for the rights and freedoms of others ..."

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[3] S.D. Nos. 11,13,15-21,25-28, 30-35 and 37-40 of 2002.

Further, he contended that, in terms of Article 15(5) of the Constitution, fundamental rights may be restricted in the interests of national economy or of the meeting of just requirements of the general welfare of a democratic society. This, he argued, was the basis whereby the legislature strove to achieve the balance between the rights of the individual and the society in general.

However the Court, disagreeing with the learned Additional Solicitor General, said that though Article 14(1) (g) was undoubtedly restricted in terms of Article 15(5) of the Constitution, this did not mean that the safeguards and protections given to persons in terms of Article 12(1) of the Constitution could be overruled.

The Court ruled that the aforementioned clauses were visibly inconsistent with Article 12(1) of the Constitution, and the Bill in the present form would need to be passed by a special majority.

## Amendments to the Bill

Preceding the Determination of the Supreme Court, a set of amendments were crafted by a drafting committee and studied by relevant ministries before they being presented to Parliament for the 3rd reading or committee stage discussions on July 23. The amendments pertaining to pharmaceuticals were introduced following intense pressure from patients' rights bodies and civic action movements.

However the amendments do not contain direct reference to the TRIPS flexibilities, but may permit same on a closer reading. Clause 86 (as amended) proposes a series of sub clauses. It refers to the exclusive rights conferred by Clause 84 and excludes acts done for scientific research, and also persons having rights under clause 87.

The amendment also permits the exploitation of a patent where the public interest requires this for public non-commercial use and to remedy anti-competitive practices. In case of parallel importation, the amendment provides for Sri Lanka to shop, on the world market, for the lowest priced patented pharmaceutical put on the market by a patent holder. An attempt to rectify Clause 87 has been proposed by granting a right to any person to object to the grant of a patent.

## Conclusion

The debate on the Intellectual Property Bill put into issue the fundamental rights of the people of Sri Lanka *vis a vis* patent rights of transnational pharmaceutical giants. In the process, it brought highly technical issues into the public arena, clearly exposing how TRIPS and the attendant patent regime could adversely affect the lives of poor patients in the developing world. No doubt the, new National Patent law will determine our drug prices and the development of the local pharmaceutical industry.

The lack of transparency and accountability in the passing of the Bill is also to be questioned. The Bill was published in the Gazette on 25th of April 2003. Despite repeated inquiries and requests, it

was only made available to the public on the 26th of May, leaving a mere two days for the public to examine the Bill and to challenge it for unconstitutionality.

The amendments, following the Supreme Court ruling, were presented on the 23rd of July and passed on 25th July, amidst heated protests from the Opposition that more time was necessary to study the Bill.[4]

The whole therefore illustrates severe defects in the passing of legislation in this country which remains to be remedied despite consistent pleas made to this effect in the past by civic action groups to permit public scrutiny of Bill and greater transparency in the process. As Sri Lanka contemplates the enacting of a Freedom of Information Act at this present moment in time, it is to be hoped that this is a concern that would be adequately addressed. Thus, the experiences that the public faced with regard to the Bill pertaining to Intellectual Property, would be avoided for the future at least.

[4] The Bill was passed with 99 for, and 59 against.