The TRIPS Agreement and Egypt's Responsibility to Protect the Right to Health

Right to Health Program

Egyptian Initiative for Personal Rights

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Glossary of Terms Used in the Policy Paper

- **Generic drugs**: pharmaceutical products that are marketed under are non-proprietary or approved name rather than a proprietary name, and whose patent has either expired or is still valid. Generic drugs usually have the same effectiveness of brand-name drugs but are sold at a significantly cheaper price.
- **Reverse Engineering:** the process by which a drug is analyzed so that its components are known then replicated. Reverse engineering were not a violation of agreements prior to the TRIPS as those protected only the 'process' rather than the 'final product' which is now also protected under TRIPS.
- **Compulsory licensing**: the grant by a government of permission to a third party to exploit a patented invention.
- **Parallel importation:** the importation of patented products from a third country where the products are cheaper.
- **TRIPS flexibilities:** sections of the agreement that allow governments latitude in the enforcement of the agreement to allow for national concerns such as, but not limited to, health emergencies.
- **TRIPS plus:** trade agreements, usually with the United States of America, that impose obligations on states that go further than TRIPS.
- **Doha Declaration:** a declaration of the WTO member states on TRIPS and public health, reiterating flexibilities in TRIPS with regard to health.
- **Article 6 of the Doha declaration** called on member states to expeditiously find a solution for states that do not have manufacturing capacity.
- **Ministerial Decision of 30 August** was a decision by the Ministerial Council of the WTO in 2003 that allowed parallel importation of generic medicines under very restricted circumstances.

1. Introduction

On 1 January 2005, the agreement on the Trade Related Aspects of Intellectual Property Rights (hereinafter TRIPS) came into force in Egypt, which is now bound by international law to implement its duties under this agreement in order to ensure full protection of intellectual property rights, including copyright, trademarks and patent rights.

A large proportion of modern drugs enjoy patent protection in developed countries, allowing multinational companies a monopoly over the production and sale of these drugs. However, generic drugs (manufactured in developing countries with or without the permission of the patent owner) have been utilised across the third world to reduce prices of essential drugs.

Traditionally, many developing countries do not provide patent protection, or provide only limited protection, for pharmaceutical products and Egypt has been one of the countries that has granted limited protection to pharmaceutical products. However, as the agreement on the trade related aspects of intellectual property (TRIPS) comes into force in many large developing countries in 2005, including in Egypt, these countries will have to extend full protection to pharmaceutical products.

Many of the medicines in the developing world are generic medicines manufactured by a process of reverse engineering in countries such as India or Brazil.[1] For countries that have relied on this supply of essential drugs the implementation of the TRIPS agreement will have a retrogressive effect on the delivery of essential drugs.

Even for countries that have generally relied on voluntary licences, such as South Africa or Egypt, the international enforcement of TRIPS limits the options available to the state in the face of a health crisis. Furthermore, for the previously mentioned countries, the reduction in supply of generic medicines from countries with a large generic drugs industry like India and Brazil may have the effect of increasing global prices for medicines which will, in turn, have a negative effect on countries where the local industries rely on voluntary licences.

This policy paper examines the normative rules of TRIPS as part of international law and the TRIPS compliant legislation on pharmaceutical products introduced by the Egyptian government. The paper analyses the expected effect of TRIPS on the ability of the Egyptian government to fulfil its legal obligations to protect its citizens' right to health. It concludes with

[1] Drahos P, "Access to medicines: after Doha" *Trade hot topics Commonwealth* Issue No. 20.

recommendations to the Egyptian government and other actors on policies that should be adopted to avoid the adverse effect of the agreement on people's access to essential medicines.

The policy paper also aims at raising public awareness on the different aspects of the TRIPS and its effects on the right to health in light of the apparent lack of information provided by the government on the issue, and its failure to involve civil society and the public in planning for the phase following the TRIPS entrance into force.

2. Intellectual Property

TRIPS is one of the World Trade Organisation (WTO) agreements that underpin the international trade system. Intellectual property has been recognised, in various forms and with different levels of protection, since the eighth century A.D. in China and the sixteenth century in Europe.[2]

Originally intellectual property grew out of a perceived need to protect the expression of ideas (cultural documents protected by the Chinese emperors, for example). However, in Europe much of the development of the concept of intellectual property revolved around trade marks (which are difficult to define as an expression of a creative idea) and patents (which are concerned more with invention than with expression). Thus copyright, which more strictly deals with expression and is more easily perceived as an individual right, is confused with patents, which are more the result of industrial research and investment.

This policy paper concentrates on patents and invention and the legal protection of the investment in invention. There are circumstances under which trade marks, or even copyright, may affect the state's obligations and capacity to protect the rights to life and to health, but the current debate over access to drugs is dominated by the question on whether or not to protect the rights of patent holders to essential medicines in developing countries, and this policy paper will concentrate on this aspect.

[2] Musungu, F "The right to health in the global economy, reading human rights obligations into the patent regime of the WTO-TRIPS agreement," in *International yearbook of regional human rights masters programmes* (2001) 194 208 – 209.

3. The Justifications for Patent Protection

It is argued that patent protection is an incentive to inventors to invent and to disclose their inventions to the public. This is also expressed as a societal contract between the inventor and the rest of society allowing the inventor certain, limited, rights to a monopoly over the commercial exploitation of the patented product or process. The effect of patent protection can best be explained as follows:

> The patent … does not grant the patentee the right to own or use the invention, as the patentee (already) possesses this right; a patent grants only the right to exclude others from using the invention.[3]

It is argued that patent protection encourages research and development of pharmaceuticals (R&D) because the money raised from patents is necessary for carrying out costly research and testing of the pharmaceutical products.[4] It has thus been argued that "pharmaceutical patents are justifiable within international human rights law, as they promote R&D which is essential for the future enhancement of rights to life and health."[5] Denying patent protection to drug companies, the argument goes on, will decrease their income flows and since it is the companies that determine how to absorb revenue losses pharmaceutical companies may decide not to allocate funds to R&D.[6]

4. Criticism of Patent Protection

Patent protection leads to a rise in drug prices keeping drugs out of reach of people in developing countries.[7] Generic drugs are less expensive than the patented, brand-name types. This means that a wider market for generics will give access to more people – especially in developing countries – to essential medicines.[8]

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[3] *Id*., at 211. See also referred to therein, Ackiron E (1991) at 148.
[4] Joseph, S, "Pharmaceutical Companies and Access to Drugs: the "Fourth Wave" of Corporate Human Rights Scrutiny," *25 Human Rights Quarterly 425* (2003) 428 at 431.
[5] *Id*., at 432.
[6] *Id*., at 439.
[7] See generally the report by Medecins Sans Frontieres (MSF) "Surmounting Challenges : Procurement of Antiretroviral Medicines in Low- and Middle-Income Countries, The Experience of Medecins Sans Frontieres" (2003) available from the MSF website <www.msf.org>, on the effect of generics on medicine prices. See also MSF, "Doha Derailed: A Progress Report on TRIPS and Access to Medicines, Medecins Sans Frontires Briefing for the 5th WTO Ministerial Conference, Cancun 2003" , "At the end of the day, the supply of affordable versions of new medicines would slow to a trickle, with developing countries having few alternatives to the high prices and long-term monopolies of originator companies …. The experience with antiretrovirals (ARV) and other drugs has amply shown that as competition rises, prices fall."
[8] Wojahn, P, "A Conflict of Rights: Intellectual Property Under Trips, The Right To Health, And AIDS Drugs," 6 UCLA J. Int'l L. & For. Aff. 463 (Fall 2001/Winter 2002) 465.

The strict application of patent rights has an adverse impact on access to essential medicines as it limits the possibility of purchasing affordable non-patented drugs.[9] Moreover, "[e]nforcement of WTO rules will have a negative effect on local manufacturing capacity and will remove a source of generic, innovative, quality drugs on which developing countries depend."[10] The inflated drug prices will prevent poorer people especially in developing countries from accessing essential drugs threatening – and in some instances violating – their right to life and health.[11]

It is also argued that relying on patent protection for R&D will impede adequate research on medicines in developing countries for tropical diseases such as malaria, because of lack of resources in developing countries which discourages pharmaceutical companies from conducting costly research on drugs that will not pool the costs of this research.[12] It is necessary, therefore, that government and academic institutions, both in developed and developing countries, continue to allocate resources to research and development, to ensure that all diseases receive the attention that is required.

It is also argued that R&D – the raison d'être of patents – is largely conducted by public funds in public laboratories and universities and does not justify the monopolies multinational pharmaceutical companies will benefit under the TRIPS.

5. Patents and the Right to Health

Because of the industrialised nature of modern society, the implementation of many rights protected at international and national law imply the provision of patented products and products manufactured by a patented process.[13] The health of the individual may depend on the provision of certain medicines or drugs which are protected by a patent and the manufacture and sale of which are legally monopolised by the patent holder. It is the potential conflict between the rights of the person to receive food or medicine and the right of the patent holder to exercise a monopoly over the patented product/process that defines the extent of the competing rights. The conflicting duties of the state – to protect the rights of the patent holder and the rights of the patient – define the obligations of states under international law.

These conflicting duties gave rise to the "flexibilities" within the original TRIPS agreement as it was seen that individual states would have to

[9] Hoen, E "Public Health and International Law: TRIPS, Pharmaceutical Patents and Access to Essential Medicines: A Long Way from Seattle to Doha" *3 Chicago Journal of International Law 27* (Spring 2002) 29.
[10] *Id*., at 29.
[11] Joseph S (note 4 above) at 432.
[12] For the 1,223 new drugs approved form 1975 until 1997, only one percent treats tropical diseases.
[13] Musungu F (note 2 above) 211.

determine for themselves in what ways the conflict between the different rights were determined.

6. TRIPS

6.1 Introduction

TRIPS was one of the agreements reached after the Uruguay round of the General Agreement on Trade and Tariffs and was signed, as part of the Final Act, by 125 governments.[14] Provisions of TRIPS reflect the strong US influence in the negotiation rounds. They are a reflection of American patent laws, in particular Article 27 which applies to new technologies that had not previously been included such as pharmaceuticals.[15]

> Many experts from developing countries criticized these provisions, arguing that the impact of IPR [intellectual property rights] protection will vary significantly from country to country.[16]

Trans-national companies (TNCs) pressurized developing countries, through the governments of developed countries, during TRIPS negotiations, in favour of strict intellectual property rules.[17] Subsequently pressure has been placed on members of TRIPS to accept obligations beyond those enshrined in the TRIPS.

Pharmaceutical TNCs that dominate the international pharmaceutical industry have monopolies over patents and charge high prices for essential drugs. The pharmaceutical industry is dominated by a small number of large firms, especially since number of mergers of pharmaceutical companies.[18]

6.2 Enforcement

The major effect of the TRIPS agreement was to introduce a dispute settlement forum for intellectual property that was parallel to the one enforced by the World Intellectual Property Organisation (WIPO), which developed countries considered ineffective.[19] It requires states to introduce

[14] *Id*., at 213.
[15] Wojahn P (note 8 above) 479.
[16] *Id*.
[17] Musungu F (note 2 above) 215.
[18] Joseph S (note 4 above) 428.
[19] The importance of the WTO dispute resolution procedure and its place in international law is demonstrated by the comment that it was "the most important change in the jurisprudence of the global economy in the second half of the twentieth century," see Nicholls P, "GATT doctrine," *2 Virginia Journal of .International Law* (1996) 380 quoted by Shanker D "The Vienna convention on the law of treaties, the dispute settlement system of the WTO and the Doha declaration on the TRIPS agreement," *Journal of World Trade* 36(4) (2002) 721 723.

legislation to create enforcement procedures and introduces an international dispute resolution mechanism (international enforcement procedures).

> The Agreement lays down certain general principles applicable to all IPR enforcement procedures (and) …. (t)he Agreement makes disputes between WTO Members about the respect of the TRIPS obligations subject to the WTO's dispute settlement procedures. [20]

The dispute resolution system is the international enforcement mechanism for the TRIPS agreement and allows governments to enforce the TRIPS agreement against other states. All international law operates on the basis of agreement and the contracting states to the WTO have agreed to allow disputes relating to the enforcement and protection of intellectual property rights in their domestic law to be determined by a WTO body.

> A dispute arises when a member government believes another member government is violating an agreement or a commitment that it has made in the WTO … Ultimate responsibility for settling disputes also lies with member governments, through the Dispute Settlement Body.[21]

The dispute resolution procedure under the WTO is potentially very serious; the Dispute Settlement Body may decide that sanctions can be levelled against a state,

> If (after the completion of the complaint and negotiations between the parties), no satisfactory compensation is agreed, the complaining side may ask the Dispute Settlement Body for permission to impose limited trade sanctions ("suspend concessions or obligations") against the other side. The Dispute Settlement Body must grant this authorization within 30 days … unless there is a consensus against the request. [22]

The wording of this clause, insisting on consensus for sanctions *not* to be applied, effectively means that once the matter has been through the Dispute Resolution Body and the parties have failed to agree on compensation the complaining party will be entitled to impose sanctions. This is very serious for

[20] TRIPS: A more detailed overview of the TRIPS agreement, Overview: the TRIPS Agreement, WTO website, <http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm>, accessed on 22 August 2004.
[21] Dispute settlement, WTO website, <http://www.wto.org/english/tratop_e/dispu_e/dispu_e.htm>, accessed on 22 August 2004.
[22] Understanding the WTO – A unique contribution, at WTO website <http://www.wto.org/english/thewto_e/whatis_e/tif_e/disp1_e.htm>, accessed on 22 August 2004.

developing countries where sanctions may be disastrous to their national economy. [23]

Another element of the TRIPS agreement is the protection under articles 3, 4 and 5 of the national and most-favoured-nation rules. These rules can be described as follows,

> "(w)hile the national treatment clause forbids discrimination between a Member's own nationals and the nationals of other Members, the most-favoured-nation treatment clause forbids discrimination between the nationals of other Members."[24]

This has the effect of restricting Egypt's ability to give preference to its own citizens and companies and to give preference to citizens or companies of countries with which it has trade agreements.

However the substantive aspects of the TRIPS agreement raise many more contentious issues, especially regarding the right to health. Developing and least developed countries were put under pressure to accept the TRIPS agreement and the procedure did not receive input from public health experts although the developed world's pharmaceutical lobby was very active during the negotiation of TRIPS, making the agreement reflect the requirements of pharmaceutical companies rather than public health.[25]

These contentious issues include the manner in which flexibilities (see below) can be applied by states and which potential flexibility should be applied in which circumstances. Much of the debate arose around the supply of cheap anti-retroviral drugs to poor countries in sub-Saharan Africa but less attention has been given to governments' duty under international law to provide essential medicines.

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[23] Musungu F (note 2 above) at 215 and cited therein, Abbott F, "The TRIPS Agreement, access to medicines and the WTO Doha Ministerial Conference" (2001) *Occasional Paper 7* Geneva: Quaker United Nations Office and Elliot R "WTO needs reminding we all deserve health care" *Toronto Star* 11 November 2001.

[24] TRIPS: a more detailed overview of the TRIPS agreement, Overview: the TRIPS Agreement, WTO website, <http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm>, accessed on 22 August 2004.

[25] See Musungu F (note 2 above) at 214 and quoted therein, Howse and Mutua "Trading in human rights: the human rights obligations of the WTO" ICHRRD (April 2000), Abbott F(note 23 above), Velasquez G and Boulet P, *Globalisation and access to drugs: Perspectives on the WTO/TRIPS agreement* (1999).

6.3 TRIPS Flexibilities

6.3.1 Introduction

There are a number of flexibilities in the TRIPS agreement relating to the working of patent protected products.[26] Article 7 states that the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, and should be to the mutual advantage of producers and users of technological knowledge. Article 7 refers to a balance of rights and obligations, allowing states to balance their obligations to patent holders with their obligations under human rights treaties. Article 8 recognizes the rights of member states to adopt measures for public health and other public interest reasons and to prevent the abuse of intellectual property rights.[27] These guidelines and principles should underlie any interpretation of the TRIPS agreement, especially the flexibilities contained in Articles 30 and 31 of the agreement which will be discussed in detail in the following section.

6.3.2 Article 30

Under article 30 member states are allowed to provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably prejudice the interests of the patent owner.

While a literal interpretation of Article 30 would allow it to be applied to compulsory licensing and parallel importation, developed countries have resisted this interpretation because of the lack of controls on such procedures under Article 30.

Arguments can be made for either interpretation – Article 30 is similar to Article 9(2) of the Berne Convention for the Protection of Literary and Artistic Works which is relied on for parallel importation, supporting a broad interpretation of the article. But the presence of the more detailed Article 31 can be interpreted as limiting the extent of the exceptions under Article 30. Much of the debate around the solution to Article 6 of the Doha Declaration was based on whether to apply Article 30 (which would have allowed a more flexible system) or Article 31 (which is more limiting on the powers of the governments).[28]

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[26] See the appendix of this policy paper for relevant provisions of the TRIPS agreement.
[27] The WTO "A More Detailed Overview of the TRIPS Agreement," at <http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm>, accessed on 22 August 2004.
[28] See Shanker D (note 19 above) at 721, Haag T, "TRIPS since Doha: How far will the WTO go toward modifying the terms for compulsory licensing?" (2002) 84 J. Pat. & Trademark Off. Society 945. See also Blacket A, "Whither social clause? Human rights, trade theory and treaty interpretation" (1999) 31 *Columbia Human*

Ultimately an interpretation of the Ministerial Declaration of 30 August 2003 indicates that the WTO prefers to deal with the issue under Article 31.

Article 30 of TRIPS has been interpreted more restrictively to allow early working – the *Bolar* exception to patent protection.[29] This allows a potential competitor to use a patented invention while it is still protected but only for research and registration of the generic (crucial in the case of generic medicines).

This fits the criteria set out by article 30 as,

> generic producers are not allowed to commercially exploit the invention before the expiration of the patent term and there is no prejudice to the legitimate interests of the patent owner."[30]

This exception is coming under increased pressure from developed countries during trade negotiations where TRIPS plus agreements often limit its application and extend patent protection to "compensate" for registration delays.

6.3.3 Article 31

Article 31 of the agreement applies to compulsory licensing, parallel importation, and government use[31] but makes these procedures subject to conditions aimed at protecting the interests of the patent owner.

Compulsory licensing has, subject to restrictions, been accepted in international law since the Paris Convention for the Protection of Industrial Property of 1883.[32] Compulsory licensing and government use, which is a variant of compulsory licensing in which the government licences itself to

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Rights Law Review I, and Drahos P (note 1 above) at page 3, who states that, "basically all developing countries were more favourably disposed to an Article 30 approach than either the US or the EU." For a view that Article 30 is inapplicable to public health situations see the EU submissions to the WTO in the *Canada – Patent protection of pharmaceutical products (Canada – Patent Protection)*, WTO doc. WT/DS114R. dated 6 March 2000, Report of the panel, where the EU stated that, "Article 30 of the TRIPS agreement was not a clause aimed at solving the public health problems of the entire world." See also the decision in the *Canada – Patent Protection* case, which accepted the EU argument that object and purpose was irrelevant in interpreting the substantive articles of the TRIPS agreement. For a contrary interpretation of the TRIPS agreement see generally Botoy E, "Potential and substantial benefits of the TRIPS agreement to the Member countries of the African Intellectual Property Organisation in the patent field," *The journal of world intellectual property* 4(1) (2001) 91 and especially at 95, "In fact, the TRIPS agreement disapproves of too strict a protection of private rights. Exclusivity of the rights are granted on the one hand, but on the other hand they strive to maintain a fair competition and an open market."

[29] See Shanker D (note 19 above) at 737 – 738.

[30] Musungu F (note 2 above) 222.

[31] Government use is specifically allowed under article 44(2) of TRIPS.

[32] Musungu F (note 2 above) 219. See also article 5 (A) (2) of the Paris Convention.

produce the medicines, are permissible under TRIPS, including for (but not limited to) public health emergencies.[33]

Article 31 of TRIPS sets out a number of restrictions on the exercise of the state's right to issue a compulsory licence, including the restriction that goods produced under a compulsory licence should be for "predominantly" local use, the requirement to pay compensation and the need for evidence of an attempt to receive a voluntary licence at commercial terms.[34] While one of the requirements for a compulsory licence is reasonable compensation for the patent holder, this is subject to the rider adequate "in the circumstances of the case," and generic medicines made under compulsory licences are markedly cheaper than brand name medicines.

6.4 Difficulties inherent in the TRIPS Agreement

The TRIPS Agreement provides developing countries with a number of obstacles, even in making use of the flexibilities of the agreement. In this context, attention should be drawn to two difficulties that will directly affect developing countries: the twenty-year term of protection of patents and difficulties in implementing compulsory licensing.

The protection of a patent for twenty years[35] gives an unnecessarily prolonged protection to the patent, depriving developing countries from the benefits of the product for this period.[36] The term of patent protection under TRIPS prevents companies other than the patent holder from producing generics, maintaining high prices of drugs and has a negative impact on access to essential medicines.[37] In the meantime, it gives the advantage to pharmaceutical companies to enjoy the profits of the patented medicine for a longer period that this necessary to cover the R&D costs.[38]

While legal impediments against compulsory licensing inherent in the TRIPS agreement are minimal, political threats exerted by pharmaceutical companies especially multinationals, have so far prevented the majority of developing countries from manufacturing generics.[39] For instance, when the South African government attempted manufacturing AIDS drugs by compulsory licensing, multinational companies took the government to court,

[33] *Id*., and Article 31 of TRIPS as read with Article 5(A)(2) of the Paris Convention.
[34] Although in public emergencies some of these requirements are relaxed, for example the requirement to prove attempts to receive a licence on commercial terms is not applicable in cases of public emergencies – Article 31 (b).
[35] TRIPS agreement, Article 33.
[36] Hamed, Mohamed Raouf. *Huquq Al Melkeya Al Fekreya: Ro'ya Janubeya Mustaqbaleya* [Intellectual Property Rights: A Southern Prospective Reading] (Cairo: Academic Bookshop, 2002), at 22.
[37] *Id*., at 23.
[38] *Id*., at 22.
[39] *Id*., at 24.

a case that took years to settle, while thousands of people died of AIDS.[40] Although the case was finally withdrawn by the pharmaceutical companies (due partly to international support for South Africa's right to compulsory licensing),[41] this incident remains a strong example of the practical impediments to using the right of compulsory licensing.

6.5 The Doha Declaration[42]

> The Doha declaration affirmed what TRIPS already permitted, namely the right of states to issue compulsory licences.[43]

Public health crises like the HIV/AIDS epidemic, malaria or tuberculosis constitute 'emergencies' under TRIPS allowing the use of exceptions in Article 31 of the agreement. The Doha Ministerial Declaration on the TRIPS and Public Health unambiguously states that HIV/AIDS, malaria, tuberculosis and other epidemics are continuing public emergencies in developing countries allowing exceptions to patents.[44]

The Doha Declaration reaffirmed the right of each state to grant compulsory licenses and determine the conditions of these licenses.[45]

While HIV/AIDS, malaria and tuberculosis were directly referred to in the Doha Declaration, Hepatitis C can be defined as a public health emergency in Egypt as statistics show that around 10-15% of the total population are infected with Hepatitis C.[46]

The Doha declaration does not limit itself to the three health crises listed in the declaration and its implementation will depend on local conditions. This means that Egypt – according to the Doha Declaration – may make use of the TRIPS flexibilities by taking action to deal with the Hepatitis C crisis. This corresponds to a recommendation in a study published by the Egyptian Council of Ministers' Information and Decision Support Center in February 2003 that urged Egyptian officials to "expand the list of diseases that enjoy an

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[40] *Id*., at 23.
[41] *Id*., at 34.
[42] Declaration on the TRIPS agreement and public health, Ministerial Conference, fourth Session, Doha 9-14 November 2001, WT/MIN (01)/DEC/W/2 dated 14 November 2001 (the Doha Declaration).
[43] Drahos P (note 1 above).
[44] Doha Declaration, para. 5.
[45] *Id*.
[46] See Mezban Z and Wakil A "Hepatitis C in Egypt," at <http://www.hcvadvocate.org/Medical_Writers_Circle/Wakil-1.htm>, accessed on 30 November 2004. The infection rate in Egypt is recognised internationally as an epidemic, see Armstrong G, "Commentary: Modelling the epidemiology of hepatitis C and its complications," *International Journal of Epidemiology* 2003;32:725–726, accessed at <http://www.archido.de/eldok/ejournals/internationaljepide_commentary_hepc_2003.pdf> on 30 November 2004.

international interest for combating them to include prevalent diseases in Egypt."[47]

The Doha declaration was important because the WTO specifically said that governments could issue compulsory licences for the manufacture of generic drugs. The declaration is essentially a clarification or interpretation of the TRIPS agreement and was the basis for the declaration of a state of emergency in Zimbabwe and the undertaking to issue compulsory licences in that country. The declaration thus assured developing countries that the granting of compulsory licences would not lead to litigation before the WTO dispute settlement bodies.[48]

The Doha declaration also extended the deadline for least developed countries from 1 January 2006 to 1 January 2016.[49] However, least developed countries are unlikely to have any manufacturing capacity and thus the extension to 2016 may be an empty gesture.

6.6 Parallel importation and the Ministerial Decision of 30 August

Parallel importation is a process whereby a product is imported into a country where it is patent protected from another country on the grounds that the patent holder was paid the first time it was sold.[50]

Parallel importation is a suitable solution for countries that do not have the infrastructure to manufacture generics through compulsory licensing. It is theoretically permissible for these countries to grant compulsory licenses for importing drugs. However, the trap is that TRIPS does not allow parallel importation of generics, which shuts the door for a source of cheap medicines.[51]

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[47] Nafi', Medhat, et al., "Athar Tatbiq Etifaqiat TRIPS 'Ala Sena'at Al-Dawa' fi Misr" [The Impact of TRIPS application on the pharmaceutical industry in Egypt] (Cairo: Information and Decision Support Center, February 2003), at 42.

[48] Before the Doha Declaration many developed states had taken the position that societal interests were irrelevant in interpreting the TRIPS agreement and this interpretation would have restricted the possible interpretative options of developing nations. Thus the EU stated that, " … the TRIPS negotiating parties had taken societal interests into consideration when agreeing on the balance of interests which were enshrined in the TRIPS agreement. Consequently individual WTO members couldn't now rebalance these interests unilaterally by modifying the level of protection provided for in the Agreement," in *Canada – Patent protection*, para 4.30(a) indent 3. The importance of the Doha Declaration in emphasising the rights of individual states to interpret the flexibilities in their interest must not be ignored, and by thus redefining the TRIPS agreement the Doha Declaration gave effect to the flexibilities, which otherwise would have been ineffective. The Doha Declaration essentially confirms the opinion that, "… countries are endowed by the TRIPS agreement with the right to adopt measures necessary to protect, for instance, public health and nutrition, and to promote the public interest in sectors of vital interest to their socio-economic and technological development in order to prevent the abuse of intellectual property by right holders," (see Botoy, note 27 above) 95.

[49] See Drahos P (note 1 above) 2 for a comment on this flexibility.

[50] Musungu F (note 2 above) 220.

[51] Joseph S (note 4 above) 450.

While TRIPS allows states to legislate to allow parallel importation from states where the goods are produced by the patent holder, or under a voluntary licence, the provisions of Article 31(f) of TRIPS restricts compulsory licences predominantly to local use, limiting the scope of parallel importation.[52]

This means that parallel importation of medicines manufactured under a compulsory licence would *prima facie* breach the TRIPS agreement. It was this situation that gave rise to article 6 of the Doha Declaration and the Ministerial Statement of 30 August 2003.[53]

Article 6 of Doha called on states to create a system to allow developing and least developed states to import medicines from other states manufacturing generic drugs to allow states without manufacturing capacity to benefit from the TRIPS agreement. The Decision of 30 August purports to be an answer to this instruction and sets up a procedure for the parallel importation of medicines.

But this system has been criticised as excessively restrictive and unworkable.[54] Rights groups criticized this accord on the basis that it gives impractical solutions to developing countries, furthering the advantages of pharmaceutical companies and Western countries.[55]

Technically the decision waives the obligations of members of the WTO under sub-articles 31(f) and 31(h) (the conditions that the products be predominantly for the local market and the requirement to pay compensation respectively) but subject to certain conditions. These conditions are onerous and include a strict notification procedure and the issuance of compulsory licences by both the exporting and importing countries.[56]

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[52] Drahos P (note 1 above) 2.

[53] Drahos P (note 1 above) 3, Gopakumar K, "The WTO deal on cheap drugs, a critique," *The journal of world intellectual property* 7(1) (2004) 99 100 and James J "Drug patents and developing countries: problems remain," *AIDS Treatment News* Issue 385 November 2002. The Ministerial decision is document number WT/L/540, 2 September 2003.

[54] Gopakumar K(note 53 above) 99, "A careful reading of the Decision and its accompanying General Council Chairperson's Statement shows that once again the developing countries have become victims of arm twisting by the West," and at 106,"(t)hus the decision has opted for a cumbersome route, ignoring a simple solution under Article 30 of TRIPS …," and at 112, "(t)he procedural, legal, and institutional requirements to implement the Decision make it an ineffective as well as an impractical solution for such an implementation."

[55] *Al-Hayat*, "Monazamat Al Tijara Tobih lel dowel al faqira estirad adweya badila qalilat al kolfa" [WTO allows poor countries to import cheap medicines], 31 August 2003, pp. 1, 6.

[56] Gopakumar K (note 53 above) 105.

6.7 Effect of compulsory licensing on availability of medicines

The power to grant a compulsory licence does not necessarily entail the granting of licences and sometimes the mere threat can be enough to bring down prices.

An example of the employment of the threat of the use of compulsory licences in price negotiations was during the anthrax scare in the USA and Canada in the aftermath of 11 September 2001 attacks against New York and Washington. The USA and Canada exerted pressure on Bayer to sell them its patented anti-anthrax drug 'Cipro' at a discounted price in 2001 or they would – in response – allow the production of generics. Both governments made a lot of fuss about the amount of profit the company was making out of the drug. In response, Bayer sold the drug to the USA and Canada at half the price. The anthrax scare in North America led the US and Canada to violate the intellectual property rules they always advocated and pressurized developing countries – facing real public health threats – to accept.[57]

It is often argued that any interference with the full enjoyment of patent rights will negatively affect access to essential medicines because companies will scale down research and development on essential drugs relevant to third world countries. However, the amounts spent on R&D by pharmaceutical companies are disproportionately small compared to amounts spent on other sectors, especially marketing.[58]

Much of R&D in the field is done in public laboratories by governmental funding.[59] Some big pharmaceutical companies spend most of its R&D budget on 'safe' research of formulas already known to be profitable and to lucrative rather than life-threatening cases (e.g. obesity rather than heart diseases).[60] This means that these companies can cut down their profits, reducing patented-drugs prices, without cutting R&D expenditure.[61] It also means that the use of generic drugs is unlikely to be the determining factor in whether new drugs are developed for diseases affecting third world countries.

6.8 TRIPS plus

Developing countries are under pressure, usually by the United States of America, to accept conditions that go beyond TRIPS obligations or the so-called 'TRIPS plus'.

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[57] Joseph S (note 4 above) 445.
[58] *Id*., at 432.
[59] *Id*., at 433.
[60] *Id*., at 435.
[61] *Id*.

> TRIPS plus is a non-technical term which refers to efforts to extend patent life beyond the twenty-year TRIPS minimum, to tighten patent protection, to limit compulsory licensing in ways not required by TRIPS, or to limit exceptions which facilitate prompt introduction of generics.[62]

Another major concern is raised by the technical assistance provided by WIPO and industrialised countries to the developing world which disregards the health needs of the latter's populations,[63] and does not guide them to use TRIPS flexibilities.

> Both of these institutions are under strong pressure to advance the interests of large companies that own patents and other intellectual property rights.[64]

> Indeed, it is possible that the worst effect of TRIPS on medicinal access has been its use, and probable abuse, in political rhetoric to bolster sanction threats, rather than its actual provisions, bearing in mind that the exceptions have rarely been authoritatively interpreted.[65]

This happens despite the fact that developed countries have a duty under international human rights law to assist developing countries to ensure the protection of these rights. Recently the United Nations Committee on Economic, Social and Cultural Rights, the international body in charge of interpreting and monitoring the implementation of the International Covenant on Economic, Social and Cultural Rights (ICESCR), queried Denmark and Italy about what these countries were doing to ensure that developing countries fully utilised the flexibilities in TRIPS. Both Denmark and Italy indicated that they supported the full use of the flexibilities inherent in TRIPS, but the most important development is that the Committee has decided to make developed countries report on their implementation of their duty to assist developing countries, hopefully indicating that more attention will be given to this in future.[66]

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[62] Hoen E (note 9 above) 29.
[63] *Id*., at 30.
[64] *Id*.
[65] Joseph S (note 4 above) 430.
[66] "UN Committee on Economic, Social and Cultural Rights Considers the Impact of Intellectual Property Rules on Human Rights," available at www.3dthree.org, accessed on 30 November 2004.

6.9 Summary on TRIPS and its flexibilities

There are a number of flexibilities inherent in the TRIPS agreement that make the agreement appropriate for the protection of the human right to health. These flexibilities include:

- The power to issue compulsory licences for essential medicines,
- The power to import generic medicines through the WTO system.

However these flexibilities need national application – both in the law and in practice. It does not meet the obligations of a state under the ICESCR to include provisions in a country's Patents Act allowing compulsory licensing but failing to issue compulsory licences and/or import generics.

The obligation under the ICESCR is to provide access to essential medicines and the flexibilities under TRIPS are merely one of the methods a state may use, especially after 1 January 2005, with the TRIPS coming into effect for countries like Egypt, to protect this right. [67]

7. Legal Protection of Health and Intellectual Property in the Egyptian Legal System

7.1 Egypt's Obligation to Protect the Right to Health

The 1971 Egyptian Constitution, in articles 16 and 17, obligates the State to provide health services and health insurance for its citizens.[68]

Notably, health services are directly regulated by the Constitution, which affirms that these services are subject to direct execution, without requiring additional laws to be passed by the legislature, whereas in the case of health insurance one finds the phrase "in accordance with the law" which indicates that the legislature must regulate it in the form of laws, statues, or regulations. The legislature, however, is bound by the obligation not to violate or abrogate any rights while drafting these laws; any such violation would render such

[67] Recently the UN Committee on Economic, Social and Cultural Rights has recommended that Chile make generic medicines available to its population utilising the flexibilities in TRIPS, see note 66 above.

[68] Art. 16, Egyptian Constitution: "The State shall provide cultural, social and health services, and shall make a special effort to ensure villages easy and regular access to them, to improve the villages' standard [of living]."
Art. 17: "The State shall provide social and health insurance, and disability, unemployment and retirement benefits to all citizens, in accordance with the law."

laws unconstitutional.[69] The Supreme Constitutional Court has adopted the concept of the progressive realization of economic and social rights.[70]

Egypt has also ratified the ICESCR in 1982, making the provision of this treaty part of the domestic legal system according to article 151 of the Constitution.

The ICESCR protects the right to access to essential medicines under article 12(1). According to the authoritative interpretation of this provision by the UN Committee on Economic, Social and Cultural Rights' General Comment no. 14, the state has an obligation to make medicines available and affordable for individuals within its jurisdiction. States Parties to the ICESCR also have an obligation to protect individuals within their jurisdictions from violations of the right to health by third parties. This means that the failure of the government to make patented medicines economically accessible to individuals is a violation of the right to access to medicines.[71]

While the ICESCR protects the right to intellectual property under article 15(1), it gives priority to the right to health and access to medicines. Thus, if the strict application of patent protection will result in a violation of the right to health, precedence should be given this right.[72]

Consequently, the Egyptian government has an obligation to respect, protect and fulfil its obligations under the ICESCR including access to medicines. This obligation to make medicines affordable and economically accessible to individuals still stands after TRIPS has come into force; requiring Egypt to balance its obligations under the ICESCR and under the TRIPS agreement.

Egypt has also ratified the African Charter for Human and Peoples' Rights in 1984. This treaty provides in article 16 that "Every individual shall have the right to enjoy the best attainable state of physical and mental health". The Charter also obligates states parties to "take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick."

Under Egypt's domestic law, Presidential Decree No. 242/1996 on the Regulation of the Ministry of Health and Population[73] specifies the goals of the Ministry of Health, from "preserving citizens' health" by means of

[69] In this regard see Supreme Constitutional Court decision no.34/13, on 20 June 1994, the *Official Gazette* , issue no. 27, 7 July 1994.
[70] See in this regard the Supreme Constitutional Court decision no. 34/15, on 2 March 1996, the *Official Gazette*, issue no. 11 *bis(a)*, 14 March 1996.
[71] Joseph (note 4 above), at 439.
[72] Report Of The Special Rapporteur on The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Paul Hunt, On His Mission To The World Trade Organization, UN Doc. E/CN.4/2004/49/Add.1.
[73] Presidential Decree 242/1996, the *Official Gazette*, Issue 30, 1 August 1996.

"providing preventive and therapeutic health services"[74] to "working towards improving the health of individuals."[75]

The Decree also specifies the full range of the Ministry's mandate, which includes "working towards making medicines available and taking the necessary steps to ensure their quality and efficacy."[76]

Egyptian law establishes the Supreme Council for Therapeutic Health Insurance Care as well as the Health Council, which is responsible for creating a general plan for ensuring medical treatment for all citizens and has a supervisory role over the delivery of health care in the country.

A number of healthcare systems are employed by the Ministry of Health to fulfil its responsibilities. These may be summarized as the health insurance system, treatment at the state's expense system, and the public hospital treatment system. While health insurance covers all employees in the government and public sectors and most of them in the private sector it excludes agricultural and domestic workers, the self-employed, craftspeople and businesspeople. The system, in its current form, has numerous problems especially the State's reluctance to contribute towards the costs of health insurance for some categories of persons and not for others.

Under international aid agreements, some hospitals in Egypt provide free treatment for road accidents, burns, and cases where the patient is unable to meet the cost of diagnosis and treatment, based on the rules defining an 'underprivileged' patient as set forth by the board of directors of the hospital.[77]

[74] *Id.*
[75] *Id.*
[76] *Id.*
[77] Art. 24 of the regulations appended to the Health Minister's Decree no 120/2000, the *Official Gazette*, issue no. 135, 18 June 2000.

7.2 Registration of Medicines

Article 59 of Law 127/1955 on the practice of pharmacy stipulates that pharmaceutical products (medicines)[78] may not be traded in unless they are registered with the Ministry of Health.[79] This condition applies both to locally prepared and imported medicines. While there is an extensive registration procedure this registration (as a medicine) has nothing to do with the patent protection accorded to the drug.

Ministerial Decree 174/1974 on the re-registration of pharmaceutical products[80] makes it compulsory to re-register products every ten years and if the concerned party fails to submit a re-registration request, the permit is cancelled and remanufacture or importation is no longer permitted.

7.3 Price controls and importation of drugs

Article 10 of Law 113/1962 Concerning the reorganisation of import, manufacture and trade of medicines and medical requisites and chemicals provides that

> In exception to the provisions of Law 163/1950, hereinbefore mentioned, medicines, medical requisites and chemicals shall be priced, or the percentage of profit in them shall be determined, whether they are locally produced or imported, by a Committee to be formed by virtue of a decree of the Minister of Health in agreement with the Ministers of Industry and Supply. Decisions taken by the Committee shall be issued by the Minster of Health in agreement with the Minister of Industry. [81]

This section is the basis for the price control regime of the Egyptian government and gives a committee of the government the power to determine the price, or the percentage mark up, on pharmaceutical products.

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[78] Article 58 of Law 127/1955 defines special pharmaceutical products as: "suspensions or compounds that contain, or are described as containing, one or more substances with medical characteristics, namely helping to cure or prevent human ailments, or use for any other scientific purpose, even if this is not mentioned explicitly when they are prepared for sale and they are not mentioned in any published pharmacopoeias and their official appendices." Article 62 of the law defines pharmaceutical products found in pharmacopoeias as "preparations and combinations found in the most recent editions of the pharmacopoeia, decreed by the Minister of Health; these may be prepared in pharmaceutical factories or dispensed in pharmacies without need for registration." The law similarly makes a distinction between "special" and "pharmacopoeic" pharmaceutical products; the first requires registration only, while the second is subject to the conditions of informing the Ministry and obtaining its approval for the preparation of drugs mentioned in the pharmacopoeia.

[79] Art. 59 of Law 127/1955: "It is forbidden to trade in pharmaceutical products, whether prepared locally or imported, until they are registered with the Ministry of Health and such products may not be registered unless the registration request is submitted by a pharmacist, physician, veterinarian or dentist, licensed to practice their profession in Egypt, or else by the owner of a local pharmaceuticals factory or the owner of a foreign factory based abroad, or their agents…"

[80] *Al-Waqa'i' Al-Masriya,* issue no. 205, 12 May 1974.

[81] Translation by The Middle East Library for Economic Services.

Currently, the Higher Committee for Pharmaceutical Policies[82] lays the foundations for pricing pharmaceutical products after the Subcommittee for Pharmaceutical Pricing[83] conducts the necessary pharmaceutical pricing studies in light of the financial costs, according to the pricing regulatory rules laid down by the Minister of Health.

The import of medicines is supervised by a supreme committee headed by the Minister of Health [84]. Its function is to specify the types of medicines needed by the local market and which have no locally produced substitute, to specify the amount of each type which must be made available according to actual need, giving priority to the categories of drugs that must be subsidized by the State, and to compare the various import bids tendered. The Committee reviews private-sector proposals in light of the medicines which have been approved by the Minister of Health for private-sector import.

The facilitation of access to cheap drugs is one of the obligations of a state under the ICESCR and the African Charter and the use of price controls by Egypt, to the extent that the system is reliable and that drugs are made affordable even to the most disadvantaged in society, would be compliance with this obligation.

However, if the prices agreed on by this committee are unaffordable for a large section of society and this sector of is unable to access medicine through any other scheme (such as health insurance), then the Egyptian government would be in breach of its obligation under the ICESCR.

[82] Formed by Ministerial Decree 179/1994, *Al-Waqa'i' Al-Masriya*, issue no. 126, 8 June 1994. Headed by the Minister of Health, it includes ten members including the Head of the Drug Policy and Planning Center, the Head of the National Authority for Drug Monitoring and Research, the head of the Doctors' Syndicate, the Head of the Central Administration for Pharmaceutical Affairs, and the Head of the Pharmacists' Syndicate.
[83] Currently formed by ministerial decree 96/2004, *Al-Waqa'i' Al-Masriya*, issue no. 103, 12 May 2004. Headed by the Head of the Drug Policy and Planning Center, it has ten technical consultants as members.
[84] Formed and mandated by Ministerial Decree 41/1996. *Al-Waqa'i' Al-Masriya*, issue no. 45, 26 February 1996. Headed by the Minister of Health, its membership includes the Head of the Central Administration for Pharmaceutical Affairs, the Head of the Drug Policy and Planning Center and its Information Sector's Director, the Advisor to the Minister of Administrative Development for Funding and Supplies, the Head of the Central Administration for Administrative Development, , the legal advisor to the Minister of Health, the Financial Controller-General, and a representative of the Ministry of Finance.

8. Patent protection in Egypt

In 2002 the Egyptian government repealed the 1949 law on Patents and Industrial Drawings and Designs and replaced it with a new law for the protection of intellectual property rights, namely Law no. 82/2002.

The new law is TRIPS compliant in most of its aspects – it makes no distinction between process and product patents and it extends patent protection to twenty years.[85]

The 1949 law, which remained in force for pharmaceuticals until 1 January 2005, granted patent protection for fifteen years, which could be extended to twenty years in some circumstances, and had a more restricted definition of an invention than either the 2002 law or the TRIPS agreement.[86] The 1949 law did not protect product patents for pharmaceuticals and only allowed a ten year period of patent protection for pharmaceutical process.[87]

In addition to the restricted protection of pharmaceutical patents, and the price control of medicines, the Egyptian government restricted the importation of pharmaceuticals in finished dosage form, and insisted on local licensing of the patents, allowing local production and thus more control over pricing. This appears to be in violation of the WTO agreements as price controls have the effect of interfering with the free trade of goods (pharmaceuticals).[88]

Egypt is likely to come under increased pressure to liberalise its market because of its potential for US pharmaceutical firms as evident from the following assessment by the Pharmaceutical Research and Manufacturers of America (PhRMA)

> Egypt is a significant market - indeed one of the largest - in the Middle East/Africa region. Even under current adverse circumstances, U.S. firms hold an estimated 18 percent share of the Egyptian pharmaceutical market, in a market estimated at more than three quarters of a billion dollars in 1997. If Egypt were to meet its WTO obligations, the U.S. share of the market would likely rise increase to at least 25%, and the market itself would likely show substantial expansion. Until the present time, for example, PhRMA member companies have been unable to move forward with an estimated 300

[85] See articles 1 and 9 respectively
[86] Infro-Pod Research (Middle East) ltd, *Intellectual property – Egypt*, accessed at <http://www.infoprod.co.il/country/egypt2d.htm> on 8 September 2004.
[87] PhRMA, "Issues and policy: International: NTE: Egypt," accessed at <http://www.cptech.org/ip/health/phrma/nte-99/egypt.html> on 8 September 2004.
[88] *Id.*

> million dollars in planned investments in Egypt's pharmaceutical sector. In addition, given its location and large population, if Egypt were to adopt a modern patent law and market-based pricing, it would become a likely regional center for multinational pharmaceutical production. Accordingly, PhRMA estimates current losses in Egypt as in excess of 100 million dollars.[89]

From 1 January 2005 pharmaceutical patents started ti be treated the same as other patents in Egypt, at the same time as Egypt's international obligations to be TRIPS compliant have came into force. Pharmaceutical patents are now granted for a period of twenty years and for product as well as process, making the reverse engineering of drugs illegal.

However, as Egypt becomes TRIPS compliant it may – indeed, it must – begin to utilize the flexibilities in the TRIPS agreement under articles 30 and 31 as interpreted by the Doha Declaration and the Ministerial Decision of 30 August 2003. This would mean – as was noted above in detail – that the Egyptian government will be entitled under TRIPS to issue compulsory licences for, *inter alia*, health purposes (including, but not restricted to, emergencies such as Hepatitis C and HIV/AIDS).

Indeed an interpretation of ICESCR and the African Charter, with reference to General Comment 14, implies that the Egyptian government has an obligation to take advantage of the flexibilities in TRIPS to ensure access to essential medicines and to protect their right to health.

8.1 The new patent law and health

While the new law appears more compliant with WTO standards there are a number of articles designed to allow flexibility,[90] such as section 17, which allows the Minister of Health to block the registration of a patent if it represents a "health value." This section would appear to be in violation of TRIPS since it is not covered by either Article 30 or 31 of the treayy. It is doubtful whether the Egyptian government would be prepared to use this provision as it would cause direct confrontation with developed countries.

Article 18 allows for the creation of a fund for the subsidisation of medicines, which may also be complained against by international drug companies as anti-competitive. The Ministry of Health decided to establish the medicines subsidisation fund to ensure the stability of the process of medicines away from sudden increases in order to make it accessible to the poor. This fund

[89] *Id.*
[90] The appendix of this policy paper includes relevant provisions of the Egyptian Intellectual Property Law and its Executive Statutes.

will subsidise chronic diseases drugs such as insulin, cancer treatments, cardiac diseases medicines, as well as babies formulas.[91] However, as this fund has not been established at the time of writing, there is no indication whether preference will be given to pharmaceuticals manufactured in Egypt. If all essential medicines are subsidised, regardless of source, this should not be in violation of free trade agreements.

The most important provisions of the new law for the purpose of this policy paper is in Article 23, which allows the grant of compulsory licences by the Patents Bureau after approval by a ministerial committee set up under a decree by the Prime Minister.[92] The ministerial committee will decide what compensation, if any, and the amount of this compensation will be granted to the patent holder.

These licences may be for public health utility purposes (article 23(1) first) or in emergencies or "conditions of utmost necessity" (article 23 (1)second). In these circumstances the licences may be granted without any negotiations with the patent holder.

Under article 23 (2) the Minister of Health may demand the issuing of a compulsory licence in a number of circumstances, including high prices of medications or where medicines are needed for "chronic, incurable or endemic diseases."

Article 23 also allows compulsory licences for non-use (which is a situation where the patent is protected but the goods are not manufactured or sold in Egypt) and anti-competitive practices by the patent holder (such as excessive prices, failure to sell the products in Egypt, discontinuing or reducing production or blocking the transfer of technology).

The executive statutes do not deal with the procedure to be applied by the Minister of Health when he declares that compulsory licences are necessary under article 23 (2) of the Act, restricting itself to the procedure to be applied when a third party applies for a compulsory licence. The Minister appears to have been given the power to grant compulsory licences himself instead of through the patents bureau and the ministerial committee on compulsory licences.

Article 24 (1) requires that compulsory licences should "basically" (an equivalent here of "predominantly") provide for local needs – thus not taking

[91] Abdel Maguid, Farouk, "Insha' Sondouq Le_tawfir Al-Adweya B_as'ar Monaseba Le_mahdoudi ed_dakhl" [the establishment of a fund to provide the poor with medicines at affordable prices], *Al-Ahram*, 17 November 2004, p 14.
[92] For patents on medicines this would be a committee in the Ministry of Health.

advantage of the Ministerial Decision of 30 August 2003 – discussed in detail above.

The rest of article 24 is concerned with procedures for applying for a compulsory licence and the conditions attached to it, such as requirements that compulsory licences should not be transferable. Notably, the applicant for a compulsory licence should show, under article 23(2) that an attempt has been made to apply for a voluntary licence from the patent owner – but this should not apply to compulsory licences under article 23(1), where it is specifically stated that the Minister of Health can grant the patents without prior negotiation with the patent holder.[93]

Articles 36 to 43 of the Executive Statutes set out the procedures for the granting of compulsory licences, and these procedures are generally straight forward; the application is brought through the patents bureau, which gives its recommendation to the ministerial committee, which issues the licence. The patent owner will be granted reasonable compensation in terms of section 41 of the Executive Statutes and will have the right to appeal all decisions of the ministerial committee to the complaints committee established in terms of section 36 of the Law.

Thus the compulsory licensing provisions of the new Law give the Egyptian government the necessary legal authority to take advantage of the flexibilities under the TRIPS agreement and this should be applied generously to allow and encourage the granting of compulsory licences to keep medicines affordable to the majority of Egyptians.

While the Act does not make any reference to parallel importation it does not expressly disallow such a scheme since it leaves the conditions of each compulsory licence to the compulsory licence committee. Although article 40 of the Executive Statutes stipulates that compulsory licences shall only be granted to entities that can exploit the patent in Egypt, giving an indication that parallel importation was not considered during drafting, the Executive Statutes appear to refer to the situations where a private individual applies for a licence on the grounds of non-working or anti-competitive acts by the patent holder. In such circumstances parallel importation would usually not be a logical solution.

But the Law allows very broad powers to the Minister of Health to determine when compulsory licences should be issued for unavailable or expensive

[93] Further, section 39 of Book One of the Executive Statutes, annexure to the Prime Minster's Decree 1366 /2003 Promulgating the Executive Statutes of Books 1,2 and 4 of the Intellectual Property Rights' Protection Law, restricts this requirement only to applications made by private persons under section 23(3) of the Law on the protection of intellectual property.

medicines and it is logical that these licences should include the power to import the medicines as one of the terms.

9. The Effect of TRIPS Compliance on the Right to Health in Egypt

> "[TRIPS'] impact is catastrophic and [will cause] a crazy rise in prices of medicines especially that 83% of medicine raw material is imported from abroad. Therefore, I demanded that the 200 medicines that have not be registered so far to be registered."[94]

Under the various agreements on TRIPS and public health Egypt had until 1 January 2005 to become TRIPS compliant with regards to pharmaceutical products. In essence this means ensuring that Egyptian legislation protects product and process patents for pharmaceutical products and that this protection is extended to a 20 year period.[95]

Legislation has been enacted and published in the Official Gazette by the Egyptian government to this effect and has been suspended until 1 January 2005. While there has been a heated debate about TRIPS and public health, especially access to essential medicines, in Egypt much of the discussion has been based on an evident lack in essential information.

One of the biggest misconceptions appears to be the belief that registration of a drug before 1 January 2005 will exempt the drug from patent laws after the that date. Thus the Minister of Health reportedly gave instructions to escalate the process of registering medicines before the beginning of 2005 and the implementation of TRIPS.[96] Dr. Mahmoud Abdel Maqsoud, Secretary General of the Pharmacists' Syndicate told the EIPR researchers that

> when TRIPS comes into force, it will be applied to medicines registered after 1/1/2005… but those available until 31/12/2004 will not be affected.[97]

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[94] Mohamed Khalil Quoita, (Member of the People's Assembly), telephone interview with the EIPR, 20 October 2004.

[95] Dr. Ahmed El-Adawi, Technical Consultant, ACDIMA International Trading, explained it as follows, "The GATT means the world is an open village. In 1994, they decided that annexes must be taken with the agreement, i.e. it is not possible for a country to accept the agreement without accepting these annexes as well. These annexes include the TRIPS agreement. Beforehand, when a company produced a new medicine, it had rights for 10 years and had rights for the process only, i.e. if another company was able to produce the same drug but with a different process it could do that. They said instead of the 10 years we'll make them 20 and instead of the process only it will be the process and the drug." Interview with the EIPR, Cairo, 25 October 2004.

[96] "Dr. Osama El-Kholi: Na'am Honak Morona fi Tasjil Al-adweya wa Lakenaha Bedawabet" [Dr. Osama El-Kholi: Yes there is flexibility in registration of medicines but with conditions] *Alam Al-Sehha*, September 2004, p 8.

[97] EIPR interview with Dr. Mahmoud Abdel Maqsoud, Cairo, 23 September 2004.

This is a view also shared by Dr. Tharwat Basily, Chairman of the Board of Amon Pharmaceutical Company and Member of the Shura Council[98] who says

> Luckily, all the [medicines] available in the market will continue as they are and the high prices will be applied only to what will be discovered after 1/1/2005 which is a small number, 5 or 6 medicines in the first year, the same second year, and the same on the third year…"[99]

Thus the government has given the impression that medicines registered before 1 January 2005 will be excluded from patent protection after 1 January 2005. This is incorrect, both under Egyptian law and under TRIPS.

Under TRIPS developing countries that took advantage of the delayed implementation of TRIPS had to operate a "post-box" to register patents that would come into effect after the compliance deadline. This means, regardless of whether the medicine has been registered before 1 January 2005 the government of Egypt has a duty under international law to ensure patent protection for these medicines after 1 January 2005 as long as the term of patent has not expired. A breach of this duty could lead to Egypt being brought before the WTO dispute settlement body. The new patents legislation, which is applicable to pharmaceutical products as of 1 January 2005, does not imply that registration of a medicine before the cut-off date excludes it from protection.

Another issue that was raised in the context of the TRIPS enforcement was the fact that most of the medicines in Egypt are beyond patent protection as they have been manufactured and marketed for more than 20 years. As Dr. Mostafa Ibrahim – Chairman of CID company and former Chairman of the Cairo Branch of the Pharmacists' Syndicate said,

> 95% of our medicines in Egypt have expired patents and the TRIPS will not be applicable to them.[100]

Indeed, according to the data of the Egyptian patent bureau, around 10 percent only of the medicines in the Egyptian market are still subject to patent protection, and around 90 percent have fallen in the public domain.

[98] Shura Council is the upper-house of Egypt's bicameral parliament.
[99] EIPR interview with Dr. Tharwat Basily, Cairo, 14 October 2004.
[100] EIPR interview with Dr. Mostafa Ibrahim, Cairo, 26 September 2004.

Therefore, there is no reason for the prices of non-patented drugs to increase if the functional component for it can be supplied locally.[101]

However, it would be a mistake to look at the situation through pink glasses and underestimate the value of new drugs. Other arguments have been made about the impact of TRIPS on the access to essential medicines in Egypt. Dr. Mohamed Ra'ouf Hamed, Professor of Pharmacology of the National Authority for Drug Monitoring and Research says that, "[n]ew medicines will be expensive, and with time the ability of the average citizen from the middle class to buy medicines will decline."[102]

Dr. Mostafa Ibrahim concedes that, "5% (of existing drugs) and some new medicines treating some diseases [will be protected under the TRIPS]."

The result will therefore be that prices of common drugs like Paracetamol will not change but drugs for more serious, and often life threatening, diseases such as heart diseases and cancer, will become more expensive. Older drugs, especially for such life threatening diseases, are often less effective than new drugs. The result could be that

> Cancer medicines, cardiac drugs, and antivirals, these are the medicines whose prices will skyrocket so much that the patient would rather die than pay for them.[103]

Ultimately, as TRIPS comes into force and drug companies enforce monopolies over patented drugs the question whether the currently patent protected drugs are 5 percent, 10 percent or more of all drugs used in Egypt will become irrelevant. Medicine is fast evolving and in areas with a large outlay in research and development (R&D) new drugs will continue to be produced at a fast rate, especially considering new biological science techniques, as pointed out by Dr. Ahmed El-Adawi, of the Arab Company for Drug Industries and Medical Appliances (ACDIMA);

> The TRIPS will have a great impact but not during the first few years. We cover now 93% of the drug consumption… The simple medicines will not be affected, but the remaining proportion will… It is naive to say that it will have a small impact as the medicines we produce now will be obsolete in a few years as the method of treatment itself changes especially after the discovery of the human genom which determines when the person will get cancer, when they will have sore tonsils… new drugs will be used in prevention of diseases not

[101] Nafi', et al (note 47 above), at 17-18 and 31.
[102] EIPR interview with Dr. Mohamed Ra'ouf Hamed, Cairo, 19 September 2004.
[103] EIPR interview with Dr. Ahmed El-Adawi, Cairo, 25October 2004.

> treatment of diseases applying the maxim 'prevention is better than cure'… the impact is inevitable.[104]

Moreover, the negative impact of the TRIPS will not only be mid or long term, it will have an immediate effect with respect to many recent drugs for serious conditions such as heart failure, HIV/AIDS and cancer as drug companies move to consolidate their international monopolies over drugs for these conditions in all major developing countries from Egypt to India and Brazil.

TRIPS compliance in January 2005, as part of an international enforcement of patent protection for pharmaceuticals, will likely see the increase in international prices of medicines as drug companies will not have to compete with generics manufactured in Brazil or India.

International studies stressed that the implementation of TRIPS will have a negative impact on the pharmaceutical industry, hence the accessibility to and the prices of medicines in developing countries.[105] The increase in prices of medicines after the implementation of TRIPS will be due to the high cost of imported patented drugs or patented drug components.[106]

Another issue may be the higher royalties claimed by international drug companies once they have legally enforceable monopolies over drugs in developing countries.

> The issue of drugs in light of the implementation of the 'TRIPS' agreement is very serious, as the possibility of an increase in prices of medicines is closer in light of the many impacts of the agreement, which will result in intensifying the problem of medicines in developing countries in which a large proportion of the population do not have access to their needs of medicines.[107]

Finally, another issue that may arise after Egypt has become bound by the TRIPS with regard to pharmaceutical products is the effect on Egyptian drug companies. This will affect not only private and public companies and their profit margin but may also affect employment in the industry and have a negative impact on the livelihood of workers.

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[104] *Id.* This understanding is shared by Dr. Mostafa Ibrahim who said, "What is the concern? Today after the discovery of the genetic map and the huge lap in treatment, the treatment method itself became new… i.e. the medicine that treats me, is different from the one that will cure you, is different from others, all according to their genetic map. This is the danger of the TRIPS."
[105] Nafi', et al. (note 47 above) at 17-18.
[106] *Id.*, at 19.
[107] *Id.*, at 20.

EIPR researchers found different opinions on the effect of TRIPS among experts during research. Dr. Galal Ghorab, Chairman of the Pharmaceuticals Holding Company,stressed that the implementation of TRIPS will result in billions of dollars annual loss because of the price differences and multinational pharmaceuticals' monopoly of the market.[108] However, Dr. Tharwat Basily, was of the opinion that

> The impact of TRIPS is not [as negative] on the industry as it is on the public… as of 1/1/2005 cheap [medicines] will not be available, only the expensive ones will be. But who will bear the burden? The patient …. the problem will appear gradually and only patients will feel it. The pharmaceutical industry will be very slightly affected."[109]

Whatever the opinion of the local industrialists is, TRIPS was designed to benefit Multinational drug companies and it is likely to increase their monopoly over drugs in Egypt and this may have the effect both of increasing prices and weakening local manufacturing capacity. Not only will imported raw material become more expensive as the international companies that produce it consolidate their monopolies, but voluntary licenses may become more expensive and difficult to obtain as international companies expand their exploitation of the Egyptian market.

10. Conclusion and Recommendations

The impact of the implementation of TRIPS in Egypt has started to affect the prices of essential drugs and the accessibility of these drugs to the Egyptian people. The effect will depend on a number of issues including, the government's determination, or lack thereof, to utilise compulsory licensing mechanisms inherent in the Egyptian legislation and the TRIPS agreement, the international drug companies' strategy towards employing these mechanisms, including whether or not they will challenge the Egyptian government's use of compulsory licenses and whether they will continue to grant voluntary licenses or attempt to meet local demand by importation.

However, one fact can be recognized, TRIPS will change the way in which the Egyptian drug industry operates and will lead to a rise in drug prices, whether immediately or on the long term.

The Egyptian government has legislated to allow it to set up a fund to subsidise essential medicines and has given itself extensive powers in the intellectual property legislation to issue compulsory licences. Both these

[108] Abdel Jayyed, Abdullah, "Ma'a Tatbiq Al-TRIPS fi Yanayer Al-Moqbel: As'ar Al-Dawa' Tatada'af thalath marat" [With the application of TRIPS next January: Prices of Medicines triple], *Al-Arabi*, 29 August 2004, p 7.
[109] EIPR interview with Dr. Tharwat Basily, Cairo, 14 October 2004.

procedures must be utilised to ensure that the government does not violate its duty under international law to protect the right to health.

The route taken by the government so far, through the gradual increase of drug prices while subsidising limited drugs out of the state's budget, will increase the burden on the Egyptian government and make the provision of essential medicines less sustainable. It is strongly recommended that the government utilises its own laws to issue compulsory licences as this will keep the prices of essential medicines within affordable limits both for the government and for vulnerable groups within the Egyptian society.

Recommendations

First– To the Egyptian Government

- The Government should make public all available information on the implementation of TRIPS and its effect on health delivery in Egypt, as well as the Government's its strategies to deal with increased prices of essential medicines after 1 January 2005.

  A public debate should take place among the Parliament, the Executive Authority, the pharmaceutical companies, and the general population to allow all concerns to be aired and for members of the public to understand what will happen to the prices of medicines in the short, medium and long term in Egypt. To this end the government of Egypt must be more open and transparent in its dealing with the issue of TRIPS compliance.

- The Government must be ready to issue compulsory licences, in accordance with the new intellectual property law, for the manufacture of generic drugs where medicines produced under patent monopoly are either too expensive or unavailable in Egypt.
-
- The Ggovernment should involve civil society and public health experts in the negotiation of any future trade agreements with a bearing on intellectual property and health in an open and participatory manner. TRIPS plus provisions in such agreements should be rejected.

Second– To Members of Parliament

- Members of Parliament – especially members of the Health Committee – should use parliamentary supervisory mechanisms to monitor the government's implementation of the TRIPS so that it would not hamper citizens' right to health. The issue of the implementation of TRIPS should be raised in parliamentary debates.

Third– To the Doctors' and Pharmacists' Syndicates

- The leaders and members of the doctors' and pharmacists' syndicates should continue pressurizing the government to refrain from raising the prices of essential drugs and demanding the government to use the flexibilities of compulsory licensing and parallel importation of medicines that are expensive or unavailable in Egypt.

Fourth – To Egyptian Pharmaceutical Companies

- Egyptian pharmaceutical companies should apply for compulsory licences to produce generic drugs in Egypt in order to ensure that medicines remain affordable and available in the local market.

Fifth– To the UN Committee on Economic, Social and Cultural Rights

- The Committee should require the Egyptian government to report on its implementation of the TRIPS and the measures it takes to avoid the adverse impact of the TRIPS on the right to health including the right to access essential medicines in its next periodic report on the implementation of the International Covenant on Economic, Social and Cultural Rights.

Sixth – to Developed Countries and Donor Agencies

- Developed countries and donor agencies should increase their technical assistance to Egypt to assist it in providing essential medicines and especially medication for Hepatitis C.
-
- Developed countries and donor agencies should assist Egypt in implementing the flexibilities in TRIPS to allow the Egyptian Government to meet its international obligation to protect the right to health.

11. Appendix

11.1 Relevant Provisions from the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

Article 7

Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8

Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

….

Article 27

Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.[110] Subject to paragraph 4 of Article 65,

[110] For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respective ely.

paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Article 28

Rights Conferred

1. A patent shall confer on its owner the following exclusive rights:

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing[111] for these purposes that product;

(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or

[111] This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.

importing for these purposes at least the product obtained directly by that process.

2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

….

Article 30

Exceptions to Rights Conferred

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

Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use[112] 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 provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In

[112] "Other use" refers to use other than that allowed under Article 30.

the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative

process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

….

Article 70

Protection of Existing Subject Matter

….

8. Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:

(a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;

(b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this

Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and

(c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).

9. Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.

11.2 The WTO Declaration on the TRIPS Agreement and Public Health (The Doha Declaration)

Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement 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.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
b. Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
c. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
d. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2. We also agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

11.3 Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health: Decision of the General Council of 30 August 2003[*]

The General Council,

Having regard to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the "Declaration") and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement and to report to the General Council before the end of 2002;

Recognizing, where eligible importing Members seek to obtain supplies under the system set out in this Decision, the importance of a rapid response to those needs consistent with the provisions of this Decision;

Noting that, in the light of the foregoing, exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products;

Decides as follows:

1. For the purposes of this Decision:

> (a) "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients

[*] This Decision was adopted by the General Council in the light of a statement read out by the Chairman, which can be found in JOB(03)/177. This statement will be reproduced in the minutes of the General Council to be issued as WT/GC/M/82.

necessary for its manufacture and diagnostic kits needed for its use would be included; (1)

(b) "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification (2) to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system set out in this Decision as importing Members (3) and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

(c) "exporting Member" means a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member.

2. The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph:

(a) the eligible importing Member(s) (4) has made a notification (2) to the Council for TRIPS, that:

(i) specifies the names and expected quantities of the product(s) needed (5);

(ii) confirms that the eligible importing Member in question, other than a least developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and

(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision (6);

(b) the compulsory licence issued by the exporting Member under this Decision shall contain the following conditions:

(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;

(ii) products produced under the licence shall be clearly identified as being produced under the system set out in this Decision through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and

(iii) before shipment begins, the licensee shall post on a website (7) the following information:

- the quantities being supplied to each destination as referred to in indent (i) above; and

- the distinguishing features of the product(s) referred to in indent (ii) above;

(c) the exporting Member shall notify (8) the Council for TRIPS of the grant of the licence, including the conditions attached to it (9). The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

3. Where a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall be waived in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

4. In order to ensure that the products imported under the system set out in this Decision are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

5. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.

6. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products:

(i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;

(ii) it is recognized that the development of systems providing for the grant of regional patents to be applicable in the above Members should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of the

TRIPS Agreement, including in conjunction with other relevant intergovernmental organizations.

7. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the Declaration. To this end, eligible importing Members and exporting Members are encouraged to use the system set out in this Decision in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of the TRIPS Agreement, paragraph 7 of the Declaration and any other relevant work of the Council for TRIPS.

8. The Council for TRIPS shall review annually the functioning of the system set out in this Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council. This review shall be deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.

9. This Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration, and to their interpretation. It is also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the present provisions of Article 31(f) of the TRIPS Agreement.

10. Members shall not challenge any measures taken in conformity with the provisions of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

11. This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration.

ANNEX

Assessment of Manufacturing Capacities in the Pharmaceutical Sector

Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.

For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

> the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector;
>
> OR
>
> (ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.

Notes:

1. This subparagraph is without prejudice to subparagraph 1(b).

2. It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

3. Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America.

4. Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 6 of this Decision on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties.

5. The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

6. This subparagraph is without prejudice to Article 66.1 of the TRIPS Agreement.

7. The licensee may use for this purpose its own website or, with the assistance of the WTO Secretariat, the page on the WTO website dedicated to this Decision.

8. It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

9. The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

11.4 The General Council Chairperson's statement accompanying the 30 August 2003 Ministerial Decision

The General Council has been presented with a draft Decision contained in document IP/C/W/405 to implement paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. This Decision is part of the wider national and international action to address problems as recognized in paragraph 1 of the Declaration. Before adopting this Decision, I would like to place on the record this Statement which represents several key shared understandings of Members regarding the Decision to be taken and the way in which it will be interpreted and implemented. I would like to emphasize that this Statement is limited in its implications to paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.

First, Members recognize that the system that will be established by the Decision should be used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives.

Second, Members recognize that the purpose of the Decision would be defeated if products supplied under this Decision are diverted from the markets for which they are intended. Therefore, all reasonable measures should be taken to prevent such diversion in accordance with the relevant paragraphs of the Decision. In this regard, the provisions of paragraph 2(b)(ii) apply not only to formulated pharmaceuticals produced and supplied under the system but also to active ingredients produced and supplied under the system and to finished products produced using such active ingredients. It is the understanding of Members that in general special packaging and/or special colouring or shaping should not have a significant impact on the price of pharmaceuticals.

In the past, companies have developed procedures to prevent diversion of products that are, for example, provided through donor programmes. "Best practices" guidelines that draw upon the experiences of companies are attached to this statement for illustrative purposes. Members and producers are encouraged to draw from and use these practices, and to share information on their experiences in preventing diversion.

Third, it is important that Members seek to resolve any issues arising from the use and implementation of the Decision expeditiously and amicably:

- To promote transparency and avoid controversy, notifications under paragraph 2(a)(ii) of the Decision would include information on how the Member in question had established, in accordance with the Annex, that it has insufficient or no manufacturing capacities in the pharmaceutical sector.
- In accordance with the normal practice of the TRIPS Council, notifications made under the system shall be brought to the attention of its next meeting.
- Any Member may bring any matter related to the interpretation or implementation of the Decision, including issues related to diversion, to the TRIPS Council for expeditious review, with a view to taking appropriate action.
- If any Member has concerns that the terms of the Decision have not been fully complied with, the Member may also utilise the good offices of the Director General or Chair of the TRIPS Council, with a view to finding a mutually acceptable solution.

Fourth, all information gathered on the implementation of the Decision shall be brought to the attention of the TRIPS Council in its annual review as set out in paragraph 8 of the Decision.

In addition, as stated in footnote 3 to paragraph 1(b) of the Decision, the following Members have agreed to opt out of using the system as importers: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America.

Until their accession to the European Union, Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia agree that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency. These

countries further agree that upon their accession to the European Union, they will opt out of using the system as importers.

As we have heard today, and as the Secretariat has been informed in certain communications, some other Members have agreed that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency: Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, United Arab Emirates.

11.5 Relevant Provisions of Law No. 82/2002 on the Protection of Intellectual Property Rights[113]

…

Article 17

The Patents Bureau shall send to the Ministry of Defence, Ministry of Military Production, Ministry of Interior, or Ministry of Health according to each case, copies of the patent requests that are connected with Defence, Military Production or Public Security affairs, or those representing a military, security, or health value, together with the attachments to these requests, within ten days from the date of completing the examination, along with notifying the applicant accordingly within seven days from the date of dispatching these applications and attachments. The Minister of Defence, Minister of Military Production, Minister of Interior, or Minister of Health, according to each case, may object to announcing the acceptance of the patent request within ninety days from the date of dispatch.

The concerned minister, according to each case, after the announcement is made about accepting the patent request, may object to carrying on with the procedures of issuing the patent, if it transpires to him that the request is connect ed with defence, military production, or public security affairs, or represents a military, security, or health value. The objection shall be within ninety days from the date the acceptance of the patent request is announced in the Patents Journal.

Objection, in the foregoing cases, shall result in discontinuing the procedures of issuing the patent.

Article 18

[113] Translation by the Middle East Library for Economic Services.

A Fund shall be established for balancing the prices of drugs that are not provided for export. The Fund shall have its juridical personality and shall be attached to the Minister of Health and Population, in order to achieve health development and ensure these prices will not be affected by the occurring variations. A decree of the President of the Republic shall be issued regulating the Fund and determining its resources, providing such resources shall comprise the contributions accepted by the State from the donor countries, and the governmental and non-governmental international organizations.

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Article 23

The Patents Bureau – following approval of a ministerial committee to be formed by vitue of a prime minister's decree – shall grant compulsory licenses for exploitation of the invention, and the committee shall determine the financial rights of the patentee upon issuing these licenses, in the following cases:

First:

If the concerned minister decides – according to each case – that the exploitation of the invention shall realize the following:

1. Non-commercial public utility purposes;

   The following are considered of these purposes: public security, health, environmental safety, and food.

2. facing emergency cases or conditions of utmost necessity.

   The compulsory license shall be issued in order to face the cases prescribed in items (1) and (2) above without need for a prior negotiation with the patentee, or due to the lapse of a period of time following negotiation with him, or because of offering reasonable conditions to obtain his approval of exploiting the patent.

3. Reinforcing national efforts in sectors of importance for economic, social, and technological development, without unreasonable prejudice to the patent owner's rights, and subject to the legitimate interests of third parties.

   The patent owner shall be notified of the compulsory licensing decision immediately in the cases prescribed in items (1) and (3) above, and

within the nearest reasonable opportunity afforded by the cases prescribed in item (2) above.

Second:

If the Minister of Health demands issuing the compulsory license in any of the cases where the quantity of patent protected medicines fails to cope with the needs of the country, or due to their low quality, or the unusual hike in their prices, or if the invention is connected with medicines for critical cases, or chronic, incurable, or endemic diseases, or with products used in protection from these diseases, whether the invention is connected with the medicines, the process of their production, the fundamental raw materials used in their production, or the method of preparing the raw materials necessary for their production.

In all these cases, the patentee shall be notified immediately of the compulsory license decision.

Third:

If the patent owner refuses to license a third party to exploit the invention, whatever the purpose of exploitation, despite offering him suitable conditions and the lapse of a reasonable negotiation period.

The compulsory license applicant shall in this case provide evidence of having exerted serious attempts to obtain the voluntary license from the patent owner.

Fourth:

If the patent owner has failed to exploit it in the Arab Republic of Egypt by himself or with his approval, or if its exploitation has been inadequate, despite the lapse of four years from the date of submitting the patent request, or three years from the date of granting it, whichever is longer, and also if the patent owner discontinues exploiting the invention without a reasonable excuse for a period of more than one year.

The patent shall in this case be exploited by processing the product subject of protection in the Arab Republic of Egypt, or by using the process of manufacture which is protected by the patent in the Arab Republic of Egypt.

However, if the Patents Bureau judges – despite the lapse of any of the aforementioned two periods – that non-exploiting the invention is due to

legal, technical, or economic reasons beyond the power of the patent owner, it may grant him another adequate period for exploiting the invention.

Fifth:

If the patent owner's arbitrariness is established, or he is proved to have exercised his rights as derived from the patent in anti-competitive manner. The following are considered instances of this sort:

1. Exaggeration in the sale prices of protected products, or discrimination between clients in terms of the sale prices and conditions of these products.
2. Failure to provide the protected product in the market, or launching it with unfair conditions.
3. Discontinuing the production of the protected commodity, or producing it in quantities inadequate to realize congruence between the productive energy and market needs.
4. Undertaking works or acts negatively affecting the freedom of competition, according to the prescribed legal controls.
5. Using the rights granted by the law in a way negatively affective the transfer of technology.

In all the previous cases, the compulsory license shall be issued without need for negotiation, or upon the lapse of the period prescribed for obtaining it, even if the obligatory license does not target the fulfilment of local market needs.

The patents Bureau shall have the authority to refuse terminating the compulsory license if the conditions that called for issuing it indicate their continuity, or predict their recurrence.

In estimating the compensation due to the patent owner, the damages caused by his abusive or anti-competitive practices shall be taken into account.

The Patents Bureau may cancel the patent if after the lapse of two years from granting the compulsory license it transpires that such license was inadequate to repair the negative effects caused to national economy on account of the patent owner's arbitrariness in using his rights or due to his anti-competitive practices.

All concerned party may contest the decision cancelling the patent, before the committee prescribed in article (36), according to the

conditions and procedures to be determined in the executive statutes of the present law.

Sixth:

If exploiting the invention by the holder of the right to use the patent cannot be realized except through exploiting another invention necessary for it which comprises a concrete technological advancement and a technical and economic importance, compared to that invention, the patent user shall then have the right to obtain an obligatory license vis-à-vis that other patent holder, and the latter shall have the same right in this case.

Assigning the licensed exploitation of either patent shall not be allowed except by assigning the exploitation of the other patent.

Seventh:

In the cases of inventions connected with semi-conductors technology, the obligatory license shall not be granted except for non-commercial public utility purposes, or for remedying the effects proven to be anti-competitive.

Granting obligatory licenses in the cases prescribed in this article, shall be according to the rules and procedures to be determined in the executive statutes of the present law.

Article 24

On issuing compulsory license the following shall be observed:

1. The application for issuing the compulsory license shall be decided according to each case separately, and the license shall basically aim to provide the local market needs.
2. The license applicant shall establish having exerted serious attempts within a reasonable period, to obtain a voluntary license from the patent holder against a fair consideration, but failed to obtain such license.
3. The patent owner shall have the right of complaining from the decision granting the compulsory license to a third party, before the committee prescribed in article (36) of the present law, within thirty days from the date he is notified of the grant of that license, according to the conditions and procedures to be determined in the executive statutes.

4. The applicant for the obligatory license, or the person in whose favour the license is issued shall have the ability to exploit the invention in a serious way in the Arab Republic of Egypt.
5. The party to whom the obligatory license is issued shall be committed to use the invention within the scope, according to the conditions and throughout the period to be determined in the decision granting that compulsory license.

   If the period of the compulsory license expires without realizing the purpose of using the invention, the Patents Bureau may renew the period.

6. Using the compulsory license shall be confined to its applicant. However the Patents Bureau may grant it to a third party.
7. The party granted the obligatory license shall have no right to alienate it to a third party except with the project, or with the portion connected with using the invention.
8. The patent holder shall have the right of obtaining a fair consideration in return for exploiting his invention. The economic value of the invention shall be taken into account in estimating that consideration.
9. The compulsory license shall terminate with the expiry of its period. However, the Patents Bureau shall be powered to decide cancelling the compulsory license before the termination of its period, if the reasons that led to granting it cease to exist, and there is no probability these reasons will recur. The procedures prescribed in the executive statutes shall be followed.
10. The owner of the invention shall have the right to request ending the compulsory license before the expiry of the period determined therefore, if the reasons that led to obtaining it cease to exist and there is no probability they will exist once more.
11. The legitimate interests of the licensee shall be observed on terminating the compulsory license before expiry of its period.
12. The Patents Bureau shall have the authority to amend the conditions of the obligatory license or revoke the license of its own initiative, or upon the request of all concerned party, if the licensee who is autho9rized to exploit the license fails to use it within two years from the date of granting it or if he violates the obligations stipulated upon the license.

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11.6 Relevant Provisions of the Executive Statutes of Law No. 82/2002 on the Protection of Intellectual Property Rights [114]

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Article 36

The request for obtaining the compulsory license for exploitation of the invention or utility design shall be submitted to the office, according to the provisions of the Law, on the form provided for the purpose.

Article 37

A Secretariat shall be formed in the office, by virtue of a decision of the head of the Scientific Research and Technology Academy. The Secretariat shall be concerned with receiving the requests for issuing the mandatory license or obtaining them along with recording them in a special register according to the date of their receipt, and for preparing them to be submitted to the office for their examination.

Article 38

The office shall take charge of examining the obligatory license requests, and ascertain the fulfilment of the formal and substantive conditions therein, along with referring by a memorandum coupled with its view the requests it considers approving the issue of compulsory license for them to the ministerial committee prescribed in article (23) of the Law.

Article 39

For granting the compulsory licenses in the case prescribed in item 'Third' of article (23) of the Law, the applicant shall establish having previously negotiated with the patentee, that a reasonable period of the negotiation has lapsed and serious attempts have been made for obtaining the optional license from him along with offering suitable conditions to him for the purpose.

The following shall be observed in judging the extend of suitability of the condition:

1. Kind of the invention
2. The period remaining of the prescribed term of protection.
3. The return offered for the optional license.

[114] Translation by the Middle East Library for Economic Services.

Article 40

The compulsory license shall not be granted except to the one cap able of exploiting the invention seriously within the range and the period to be determined by the decision granting the license and according to the conditions prescribed therein, through an estabioishment operating in the Arab Republic of Egypt.

Article 41

The owner of the patent in respect of which a compulsory license is granted shall have the right to obtaining a fair compensation in return for exploiting his invention, to be estimated by means of a specialized committee to be formed by a decision of the head of the Scientific Research and Technology Academy. In estimating the compensation, the committee shall in particular observe the following:

1. The period remaining from the term of protection.
2. Volume and value of the licensed production.
3. The proportion between the price of the product and the average general income per capita.
4. Volume of the investments required for the research necessary for commercial floatation.
5. Size of investments necessary for production.
6. Extent of availability of a similar product on the market.
7. Harms caused by the arbitrary practices of the patent owner or the anti-competition practices.

The committee's estimation of the compensation shall be submitted to the ministerial committee referred to in article (23 of the Law to issue its decision determining the financial rights of the patent owner according to the provisions of the article itself when issuing the compulsory license.

Article 42

The office shall notify the patent owner of the decision granting the compulsory license and the decision issued estimating the compensation. The notification shall be given forthwith by registered letter with acknowledgment of receipt, in the cases prescribe din items (1) and (3) of the clause (first) and clause (Second) of article (23) of the Law, and on the nearest reasonable chance provided by the cases prescribed in item (2) of the clause (First) of the same article.

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