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The Egyptian Pharmaceutical Industry After TRIPS — A Practitioner's View

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Nermien Al-Ali

Abstract

The pharmaceutical industry in Egypt is the largest in the Middle East and North Africa (“MENA”) region, and one that has attracted foreign investment despite the fact that Egyptian law has not always provided pharmaceuticals with patent protection. The situation changed with the signing of the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS agreement” or “TRIPS”), strengthening the interest of the U.S. and other pharmaceutical companies in increasing their investment in Egypt. The Egyptian pharmaceutical industry is currently undergoing many changes spurred by the implementation of TRIPS and the globalization of trade. Many of these changes can be seen through examining the new Intellectual Property Code, which Egypt passed in June 2002 to comply with the provisions of TRIPS. This Article examines the changes in the law and the economic policies of Egypt that pertain to the pharmaceutical industry in light of TRIPS, viewed in the context of the global debates that have revolved around the effects of extending patent protection to pharmaceuticals in the developing countries. Part I of this Article introduces the TRIPS agreement and the conflicting interests of the developed and the developing countries that overshadowed its drafting. Part II outlines TRIPS provisions relating to the protection of pharmaceuticals and sheds light on how the conflicts mentioned in Part I shaped the final version of TRIPS that Members signed in late 1994. This Part also examines the anomalies of TRIPS implementation within the first few years of its coming into effect, leading to the Doha Declaration in 2001. Part III examines the new Egyptian intellectual property law enacted in June 2002 to comply with TRIPS, with particular emphasis on the protection of pharmaceuticals. Part IV takes a closer look at the Egyptian pharmaceutical industry, its size and prospects for growth, as well as the challenges it has to address. The main challenge to the Egyptian government is how to strike a balance between facilitating an open-market policy to promote investment by foreign research-based pharmaceutical companies, while at the same time ensuring adequate public access to essential medicines and promoting the development of the economic and healthcare infrastructures.

THE EGYPTIAN PHARMACEUTICAL INDUSTRY AFTER TRIPS — A PRACTITIONER'S VIEW

*Nermien Al-Ali**

INTRODUCTION

The pharmaceutical industry in Egypt is the largest in the Middle East and North Africa ("MENA") region, and one that has attracted foreign investment despite the fact that Egyptian law has not always provided pharmaceuticals with patent protection. The situation changed with the signing of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS agreement" or "TRIPS"),¹ strengthening the interest of the U.S. and other pharmaceutical companies in increasing their investment in Egypt. The Egyptian pharmaceutical industry is currently undergoing many changes spurred by the implementation of TRIPS and the globalization of trade. Many of these changes can be seen through examining the new Intellectual Property Code,² which Egypt passed in June 2002 to comply with the provisions of TRIPS. This Article examines the changes in the law and the economic policies of Egypt that pertain to the pharmaceutical industry in light of TRIPS, viewed in the context of the global debates that have revolved around the effects of extending patent protection to pharmaceuticals in the developing countries.

Part I of this Article introduces the TRIPS agreement and the conflicting interests of the developed and the developing countries that overshadowed its drafting. Part II outlines TRIPS provisions relating to the protection of pharmaceuticals and sheds light on how the conflicts mentioned in Part I shaped the

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1. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, *LEGAL INSTRUMENTS — RESULTS OF THE URUGUAY ROUND* vol. 31, 33 I.L.M. 1197 (1994) [hereinafter TRIPS].

2. Intellectual Property Law No. 82 of 2002 (Egypt) [hereinafter Law No. 82]. The version of the Law No. 82 used in this Article is based on the author's translation. Full text of the Law No. 82 is also available at <http://www.agip.com/laws/egypt/p.hum>.

final version of TRIPS that Members signed in late 1994. This Part also examines the anomalies of TRIPS implementation within the first few years of its coming into effect, leading to the Doha Declaration in 2001. Part III examines the new Egyptian intellectual property law enacted in June 2002 to comply with TRIPS, with particular emphasis on the protection of pharmaceuticals. Part IV takes a closer look at the Egyptian pharmaceutical industry, its size and prospects for growth, as well as the challenges it has to address. The main challenge to the Egyptian government is how to strike a balance between facilitating an open-market policy to promote investment by foreign research-based pharmaceutical companies, while at the same time ensuring adequate public access to essential medicines and promoting the development of the economic and healthcare infrastructures.

*TRIPS AND CONFLICTING INTERESTS –
HEATED NEGOTIATIONS*

The time was late 1994; the place was Marrakesh. The exotic capital of Morocco was then housing one of the most important and intense negotiations in the history of the “new world order” — the TRIPS agreement. Lobbyists representing copyright owners (the motion picture, music and software industries, content and database providers), patent holders (mainly the pharmaceutical industry), and owners of famous trademarks were pushing for reforms in intellectual property laws of developing countries. One of the hottest debates involved the provision in TRIPS for patent protection of pharmaceuticals, which were not protected under the intellectual property systems of most developing countries. In these countries, pharmaceutical compositions were part of the public domain, and although originators did not necessarily publish particular compositions, they were available through patent records of other countries or discoverable through reverse engineering.

Countries that denied patent protection to pharmaceuticals were still interested in promoting innovation, and most had in place relatively strong patent systems. The exclusion of pharmaceuticals from patent protection, however, was to satisfy the overriding public interest in keeping pharmaceuticals affordable to the poor masses. As such, the debate was characterized

as that of the developed countries and their powerful pharmaceutical industries, against the developing countries with their local pharmaceutical industries that provided for the poor masses through copying unprotectable³ product compositions. The debate, therefore, was not only vibrant, but intense, with polarized views and positions.

In some developing countries this debate boiled down to a particular government's responsibility to protect the local pharmaceutical industry, which was heavily dependant on copying unprotectable product compositions and which had successfully provided affordable pharmaceuticals for the poor masses. On the one hand, the developed countries were trying to protect the economic interests of one of their most powerful industries — the pharmaceutical industry — while on the other hand, the developing countries were concerned about the demise of their local pharmaceutical industries, which lacked the infrastructures that would enable them to effectively compete with multinational corporations. While the developed countries were seen as self-interested, caring little about the poverty and the suffering of the poor masses in the developing countries, the developing countries were seen as over-protective of their domestic pharmaceutical industries that were free-riding on the successes of pharmaceutical companies in the developed countries.⁴ The debate and the polarization of positions involved a number of issues that can be summarized in the following table:

3. I resist the tendency to refer to the copying activity of pharmaceutical companies in the developing countries prior to TRIPS as "pirating," as it has been referred to in some Articles. This is because respecting the sovereignty of every country in setting its laws entails looking at the activity from the perspective of the domestic law and policy. Under the domestic laws of most developing countries that provided no patent protection for pharmaceuticals prior to TRIPS, it was perfectly legal to copy the composition (not the process of production) of pharmaceuticals. As such, it cannot be described as "pirating" except when judged through the perspective of a foreign system of law, where pharmaceuticals are protectable by patent law. This distinction is of utter importance as it highlights the difference in perspective between those systems that provide patent protection for pharmaceuticals and those that do not. To generalize and to use the term "pirating" to include activities that are legal under the domestic laws both, confuses the issues and creates ill will between the local and foreign interests.

4. For more information as to the interest groups that had major impact on TRIPS negotiations, in particular the U.S. pharmaceutical research-based companies, groups from the developing countries (including India and Egypt), and other global NGOs opposing strong protection of pharmaceuticals see George Foster, *Opposing Forces in a Revolution in International Patent Protection: the U.S. and India in the Uruguay Round and its Aftermath*, 3 UCLA J. INT'L. L. & FOREIGN AFF. 283 (1998).

Type of Research and Development ("R&D")	Developed Countries' Views	Developing (& the Least Developed) Countries' Views
R&D in general	Patent protection will promote R&D in general and encourage local companies to file for patents around the globe. ⁵	Patent protection cannot promote R&D by local companies when they lack technical capabilities and the requisite economic infrastructures.
R&D in local diseases	Patent protection will promote R&D expenditures by multinationals to find cures for local diseases.	Patent protection will not promote R&D in local diseases, given that the expected returns are much less than those required by multinationals to invest in R&D. ⁶
Affordable pharmaceuticals	Patent protection will not raise the prices of pharmaceuticals in the long run. Other factors affect access to pharmaceuticals.	Patent protection will increase the price of pharmaceuticals, accentuating the problem of access of the poor masses to essential pharmaceuticals.
Safety, quality and effectiveness	Patent protection will promote safety and quality of medicines as the developing countries have been dumping grounds for adulterated generic pharmaceuticals.	Patent protection has no effect on quality or safety as all are subject to regulatory procedures. Adulterated pharmaceuticals are more a result of corruption.
Protection of domestic industry	Patent protection will promote the development of local pharmaceutical companies as they can file their own patents.	Patent protection will destroy the local industry which is dependant on copying compositions and lacks resources and infrastructure to establish R&D. ⁸

5. India is cited as an example where R&D by local companies increased six-fold from 50 Rs. Crores (1 Rs. Crores = 1 million Rs.) in the late 1980s to 320 Rs. Crores by 2000. See Organisation of Pharmaceutical Producers of India ("OPPI"), *Pharmaceutical Industry in India*, available at <http://www.indiaoppi.com/intelprop.htm>. Another example is Mexico where R&D expenditures tripled following the provision of patent protection for pharmaceuticals.

6. It is reported that pharmaceutical companies need to ensure that a new product will generate between U.S.\$350-\$550 million to support their high R&D expenditures. Estimates reach around U.S.\$800 million for the production of new breakthroughs over ten to twelve years of R&D. A blockbuster appears approximately every five years and only one in fifty has sales that exceed U.S.\$2 billion. As a result, a new product, which is estimated to generate less than U.S.\$200 million, is hardly considered for R&D. Most diseases in the developing countries fall within this range. That being said, the leading pharmaceutical companies allocate marginal investment for R&D in diseases like malaria and T.B. in order to appear "good citizens". See M.D. Nair, *Emerging R&D Scenario in the Indian pharmaceuticals industry*, available at www.pharmabiz.com/newsfeat/feat84.asp. See also *infra* Part IV.

7. Brazil, China, South Korea, and others are cited as examples of countries where patent applications filed by local companies for protection inside and outside their countries increased with pharmaceutical patent protection. In South Korea, it is reported that 75% of pharmaceutical patent applications are filed by the local industry. It is also reported that pharmaceutical patents applications filed by Indian local companies reached 2,500 applications, in addition to 600 applications filed abroad.

8. Most of these companies have no infrastructures to support high R&D expendi-

Compulsory licensing	Will adversely affect R&D expenditures. ⁹ TRIPS provisions in that regard should be read narrowly and be invoked only in cases of extreme emergency. ¹⁰	Will be necessary to address interest of public health, and to deal with emergencies. TRIPS provisions in that regard should be read broadly, provided that the conditions for their use (stipulated in TRIPS) are satisfied.
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It is important to understand the conflicting interests that overshadowed the drafting of TRIPS and how they shaped the final provisions of TRIPS, as elaborated further in Part II.

II. *PATENT PROTECTION FOR PHARMACEUTICALS UNDER TRIPS — THE FINAL COMPROMISE*

It is true that the debate was resolved, despite fierce resistance by a number of interest groups in the developing countries, in favor of patent protection for pharmaceuticals. The matter, however, is far from simple. What is not clear to many is that TRIPS incorporated provisions that allow Members to create effective exceptions to patentability in general (under Article 30)¹¹ and to impose compulsory licenses over pharmaceutical patents, subject to certain conditions (Article 31).¹² It seems

tures over long periods of time. This issue is actually considered one of the main entry barriers for smaller pharmaceutical companies in the developed economies, and is one of the drivers of mega-mergers in the pharmaceutical industries.

9. The example of Canada is always cited in support of this argument since R&D expenditures increased over 700 times between 1987 and 1998 following the repeal of compulsory licensing provisions. Canada's economic and health care infrastructures and problems, however, are not comparable to those of the developing countries, where the problem of public access to pharmaceuticals is life-threatening (mainly due to poverty).

10. See Michelle Nerozzi, *The Battle Over Life-Saving Pharmaceuticals: are Developing Countries Being "TRIPped" by Developed Countries?*, 47 *VILL. L. REV.* 605, at 616 (2002) (citing developed countries' resistance to use of compulsory licensing even though it is allowed under Article 31 of TRIPS).

11. See TRIPS, art. 30. Article 30 provides:

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.

Id.

12. *Id.* art. 31. Article 31 provides:

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

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- (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 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

that Articles 30 and 31 were added as a last compromise to induce the developing countries to agree to extend patent protection to pharmaceuticals. In general, Articles 30 and 31 entitle Members to limit or revoke certain pharmaceutical patents to respond to public health necessities or emergencies. However, the practice of the developed countries, particularly the United States, intimidated many developing countries a few years after TRIPS came into effect. These countries feared using Articles 30 and 31 and thereby adversely affecting their trade positions. As a result, it was necessary for the Members to meet again in Doha, Qatar in November 2001, to affirm the right of the developing countries to invoke Articles 30 and 31 in addition to other declarations.¹³ Below is an examination of the various TRIPS provisions and the issues that arose regarding their application.

A. Patent and Other Protection for Pharmaceuticals

TRIPS does not expressly extend patent protection to pharmaceuticals, but rather, specifies what could be excluded from patentability. Pharmaceuticals are not on this list of excluded items.

Article 27 of the TRIPS agreement provides:

- (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 [. . .].
- (2) Members shall 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 and animals;

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

Id.

13. For full text of the Doha Declaration see World Trade Organization, *Ministerial declaration* [hereinafter Doha Declaration], available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm.

- (b) plants and animals other than microorganisms, 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 [. . .].¹⁴

In effect, Article 27 provides for extended patent protection for all types of inventions regardless of technology, except for the areas specifically excluded under paragraph 2.

In addition, TRIPS provides further protection for pharmaceuticals. Research-based pharmaceutical companies have faced another problem in registering their pharmaceuticals in the developing countries. Either for lack of protection or vague registration procedures, generic producers have unfairly benefited from the test data which was presented by the pharmaceutical companies to prove the safety and efficacy of their generic versions. Pharmaceutical companies lobbied, therefore, for clear provisions that ensured that this type of proprietarily valuable information would only be used for the purposes for which it was submitted and that it would be protected from any unauthorized disclosure. Accordingly, TRIPS provides for the protection of undisclosed information or trade secrets in a general manner under Article 39.¹⁵ In addition, Article 39(3) addresses the situation relating to the registration process of pharmaceuticals as follows:

Members, when requiring, as a condition of approving the

14. TRIPS, art. 27.

15. *See id.* art. 39(1)-(2). Article 39(1)-(2) provides:

1. In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.

2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices so long as such information:

- (a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
- (b) has commercial value because it is secret; and
- (c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

Id.

marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.¹⁶

Under the general principles of trade secret law, which are reiterated under Article 39, undisclosed information is protected as long as it remains secret, secrecy has commercial value, and reasonable security measures are undertaken to protect this secrecy. For the originator, the dilemma of test data being presented to public agencies to obtain marketing approvals for pharmaceuticals, is that such data may be used by competitors, mainly generic producers, who may want to rely on it to prove the bio-equivalency of their generic products. Of course, in the developing countries many local producers have tried to rely on this information when possible to avoid performing their own clinical tests. Although Article 39(3) addresses this very problem, it does not provide a solution.

The main issue, however, that persisted to the final TRIPS negotiations, was how to enable developing countries with their weak economic and healthcare infrastructures to provide affordable pharmaceuticals to the poor masses after price increases resulting from the implementation of TRIPS. In addition to the high levels of poverty and the weak infrastructures, developing countries needed to reform their legal systems to provide adequate patent protection for pharmaceuticals. Since the developing countries had denied patent protection to pharmaceuticals for so long, their legal systems lacked the requisite financial resources and knowledge to handle patent applications relating to pharmaceuticals. The patent offices of the developing countries had not maintained records of similar patents in other countries, or if they had, they had failed to train patent examiners regarding the use and the examination of these patents. These countries currently face a strong need for additional expert patent examiners; training; an update of databases; and a strengthening of the judicial and enforcement systems.

16. *Id.* art. 39 (3).

The situation in Egypt exemplifies these concerns. In a submission to the United Nations ("U.N.") by M. El-Magdoub, it was estimated that Egypt would need U.S.\$98,000 to increase patent personnel and add equipment; U.S.\$192,000 to strengthen the judicial framework; and U.S.\$1,000,000 to train and develop custom authorities. These estimates do not include the costs needed to seek and obtain technical assistance for the development of human resources.¹⁷

Weaknesses in the economic and healthcare infrastructures of the developing countries are very serious and deep-rooted. On the one hand, the local pharmaceutical industries' infrastructures have not developed the research capabilities that would enable them to effectively compete with foreign pharmaceutical companies. On the other hand, there are no health care infrastructures (effective public medical insurance or affordable private medical insurance) that ensure that the masses will have adequate access to necessary medicines. In many developing countries, the pharmaceutical industries' research capabilities have been limited for a long time to the reformulation of product compositions, rather than to the creation of new ones. The local companies have mainly depended on copying the composition of products that may be patented in other countries, and which are in the public domain within their domestic territories. These industries' research capabilities, therefore, have been limited to reformulating compositions, from perusing the claims of foreign patents, to reverse engineering of foreign products. In these countries, R&D expenditures in the pharmaceutical sector have been negligible when compared to the amounts spent in the developed countries. Given the high expenditures related to R&D, which the local pharmaceutical industries in the developing countries have not supported, let alone incorporated in their infrastructures, the domestic pharmaceutical industries in the developing countries are currently threatened with extinction or dwindling market shares. Thus, the protection of pharmaceuticals has put the local pharmaceutical industries in a weak competitive position, and has forced them to enter into agreements with the more experienced and

17. See UNITED NATIONS CONFERENCE ON TRADE & DEVELOPMENT ("UNCTAD"), *THE TRIPS AGREEMENT AND DEVELOPING COUNTRIES*, 23-24 (1996).

powerful foreign pharmaceutical companies, where their bargaining position is relatively feeble.

The weak economic and healthcare infrastructures pose a major risk, since there are no infrastructures to absorb or distribute through effective medical insurance the higher costs of "patented pharmaceuticals." As a result, these higher costs of access to necessary medicines are passed to the masses, a significant proportion of whom fall under the poverty line. Many developing countries, therefore, have argued that patent protection for pharmaceuticals, when they lack the requisite infrastructures (legal, industrial, and health care), may seriously affect their ability to adequately provide affordable pharmaceuticals to their poor masses. The developed countries, as a result, have had to compromise, and despite the immense pressure and lobbying by their pharmaceutical industries, have attended to the evident hazards that the developing countries may face in introducing pharmaceutical patent protection. That compromise was incorporated in TRIPS in two major ways: the transitional and the "exceptions to rights" provisions.

1. Transitional Provisions — Developing Countries Given Time to Get It Right

The developing and the least developed countries were allowed five and ten years, respectively, before they were required to comply with any of the TRIPS provisions. This took the January 1995 deadline to January 2000, according to Article 65(4) of TRIPS.¹⁸ The least developed countries are those identified as such by the U.N. classification,¹⁹ while the developing countries' status is determined by the World Trade Organization

18. See TRIPS, art. 65(4). Article 65(4) provides:

To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.

Id.

19. See UNCTAD, *Least Developed Countries (LDCs)*, available at <http://www.unctad.org>; see also *Least Developed Countries*, at <http://www.uncdf.org/projects/html/ldc.htm>.

("WTO").²⁰

In addition, the developing countries may opt to extend this grace period in relation to providing protection for pharmaceuticals for another five years until January 2005. This additional grace period, however, has many strings attached to it. The countries invoking the additional grace period have to provide interim protection measures for pharmaceuticals. These are stipulated under Article 70(8) as follows:

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 the 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 [20 years term],²¹ for those of these applications that meet the criteria for protection referred to in subparagraph (b).²²

Applications filed in the mailbox are not required to be examined by the patent office of the Member, but must merely be accepted and kept until the five-year grace period expires. Priority is guaranteed from the date of the application. The main problem with this system is that backlogs in the patent systems of the developing countries, where such applications have not been customarily accepted, is going to escalate, extending the subsequent period of examination. This problem is not addressed by

20. See World Trade Organization, *Who are the developing countries in the WTO?*, available at http://www.wto.org/english/tratop_e/devel_e/dlwho_e.htm.

21. *Emphasis added.*

22. TRIPS, art. 70(8).

Article 70(9), which provides for Exclusive Marketing Rights ("EMRs") until the Patent office decides on the application, or for five years, whichever is shorter, as follows:

Where a product is subject to a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted [. . .] 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 has been granted for that product in another Member and marketing approval obtained in such other Member.²³

Thus, the five years stipulated by Article 70(9) would provide the applicant with EMRs, provided that the specified conditions are met. The most important condition is that a patent application relating to the pharmaceutical in question must be filed prior to January 1995. This condition already resulted in the exclusion of Viagra from the protection of Article 70 where Eli Lilly and other multinational pharmaceutical companies in Egypt are preparing to produce it.

The EMRs, however, extend only to the shorter of the two periods: either for five years from the date of the marketing approval, or until the application is decided. It is noted that with backlogs in the patent office, there may be a "protection void" where EMRs expire long before a decision on patentability is reached. Still, the mere fact that there is a patent application awaiting a decision will probably deter competition from pursuing an R&D in the areas covered by the application. This deterrent effect, however, may not be sufficient. Despite this, Articles 70(8) and (9) still provide ample protection compared to the situation prior to TRIPS and until Members provide for their own patent protection.

2. Exceptions to Rights and Compulsory Licensing – the Provisions Loathed by Developed Countries

Articles 30 and 31 contain the main exceptions to intellectual property rights protected by TRIPS. Article 30 expressly provides that Members may provide for limited exceptions to the

²³ *Id.* art. 70(9).

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.”²⁴

Article 31, also known as the compulsory licensing provision, does not expressly provide for compulsory licensing but stipulates that where the law of a Member allows for use “other than that allowed under Article 30” of the subject matter of a patent without the authorization of the right holder, certain conditions should be satisfied.²⁵ According to Article 31, compulsory licensing can be imposed on a patent, provided that the person applying for the license failed to obtain a license from the right holder on reasonable commercial terms over a reasonable period of time. This condition, however, does not apply in cases where the compulsory license is needed to respond to a “national emergency” or “other circumstances of extreme urgency”; where the invention is used for “public non-commercial use”; or to remedy anti-competitive practices committed by the right holder.²⁶ That being said, the right holder should still be informed promptly of the decision relating to the compulsory license. In all cases the right holder should be adequately remunerated, taking into consideration the commercial value of the invention. Every case should be decided on its own merits and both, the decision to issue the compulsory license, and that determining the value of the remuneration, should be subject to judicial review.

The compulsory license should also incorporate the following terms:

- Be limited in scope and duration to its purpose and be terminated when the situations leading to its existence “cease to exist or are unlikely to recur”;
- Be limited to the supply of the domestic market only;
- Be non-exclusive and non-assignable, except as part of the enterprise; and
- In cases where the license is imposed to enable the exploitation of another patent that cannot be exploited without infringing on the licensed patent and the other patent

24. TRIPS, art. 30.

25. *Id.* art. 31.

26. *Id.*

involves an important technical advance of considerable economic significance, the owner of the licensed patent should be entitled to a cross-license over the other patent, and the license cannot be assigned without the assignment of the other patent.²⁷

Both Articles 30 and 31 should be read in conjunction with Article 8, which states the purpose of the TRIPS agreement. Article 8(1) asserts that Members may adopt "necessary measures to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socioeconomic and technological development, provided that such measures are consistent with the provisions of this Agreement."²⁸ Article 8(2) extends such measures to laws that are designed to prevent abuse of intellectual property rights by the right holders and practices that may hamper international technology transfer.²⁹

The ambiguity and confusion that surround the interpretation of Articles 30 and 31 and the tendency of the developed countries to limit their application to situations of extreme emergency, have been drastically highlighted by the AIDS/HIV case of South Africa.³⁰ The South African Ministry of Health imposed a compulsory license over a number of AIDS medications. As a result, thirty American pharmaceutical companies lobbied the U.S. government to sue the South African government for violation of TRIPS. South Africa was also removed from the "most favored member trade status" under the U.S. Special 301.³¹ The U.S. policy and actions were strongly criticized by humanitarian organizations including Doctors Without Borders, the World Bank, and the World Health Organization ("WHO");³² and the reputation of the U.S. pharmaceutical com-

27. *Id.*

28. *Id.* art. 8(1).

29. *See id.* art. 8(2).

30. *See e.g.*, Andrea M. Curti, *The WTO Dispute Settlement Understanding: an Unlikely Weapon in the Fight Against AIDS*, 27 AM.J.L. AND MED. 469 (2001).

31. Trade Act of 1974, Pub. L. No. 93-618, Title III, Sec. 301, *as amended*, 19 U.S.C. Sec. 2411 (1979) [hereinafter Special 301]. Special 301 is the principal statutory authority under which the United States may impose trade sanctions against foreign countries that maintain unjustifiable, unreasonable or discriminatory acts, policies, or practices; violate or deny rights; and restrict U.S. commerce. *See also* Exec. Ord. No. 13155, *Access to HIV/AIDS Pharmaceuticals and Medical Technologies*, 65 F.R. 30521 (May 10, 2000).

32. *See e.g.*, Karl Vick, *African AIDS Victims Losers of a Drug War: U.S. Policy Keeps Prices Prohibitive*, WASH. POST, Dec. 4, 1999, at A1.

panies was battered. As a result, the United States and the leading pharmaceutical companies backed down, dropped the lawsuit on April 19, 2001, and donated AIDS medications both, free of charge, and with considerable price reductions to South Africa and other African countries.³³

The implications of this case are very serious as they show that even in cases of extreme emergency (AIDS epidemic in Africa), a developing country, South Africa in this case, may be fiercely attacked and its trade position with the United States jeopardized for rightfully invoking one of the provisions of TRIPS.³⁴ The South African case is not the only incident. In fact, the United States has threatened to "curtail economic aid programs to South Africa and Thailand, among others, for adopting or preparing to adopt measures to allow them to address their healthcare crises, including broadly interpreting TRIPS to allow compulsory licensing and other forms of loose patent protection."³⁵

The U.S. tradition of acting unilaterally is one of the tendencies that the Global Agreement on Tariffs and Trade ("GATT")³⁶ tried to moderate. The GATT provides that a Member should refer a violation by another Member to the Dispute Settlement Body ("DSB") of the WTO.³⁷ Unlike all predecessor international treaties, the GATT has more teeth and can result

33. GlaxoSmithKline offered antiretroviral Combivir to AIDS patients at only U.S.\$4 a day; Merck cut its prices considerably; BristolSquibbMyers supplied its AIDS medication 90% below cost; and Pfizer offered its antifungal medicine to AIDS patients at no charge, and promised to construct an AIDS training clinic in Africa to strengthen the medical infrastructure. Despite attempts by the leading multinational pharmaceutical companies to mend the situation, many humanitarian organizations are still skeptical if these programs are going to last. See Oxfam Policy Papers, *South Africa vs. the drug giants* (Apr. 2001), available at <http://www.oxfam.org.uk/policy/papers/safrica/safrica2.htm>.

34. See Susan K. Sell, *TRIPS and the Access to Medicines Campaign*, PROCEEDINGS OF THE 2002 CONFERENCE ACCESS TO MEDICINES IN THE DEVELOPING WORLD: INTERNATIONAL FACILITATION OR HINDRANCE? PANEL #2: TRIPS AND ACCESS TO MEDICINES, 20 WIS. INT'L L.J. 481 (Summer 2002). See also Bess-Carolina Dolmo, *Examining Global Access to Essential Pharmaceuticals in the Face of Patent Protection Rights: the South African Example*, 7 BUFF. HUM. RTS. L. REV. 137 (2001).

35. See Nerozzi, *supra* n.10, at 616.

36. General Agreement on Tariffs and Trade, Oct. 30, 1947, GATT Secretariat, Geneva, July 1986.

37. Marrakesh Agreement Establishing the World Trade Organization, LEGAL INSTRUMENTS — RESULTS OF THE URUGUAY ROUND vol. 1, 33 I.L.M. 1441 (1994) [hereinafter WTO Agreement].

in serious trade sanctions. The DSB is governed by the Dispute Settlement Understanding ("DSU") which provides a mechanism for referring the dispute to Members for consultation, and investigation and arbitration by a Panel, which can impose a number of trade sanctions that are same-sector, except if ineffective, on the violating Member until compliance.³⁸ Although the power of the United States to take unilateral action under Special 301 is arguably curtailed by the GATT,³⁹ a number of authors have suggested that the United States may or should invoke Special 301 penalties in violation of TRIPS and use its "unilateral arsenal" to coerce countries into providing adequate protection for intellectual property.⁴⁰ Bello and Holmer, for instance, suggest that "[t]he expectation engendered by the new system [referring to DSU] — that little countries as well as big powerful ones might be able to stand up to U.S. 'bullying' under section 301 — could undermine the credibility of the U.S. threat of unilateral action, and thus the success of section 301-type programs."⁴¹ Regardless of how the United States intends to use Special 301 and other measures to take retaliatory action or issue intimidating threats, it seems that the less powerful Members will have some recourse.

That being said, "the developing countries would be forced to accept the terms set forth by the powerful developed countries or risk harm to their relationship in the international trade market."⁴² It is important to note that the threat of retaliation by the developed countries is destructive, as it deepens the culture of mistrust and frustration experienced by many developing countries, and hence may defeat desired collaboration to comply with TRIPS. Creating good will and a relatively balanced use of

38. Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, WTO Agreement, Annex 2, LEGAL INSTRUMENTS — RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 1226 (1994) ("DSU"). The WTO Agreements covered by the DSU consist of all multilateral agreements listed in the WTO Agreement Annex 1 and 2, and all plurilateral agreements listed in the WTO Agreement Annex 4.

39. See Special 301. See also Robert Pechman, *Note, Seeking Multilateral Protection for Intellectual Property: the U.S. TRIPS Over Special 301*, 7 MINN. J. GLOBAL TRADE 179 (Winter, 1998); see also Ronald Corbett, *Protecting and Enforcing Intellectual Property Rights in Developing Countries*, 35 INT'L LAW. 1083 (2001).

40. See Pechman, *supra* n.39, at 206-09; see also Judith H. Bello & Albert F. Holmer, *Dispute Resolution in the New World Trade Organization: Concerns and Net Benefits*, 28 INT'L LAW. 1095, 1096-97 (Winter, 1994).

41. See Bello & Holmer, *supra* n.40, at 1102.

42. See Nerozzi, *supra* n.10, at 627.

power, at least through mutual respect of international agreements, is essential to ensure not only that domestic laws are enacted to comply with TRIPS, but also to ensure that they are effectively enforced. One of the problems often cited regarding legal systems of the developing countries is ineffective enforcement of the rights of multinational companies caused by the judiciary's concern about accentuating inequities. This is not caused by an irrational desire to protect the local companies or industries, but is the result of actual incidents where power is abused and the judicial consciousness is troubled by prevalent injustice.⁴³ These concerns did not go unnoticed, particularly after the South African case. Members, therefore, had to meet again in Qatar to address these issues.

B. The Doha Declaration – Developed Countries Promise to Behave!

The grave concern regarding rendering the compulsory licensing provisions useless by the threat of retaliatory measures from the developed countries and their powerful pharmaceutical industries, was one of the many reasons that spurred the TRIPS Council to meet on June 20, 2001. Participants, including the United States, Europe, and Japan, agreed at the TRIPS Council meeting on June 20, 2001, that the HIV/AIDS epidemic is clearly an emergency in Africa and other countries warranting the invocation of Articles 30 and 31.⁴⁴ That was not enough, however, and it was still necessary for the Members to meet again in Doha, Qatar on November 14, 2001 to declare, among other statements, that the developing and the least developed countries should feel free to use compulsory licensing to deal with medical urgencies and cases of emergency as long as TRIPS conditions are satisfied.⁴⁵

The Doha meeting also acknowledged the limitations of the compulsory licensing system in meeting public health emergencies in cases where a country lacks the necessary technological

43. It is worth noting here the different roles of the judiciary in the common law (Australia, Britain, Canada, India, United States, etc.) and civil law systems. While the former restricts the role of the judge to the facts presented by both parties with an adversarial perspective, the latter gives the judge more leeway in considering other facts. The role of the judge in most civil law systems is inquisitorial where the judge may direct the parties to present more evidence or submissions on a certain point.

44. See Doha Declaration, *supra* n.13.

45. *Id.*

expertise and resources to manufacture the required pharmaceuticals. Compulsory licensing seems to be a powerful weapon in the hands of those countries that have a strong infrastructure where the licensed pharmaceutical can be manufactured to respond to public health needs. After the September 11th terrorist attack on the United States and the anthrax scare, the United States used the threat of compulsory licensing as a powerful weapon in negotiating the reduction of prices and production of mass quantities with the holder of the patent on Anthrax vaccines — Bayer. The same weapon is not as effective in the hands of many developing countries.

In addition, Members acknowledged that providing patent protection for pharmaceuticals in the developing countries would not encourage R&D expenditure for cures of local diseases (e.g., malaria, tuberculosis, and AIDS), given the low expected financial returns. This has been characterized by a number of non-governmental organizations (“NGOs”) (e.g., Oxfam), as the “fundamental imbalance in TRIPS.”⁴⁶ Although the Doha Declaration did not come with solutions to remedy this identified imbalance, it charged the TRIPS Council with finding expeditious solutions, and with reporting back to the General Council by the end of 2002. Despite the fact that the Doha Declaration did not provide “satisfactory” answers to TRIPS “imbalances,” it did help in easing the anxieties of the developing countries, once the developed countries promised to behave. That being said, it is noted that the TRIPS Agreement did envisage the “imbalance” problem and therefore ensured in Article 67 for the provision of aid by the developed countries. Article 67 states that the developed countries “shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favor of developing and least developed countries Members.”⁴⁷ Article 67 has not been given much effect, as many promises by the developed countries to provide aid remain unfulfilled.⁴⁸

Amidst these uncertainties regarding the effect of TRIPS on the developing countries, and in that convoluted global environ-

46. See Oxfam Policy Papers, *TRIPS and Public Health: the Next Battle* (2002) [hereinafter *TRIPS and Public Health*], available at <http://www.oxfam.org.uk>.

47. TRIPS, art. 67.

48. See TRIPS and Public Health, *supra* n.46.

ment, most developing countries enacted laws to comply with TRIPS. In such compliance, the Arab Republic of Egypt⁴⁹ passed the Intellectual Property Code in June 2000, and opted to adopt the transitional period so that patents are available for the protection of pharmaceutical products by the end of 2005. Meanwhile, Egypt was required to provide for mailbox applications and EMRs by January 2000. That did happen, but only many months later.

III. EGYPTIAN LAW RELATING TO PHARMACEUTICALS IN COMPLIANCE WITH TRIPS PROVISIONS

A. *Protection of Pharmaceuticals Prior to TRIPS*

The old Egyptian Patent Law No. 132, as amended, was enacted in 1949.⁵⁰ The old law excluded pharmaceutical products from patent protection but extended such protection to the process — “the method of production.” Prior art only extended to the past fifty years. In comparison with the U.S. patent law, the old Egyptian law provided for clear rights to the employer where the subject matter of the invention was within the business, and entitled employers to acquire patents, provided that the inventor was compensated fairly. Patents extended over a term of fifteen years, and the patentee could apply for a five-year extension upon proving that the invention was not adequately exploited.⁵¹

Under the old law, patents had to be used within three years of the date of issue within Egypt, after which date the Egyptian Patent Office (“EPO”) could impose a compulsory license over the patent. It was possible to impose compulsory licenses over patents in cases where the patent was worked but where its exploitation was insufficient for a country’s needs, or if the patentee discontinued the exploitation of the invention for two consecutive years. The compulsory license in this case was offered a party that was unreasonably refused a license by the patentee; where the patentee requested unreasonable compensation; or where the patentee denied a license to a third party owning a

49. Egypt has an area of around one million square kilometers with twenty-six Governorates. It has a population of 69,523,644 as of July 2001 with a growth rate of 1.69% as of the year 2001. The national Gross Domestic Product (“GDP”) growth rate, as of the year 2000, is 5%.

50. Egyptian Patent Law No. 82 of 1949. Full text of this law is *available at* <http://www.reldekki.com/lib02.html>.

51. *Id.*

related patent precluding the latter from the practice of its economically significant invention. All these decisions were subject to review by the administrative court.⁵²

As is evident from the foregoing brief outline, the old law contained the main principles for patent protection of all inventions including chemical processes, but excluded pharmaceutical products. Egypt signed TRIPS in 1995, with an effective date of 2000. That, however, did not silence the debate as to the disadvantages of extending patent protection to pharmaceuticals inside Egypt and in many other developing countries. Although Egypt was very well aware of its commitment to comply with TRIPS, the transition period for providing pharmaceuticals with patent protection required more time for Egypt to decide for itself how it would strike a balance between the conflicting issues of creating attractive market conditions while, at the same time, preserving the local industry and dealing with the access problem. This contributed considerably to delays in passing the new TRIPS-compliant law.

B. Egypt and TRIPS — to TRIP or not to TRIP

On the global level, Egypt shared with other developing countries anxieties regarding its ability to effectively invoke the exceptions to patentability stipulated in TRIPS without being subjected to retaliatory trade measures from the developed countries. These anxieties were eased through assurances from the developed countries in a number of meetings throughout 2001 and 2002 that the developed countries would not abuse their power or at least would be more considerate of the serious problems of poverty and inadequate access to essential medicines. It was not until the Doha Declaration of November 14, 2002 that the developing countries were assured they would not be subjected to unilateral retaliatory measures if they invoked Articles 30 and 31 of TRIPS.⁵³ Another major concern was that the invocation of these provisions did not in any way guarantee that the developing countries could solve problems of access to medicines without the serious commitment and collaboration of the developed countries and multinational pharmaceutical giants.

52. *Id.*

53. See Doha Declaration, *supra* n.13.

On the domestic level, the scene was not much different. Similar issues and debates persisted in relation to how TRIPS would be implemented under Egyptian law and as to the scope of patenting exceptions to be incorporated. The first debate that ensued in the Egyptian Parliament beginning in 1999, was whether Egypt should take an additional grace period until 2005 to provide patent protection for pharmaceuticals, particularly given the fact that it was already committed to providing other rights throughout the transitional period (e.g. EMRs). A number of interest groups on both sides of the debate lobbied the Egyptian Parliament, and the intense unresolved debates considerably contributed to more delays in passing a TRIPS-compliant law by January 2000.

On the one side, the mainly multinational, research-based pharmaceutical companies lobbied for compliance in 2000. Both the Minister of Health and the EPO supported that position. The Minister of Health, Dr. Ismail Sallam, argued for the legislation based on the government's economic reforms and the need to move to a free and open market. In addressing the fear of high increases in pharmaceuticals' prices, Dr. Sallam reflected on the good will between the Ministry of Health and the multinationals in negotiating prices and collaborating to maintain adequate access to essential medicines. The problem of price increase⁵⁴ was seen as one based on a multitude of factors, not limited to the introduction of patent protection. The EPO also supported compliance by the year 2000 mainly because the mailbox application system would cause backlogs in the office that the EPO would rather avoid. The EPO also explained that the fact that those applications, subject to certain conditions, would be entitled to EMRs, defeated the motivation for the delay. It was argued that it would be better to decide on the applications as soon as possible, instead of having EMRs for products that may not satisfy the Egyptian patentability requirements.

Despite the well-articulated positions of the Minister of Health and the EPO, the local pharmaceutical producers lobbied for invoking an additional five-year grace period. Dr. Galal Ghorab, the Chairman of the Holding Company for Pharmaceuticals and Chemicals ("HCPC"), led the campaign

54. See *infra*. IV.A. *Price Control, Differential Pricing and Parallel Imports*.

against compliance with TRIPS by January 2000⁵⁵ and represented a number of local pharmaceutical companies. Dr. Ghorab and other representatives of the local “reformulation” companies vehemently argued that Egypt should wait until 2005 for compliance, mainly to give the local producers more time to build their research capabilities, which had been limited to reformulation and reverse engineering of pharmaceuticals. Furthermore, there were allegations that the Egyptian government, represented by the practices of the Ministry of Health, discriminated against the local industries and particularly the companies with substantive public holdings, by forcing them to price products at a loss, and by not paying back outstanding debts (supply to public hospitals and clinics), which amounted to over £E 350 million.⁵⁶ These factors, Dr. Ghorab argued, undermined the local companies’ ability to compete effectively and hence, should be addressed in the transitional period.

The debate was resolved by invoking the additional transitional period of the year 2005. According to TRIPS, however, Egypt still had to comply with the mailbox, EMRs, and undisclosed information provisions by January 2000. The debates on the global level concerned compulsory licensing and access of the poor masses, and those on the domestic level concerned the economic and healthcare infrastructures. Drafts went back and forth in the Parliament until the law was eventually passed in June 2002.

C. The New Law – the Intellectual Property Code No. 82 of 2002

To comply with TRIPS, the Egyptian patent law had to change to accommodate for pharmaceutical patents; mailbox applications; EMRs; protection of undisclosed information, including that related to pharmaceuticals; and to regulate compulsory licensing in compliance with Articles 30 and 31 of TRIPS.

55. Originally, the HCPC was a holding company of public pharmaceutical companies. Later, in conformity with Egypt’s policy on privatization, many of the affiliated companies were privatized, where public holdings were considerably reduced. The HCPC holds eleven companies, seven of which are producers of pharmaceuticals. The other companies include packaging material, medical appliances, and baby milk producers.

56. See Adam Morrow, *Egyptian Health Ministry Sticks to Old Exchange Rate*, MIDDLE EAST NEWS ONLINE (Mar. 6, 2002), available at <http://www.middleeastwire.com>.

1. Patent and Other Protection for Pharmaceuticals

Section 2 of the Presidential Decree promulgating the new law provides that pharmaceutical products will be excluded from patent protection until January 2005, without prejudice to Articles 44 and 45 of the law pertaining to mailbox applications and EMRs.⁵⁷

According to Article 1, to be patentable, an invention should be novel, contain a creative (innovative) step, and be industrially applicable.⁵⁸ Patent protection does not extend to any of the following according to Article 2:

1. Discoveries and scientific theories, mathematical formulae, computer programs, and diagrams.
2. Diagnostic and surgical methods for humans and animals.
3. Plant and animal varieties, regardless of their uniqueness, if derived through biological (sexual) means, except microorganisms, and plants and animals derived by non-biological (asexual) means.
4. Live organs, tissues, and cells; natural biological matter, amino acids and the genome.⁵⁹

Article 13 adds more exceptions to cover the patenting of folk remedies and indigenous culture. It stipulates that the inventor should show that s/he has obtained the invention using legitimate means, which probably refers to compensation of the original owners.⁶⁰ Along with many other provisions of the new law, this Article will be further clarified in the Executive Regulations, which are yet to be passed.

Article 10 goes further to define non-infringing uses as follows:

1. Scientific research.
2. The making of a product, or the use of a method, by a party in Egypt who has, in good faith, used the method or the product prior to the date of the patent application relating to the same patented invention. The party entitled to use the invention can only use it in its own interest and cannot assign these operations, except as part of the whole business.
3. Indirect uses of the method of production, which form the

57. Author's trans. Presidential decree is *available at* <http://www.agip.com/laws/egypt/p.htm>.

58. *See* Law No. 82, art. 1 (author's trans.).

59. *See id.* art. 2 (author's trans.).

60. *See id.* art. 13 (author's trans.).

patented invention, to produce other products not covered by the patent.

4. The use of the invention in land, air, or maritime transportation by one of the WTO Members, or those that afford Egypt reciprocal treatment, whenever their vehicles are in Egypt on a temporary or casual basis.
5. The making, use, composition, or sale of the product by another within the patent term for the sole purpose of obtaining marketing rights thereon, provided the product is not marketed until the expiry of the patent.
6. Any other acts performed by others provided that they do not unreasonably interfere with the normal use of the patent, or unreasonably hinder the legitimate interests of the patentee, and provided that the legitimate interests of others are not jeopardized.⁶¹

It is not clear what uses Article 10(6) permits. The more important Article, however, is Article 10(5),⁶² which is aimed at striking a balance between the interests of the generic and the research-based pharmaceutical companies, known as the regulatory exception, or “boiler” provision. Such provisions allow the generic producers to use the patented invention for the purpose of developing a bio-equivalent copy to be marketed immediately after the patent expires. It should be read in conjunction with the provisions protecting the test data presented in connection with marketing approvals, and which is protected as “undisclosed information.”

Articles 55 and 56 provide for the protection of undisclosed information in general and the information submitted to seek marketing approvals for pharmaceuticals. The “competent authorities” — the Ministry of Health for pharmaceuticals — shall protect the undisclosed information from being divulged, or from being subject to unfair competitive use for five years from the date this information is provided, or until it is no longer a secret, whichever is shorter.⁶³ In that respect, Egypt follows the

61. See *id.* art. 10 (author’s trans.).

62. See World Trade Organization, *Canada — Patent Protection of Pharmaceutical Products*, Report of the Panel, WT/DS/114R, at Secs. 7.88-7.93 (Mar. 17, 2000), available at <http://www.wto.org>. Article 10(5) mirrors the corresponding Canadian provision, which was upheld in a case by the WTO Dispute Settlement Body. The Canadian provision is different from similar provisions in the United States, for example, in that it allows the sale of the patented product as well as its use.

63. See Law No. 82, art. 55-56 (author’s trans.).

example of many European countries that limit protection of such information for periods ranging from five to ten years. It seems that this point has not been thoroughly debated. The main concern for research-based pharmaceutical companies when it comes to protection of such information (test results, clinical and other studies to show the safety and efficacy of the pharmaceutical in question for obtaining market approval) is that such information is not relied upon either by the Ministry of Health or the generic producer to obtain approval for generic products, and hence free ride on the test data, which costs tens of millions.

The unauthorized use of test data is a serious problem in Egypt for research-based companies. In late 2001, a group of research-based companies complained to the Ministry of Health after noticing a chain of approvals granted to generic producers in a short time, strongly implying that they did not generate their own test data.⁶⁴ Now, with the passage of Articles 55 and 56, the Ministry of Health is obliged to ensure that there is no access to the test data except for the purposes of examining the application of the originator of the information. Article 57 goes even further by providing that the liability of the Ministry of Health is not exonerated when that information is used by another party without authorization, unless the Ministry of Health proves that it took all reasonable and sufficient measures to protect it.⁶⁵ Article 57 goes steps further than required by TRIPS to instill trust in the regulatory bodies and to send a strong message that test data will be used only in the interest of the originator.⁶⁶ It is not clear whether the Ministry of Health is entitled, after the expiry of the five-year protection period, to consider the test data in approving subsequent applications by generic producers. It is submitted that such an allowance is desirable as it boosts the local generic production of pharmaceuticals. The experience of the United States in that regard can be used as a guide.

The U.S. Drug Price Competition and Patent Term Restoration Act, known as the Hatch Waxman Act, allows research-based companies to apply to "restore" the term of their patents, consid-

64. See Niveen Wahish, *At Loggerheads over Patent Rights*, AL-AHRAM WEEKLY ONLINE, (May 24-30, 2001), available at www.ahram.org.

65. See Law No. 82, art. 57 (author's trans.).

66. *Id.*

erably shortened by the long testing and registration process, in return for allowing the generic producers to refer to the test data submitted by the former to the Federal Drug Administration for marketing approval.⁶⁷ The research-based companies can apply for up to five years to restore the term of their patents, provided that the “effective life” of the patent does not exceed fourteen years. This allows the research-based companies to recoup more of their investment costs in cases where the testing and drug registration processes take very long, adversely affecting the exploitation period. On the other hand, the generic producers can avoid spending millions to prove that the generic product is safe and effective by referring to the test data previously presented by the research-based companies. Generic producers only have to show that the generic product is bio-equivalent to the branded pharmaceutical, and save tens of millions in the process.

The Hatch Waxman Act was very successful in striking the desired balance with positive results for both, the generic and the research-based companies. It is reported that since 1983, the generic producers’ market share grew from 19% to 50% to date, valued at U.S.\$10 billion in 1999 and expected to double by 2010. The Act also enabled price reductions at an earlier time. While under the old system it took two to five years after the expiry of the patent for a generic to be introduced into the market, now the generic gets introduced immediately and sells for around 25% of the price of the branded pharmaceutical. In addition, it is claimed that the ability to “restore” patent terms has encouraged research-based companies to increase their R&D expenditures, which rose to U.S.\$26 billion in 2000 compared to U.S.\$3.6 billion in 1984.⁶⁸

2. Mailbox and EMRs

Although the new law does not provide patent protection for pharmaceuticals until 2005, it provides for acceptance of patent applications in a “mailbox” as of January 1995. Article 43 provides that the EPO shall accept patent applications starting from January 1, 1995, relating to chemical and agricultural food,

67. Pub. L. No. 98-417, Title II (1984).

68. See Pharmaceutical Research Manufacturing Association (“PhRMA”), *Hatch-Waxman: the Results are in*, available at <http://innovation.phrma.org>.

and chemical pharmaceutical products, and shall keep it until January 1, 2005, at which time they would be due for examination.⁶⁹ The Article provides further that once a patent is issued, protection starts from the date of issue for twenty years as though from the date of filing an application.⁷⁰

Article 44 provides that the applicant may apply for EMRs provided that:

- An application has been lodged after January 1, 1995;
- A patent covering the same invention has been granted in a Member pursuant to an application submitted after January 1, 1995;
- The applicant has obtained marketing approval in that Member for the same product; and
- The applicant has obtained marketing approval from the competent authority in Egypt.⁷¹

The Article further stipulates that the EPO shall grant an EMR certificate after the approval of a Ministerial Committee to be formed by the Prime Minister.⁷² So far, the new law complies with TRIPS in that it provides for mailbox and EMRs. However, with vague terms as to who will receive and decide on EMR applications, more delays are on the horizon until the executive regulations are issued and the Ministerial Committee is actually formed.

Article 44 also adds another qualification, providing that if the application was published one year from the date of being lodged with the EPO, it cannot be subject to an EMR application.⁷³ It is not clear what is intended by this qualification or what is meant by "publication." TRIPS and the new law condition the grant of EMRs on applying and obtaining a patent as well as marketing approval in another Member after January 1, 1995. The question remains — would having a patent issued and published in 1996, for example, defeat the right to an EMR if an application was actually lodged in the mailbox in 1997? Again, it is not clear what would happen in such a case.

EMRs, in compliance with TRIPS and the new law, extend over five years or until a patent application is decided, whichever

69. See Law No. 82, art. 43 (author's trans.).

70. *Id.*

71. See *id.* art. 44 (author's trans.).

72. *Id.*

73. *Id.*

is shorter. The above-mentioned Ministerial Committee may, in certain cases, revoke the EMR where the right holder abuses the right. Although it is not mentioned on what basis such an abuse will be reviewed, the decision of the Ministerial Committee is reviewable by the Administrative Court, according to the general rules of the Egyptian Administrative Law.

3. Exceptions to Patent Rights and Compulsory Licensing

The new law bases its governing use and compulsory licensing provisions on Articles 30 and 31 of TRIPS, and clearly identifies circumstances under which they can be invoked. Article 17 of the new law is based on Articles 8, 27(2), and 30 of TRIPS, which allow Members to adopt measures to protect public health and interest as well as the environment. Article 17 of the new law provides:

The EPO shall send to the Ministry of Defense, the Ministry of Military Production, the Ministry of Internal Affairs, or the Ministry of Health as the case may be, copies of patent applications which pertain to defense, military production, public security, or have value to military, security or health concerns [. . .].⁷⁴

Article 17 entitles the Minister of any of the mentioned ministries "to oppose the approval of the patent application within ninety days of receipt." In such circumstances, the issuance of the patent is halted. The procedures are not specified and it is not clear whether the patent applicant may apply for judicial review of this decision.⁷⁵

The wide scope of Article 17 may be alarming, particularly as it is a new addition when compared to the old law. The old law did provide for revocation of patent rights on the grounds of national security and public interest. Article 25 of the new law provides the same and adds the ground of public health as well. It provides that in cases where compulsory licensing is insufficient, the patent may be revoked. The patentee is to be compensated for the fair commercial value of the invention and may appeal the decision of confiscation as well as the amount of compensation within sixty days.⁷⁶

74. *See id.* art. 17 (author's trans.).

75. *Id.*

76. *See id.* art. 25 (author's trans.).

It seems that Articles 17 and 25 address similar situations to halt the issuance of a patent or revoke it after it is granted. With these Articles, Egypt is arming itself with all the provisions necessary to respond to pressing public needs.

More exceptions are provided in Article 23, which outlines the conditions and the procedures for compulsory licensing.⁷⁷ The provisions stipulated under Article 31 of TRIPS are reiterated here. In addition, Article 23 stipulates other situations where compulsory licensing may be invoked. Article 23(1)-(3) provides that a compulsory license may be imposed "to support national efforts for the economic, social and technological development of vital sectors, without prejudice to the rights of the patentee."⁷⁸ Although compulsory licensing is not covered under TRIPS Article 31, it is alluded to in Article 8, which allows Members to adopt measures designed "to promote the public interest in sectors of vital importance to their socio-economic and technological development."⁷⁹

Article 23(1)-(3) is designed to address the issue of developing the local pharmaceutical industry to deal better with the problem of access to necessary medicines.⁸⁰ That being said, this Article may be challenged given the developed countries' insistence that no exceptions should be made, regardless of the TRIPS Articles, except in the most extreme situations. Using the TRIPS compulsory licensing for development, other than for strict healthcare purposes, was discussed in the TRIPS Council meeting of June 20, 2001, where both, the United States and Switzerland opposed the developing countries' contention that TRIPS exceptions can be used to develop local pharmaceutical production. The United States and Switzerland argued that any such action falls outside of the TRIPS provisions as it relates to industrial rather than health policies.⁸¹ This point needs to be further clarified by the TRIPS General Council in light of Article 8.

Article 23(2) expressly provides for compulsory licensing of

77. *See id.* art. 23 (author's trans.).

78. *Id.*

79. TRIPS, art. 8.

80. *See* Law No. 82, art. 23(1)-(2) (author's trans.).

81. *See* World Health Organization and World Trade Organization Secretariats, *Workshop on Differential Pricing and Financing of Essential Drugs: Executive Summary of Report* (Apr. 8-11, 2001), available at <http://www.who.int>.

pharmaceuticals in a way that mirrors the French Intellectual Property Code provisions.⁸² It provides that the Minister of Health may impose a compulsory license over a patented pharmaceutical whenever the supply does not satisfy local need, or the pharmaceutical is of unacceptable quality, or offered at unreasonable prices. This provision seems to fall within the ambit of TRIPS Article 31, although unlike Article 31, it foregoes the condition that there be a case of urgent emergency. The fact that it is a provision incorporated into the laws of some developed countries makes it interesting to see how it will be accepted by the other developed countries.

Furthermore, Article 23(4) repeats the condition of "working the patent" stipulated in the old law, but extends the period to four years from the date of the application or three years from the date of issue, whichever is longer.⁸³ This does not seem to make much difference except in cases where the patent issues in less than a year, a possibility that seems too remote, particularly for applications covering pharmaceuticals. This rule, however, is not to be applied strictly, as the Article further provides that the EPO should extend this period if the delay in exploitation is caused by technical, legal, or economic reasons beyond the control of the patentee.

The new law has more teeth because its deterrent effect exceeds that of the old law. The old law's penalties for patent infringement included two years of imprisonment, and statutory damages ranging from £E 10 to £E 300 for each incident, which is of no deterrent effect. The new law reinstates the same term of imprisonment but only in cases of repeated infringement. Most importantly, it raises the statutory damages from 100% to 300% in the order of £E 20,000 to £E 100,000 for each infringement, which are doubled in cases of repeated infringement. Although it is arguable that the amount of statutory damages is still not deterrent in cases of pharmaceuticals, it is a leap from the damages that could be awarded under the old law. In addition to that, the Court has the discretion to issue injunctive orders, and is required to order confiscation of the infringing products.

82. See Law No. 82, art. 23(2) (author's trans.). See also France Intellectual Property Code, art. L. 613-16 (providing for compulsory licensing of patents issued on drugs whenever patented drugs are supplied in insufficient quantity, are of poor quality, or offered at abnormally high prices).

83. See *id.* art. 23(4) (author's trans.).

Overall, the new law complies with TRIPS provisions and in some cases expands on them. Until complete patent protection is given to pharmaceuticals in 2005, market exclusivity is guaranteed for the pharmaceuticals that satisfy the specified requirements. The process of obtaining market exclusivity, however, is still not clear and more delays will be involved until the executive regulations are passed and the Ministerial Committee entrusted with the process is formed. Meanwhile pharmaceutical companies are assured the protection of their test data under the undisclosed information provision, which is of extreme importance for research-based pharmaceutical companies in Egypt. Having good laws, however, is only the first step, as the ability to take effective enforcement action is of critical importance. In that regard, the collaboration of the regulatory bodies as well as the judiciary to apply the new law and to effectively enable enforcement, is essential. The law cannot be applied in a vacuum and the pharmaceutical industry is certainly affected by more than intellectual property laws. There are other legal and economic considerations that have significantly shaped and still shape the Egyptian pharmaceutical industry, as outlined below.

IV. THE EGYPTIAN PHARMACEUTICAL INDUSTRY – CHALLENGES OF GLOBALIZATION

The pharmaceutical industry in general is divided into two main groups: the research-based (or innovator) companies and the generic producers. The first group is extremely dependant on patent protection due to the enormous R&D costs involved (around U.S.\$800 million) to produce a breakthrough (one out of 5,000 compounds), and the extended period of ten to twelve years that it takes to introduce it into the market.⁸⁴ Patent protection allows the company to charge high prices and hence, recoup its investment. Global expenditures on pharmaceutical R&D reached an estimated U.S.\$40 billion in 2000, where over 50% was expended by U.S. companies. The top ten companies are reported to spend between U.S.\$1.5 to U.S.\$2.5 billion a year on R&D. The U.S. (research-based) pharmaceutical industry is very profitable, with profits reaching nearly four times the median rate for all Fortune 500 companies.⁸⁵ Some reports indi-

84. See Nair, *supra* n.6.

85. *Id.*

cate that pharmaceuticals, to which no generic yet exists, cost around U.S.\$25 and are sold for around U.S.\$300. The leading pharmaceutical companies report gross profits between 70%-80% as prices rise faster than the inflation rate.⁸⁶ Forty percent of all sales of the U.S. pharmaceutical companies come from overseas and they supply nearly 50% of major pharmaceuticals sold worldwide, with a growth rate of 3%-5% annually.⁸⁷

The U.S. generic pharmaceutical industry is also of considerable size, with 320 companies manufacturing generic drugs some being owned by, or in a joint venture with, the research-based companies. The generic industry has a growth rate of 2.5% over five years.⁸⁸ It is estimated that as of the year 2000, 300 best-selling brand name drugs were available in generic form. Prices usually drop from 40% to 65% after the generic version is introduced into the market.⁸⁹ The generic producers play an integral part in reducing the price of pharmaceuticals, and hence, in increasing the level of access to essential medicines.

There is no basis for comparison between the U.S. and the Egyptian pharmaceutical industries. Still, the Egyptian pharmaceutical industry is very attractive to the U.S. and other foreign pharmaceutical companies, given its size and growth potential. The Egyptian pharmaceutical industry is the largest producer and consumer of pharmaceuticals in the MENA region, where it provides 30% of the supply.⁹⁰ U.S. pharmaceutical companies hold around 18% of the market share in the Egyptian pharmaceutical industry, which was estimated at U.S.\$1.28 billion in 1999 with a growth rate of 14% annually.⁹¹ The U.S. companies' market share is expected to grow to 25% where the U.S. Pharmaceutical Research Manufacturing Association ("PhRMA") estimates over U.S.\$300 million will be invested by PhRMA members in the few coming years.

The local pharmaceutical production is based on drug re-

86. *Id.*

87. See *Pharmaceutical Industry Profile*, U.S. BUS. REPORTER, available at <http://www.activemedia-guide.com>.

88. *Id.*

89. *Id.*

90. See Cairo American Chamber of Commerce ("AmCham"), *The Egyptian Pharmaceutical Industry* (Feb. 2002), available at www.amcham.org.

91. See Corporate Information, *Pharmaceuticals and Corporate Information*, available at <http://www.corporateinformation.com>.

formulation rather than R&D where 92.5% of pharmaceuticals are produced locally and 7.5% imported in the finished form. Nearly 85% of the raw materials used in the production are imported.⁹² This limits the ability of the Egyptian market to stabilize prices. Added to that are a number of economic, social, and regulatory factors that affect competition in the Egyptian pharmaceutical industry. The most important relate to price control, parallel imports, and the economic policies that will be employed to develop the healthcare infrastructure. To that we now turn.

A. Price Control, Differential Pricing and Parallel Imports

Price increases beyond the purchasing ability of the poor masses constitute one of the major concerns stemming from the extension of patent protection to pharmaceuticals in all developing countries. There are an estimated 1.2 billion people worldwide surviving on less than one-dollar-a-day, and 2.8 billion on less than two dollars a day, 90% of whom live in South or East Asia and Africa.⁹³ When it comes to Egypt, around 20.15% of its approximate population of 70 million people is below the lower poverty line, and 49.6% below the upper poverty line.⁹⁴ The highest poverty incidence is reported in the Upper Egypt urban region, amounting to 36%, where the poor masses' access to healthcare facilities is not the problem — its cost is. In Egypt, between 14 and 35 million people will be hit hard with any increases in the prices of pharmaceuticals, particularly those related to diabetes, renal and heart diseases, and cancer. These statistics make maintaining the prices within affordable limits essential. The goal can be achieved only if the real reasons behind the increase of prices are understood.

Determining the causes behind price increases and hence, the intensification of the access problem, is essential for identifying solutions, and the formulation of appropriate economic poli-

92. *Id.*

93. See Commission on Intellectual Property Rights ("CIPR"), *Integrating Intellectual Property Rights and Development Policy*, at 8 (Sept. 2002), available at <http://www.iprcommission.org>.

94. See Heba El-Leithy, *Gender Dimensions of Poverty in Egypt*, Forum Newsletter, ECON. RES. F. FOR THE ARAB COUNTRIES, IRAN & TURKEY, Vol. 8, No.2 (Oct. 2001), available at http://www.erf.org.eg/nletter/oct01_9.asp (citing statistics based on 1999/2000 household income and expenditure survey by CAPMAS).

cies to regulate the pharmaceutical industry and the market as a whole. A lot of discussion has ensued as to whether patent protection is the prime cause behind the price increases of pharmaceuticals, with reports and studies in support of both sides. NERA Economic Consulting studied pharmaceutical prices in nine developing countries over eleven years. In 1998, it concluded that patent protection did not significantly impact pricing but instead, pricing was a result of market-based factors e.g., competition from other pharmaceuticals. This seems to be true in countries where the healthcare and economic infrastructures are developed to an extent that local and generic producers can effectively compete, causing prices to drop, a prerequisite that is lacking in Egypt to a considerable extent. In addition, as other studies indicate, the prices of many essential pharmaceuticals did increase following the introduction of patent protection. Abdul-Aziz Saleh of the WHO, cites a number of studies reporting that prices of pharmaceuticals have increased from 5% to 76.7% in the developing countries.⁹⁵ Furthermore, Dr. J. Quick, WHO Director of Essential Drugs and Medicines Policy, adds that when a patent expires, the price of the branded pharmaceutical drops by 40% when there is one generic competitor, and by 71% when there are ten generic competitors. He adds that with strong generic industries in only a handful of countries, mainly the developed countries, price increases following patent protection are certain.⁹⁶

There is no doubt that patent protection is at least one of the main factors behind the increase of pharmaceutical prices. The real question, however, is what is the cost to society and the global community if such protection is lacking. There is ample evidence that lacking patent protection will significantly dry up R&D expenditures and hence, may be even more costly as diseases get out of control. One of the best analyses of the reasons behind price increases is that presented by Dr. Bale of IFPMA, showing that the cost to society of lack of protection may be

95. See Abdul Aziz Saleh, *Impact of Globalization on Drug Industry: Possible Risks and Means to Overcome Them*, THE SEVENTH INTERNATIONAL CONFERENCE ON "THE IMPACT OF GLOBALIZATION ON DEVELOPMENT AND HEALTH CARE SERVICE IN ISLAMIC COUNTRIES" (March 23-27, 2002), available at <http://www.islamset.com>.

96. See Jonathan Quick, *Ensuring Access to Essential Medicines in the Developing Countries and Least Developed Countries — Framework for Action*, IOMS CONFERENCE, available at <http://www.islamset.com>.

much higher. Dr. Bale explains that the cost of no protection is infinite, which, while high during patent protection, will decline in the long run. This decline may take place before the expiration of the patent term, upon introduction of other similar pharmaceuticals into the market.

In Egypt, prices of pharmaceuticals are certainly affected by many other factors in addition to patent protection. First, the fact that 85% of the raw materials that go into the local production of pharmaceuticals are imported, increases prices dramatically.⁹⁷ This was accentuated in the previous two years with the devaluation of the Egyptian pound from £E 3.84 per U.S.\$1.00 in 2001 to £E4.58 per U.S.\$1.00 as of the date of this Article. Since the start of 2002, the prices of many essential pharmaceuticals have skyrocketed. An example is Intergel, an anti-adhesive substance whose price experienced a 70% increase within four months.⁹⁸ The Egyptian government reacted by forcing local producers (private/public companies) to set their prices at the old conversion rate, affecting their ability to compete with the multinationals. In fact, this stirred accusations from HCPC and other companies that they were discriminated against by the government. Dr. Ahmed Al-Minawi of the Egyptian Medical Magazine explained that the government had to take such action to prevent public hospitals and clinics from going bankrupt.⁹⁹

The roots of the problem of pharmaceutical price increases in Egypt go even deeper. They are based in the inability of the local producers to effectively compete with the multinationals due to the weak economic and healthcare infrastructure. Dr. Sarwat Basily, President of the Ministry of Health Chamber of Pharmaceutical Industries, explained that despite the best efforts of the Egyptian government to move to a free market, "market forces cannot be applied — as they are in the U.S. — to the pharmaceutical industry."¹⁰⁰ Despite this, Egypt is resisting an utterly paternalistic approach to the local pharmaceutical indus-

97. See Dr. Harvey Bale, Jr., *TRIPS, Pharmaceuticals and Developing Countries: Implications for Drug Access and Drug Development*, WHO WORKSHOP ON THE TRIPS AGREEMENT AND ITS IMPACT ON PHARMACEUTICALS, Jakarta, Indonesia (May 2, 2000), available at <http://www.ifpma.org> (citing study showing that prices of equivalent drugs in Mexico and Taiwan with patent protection were less than prices offered in Egypt even though no patent protection was available then).

98. See Wahish, *supra* n.64.

99. *Id.*

100. *Id.*

try, as well as the use of stringent price controls. Instead, the Minister of Health has presented, as the ideal solution, setting some price controls through negotiation with the various pharmaceutical companies.

The following are other solutions, some of which have already taken effect.

B. *Differential Pricing*

Differential pricing is where the same pharmaceutical is sold for less in the developing country, taking into account the purchasing ability of the poor masses. Many multinationals have expressed preference for this method as opposed to price controls, provided parallel imports are restricted.¹⁰¹ So far, this seems to be the best option, as it fosters good will between the government and the pharmaceutical companies, particularly the multinationals, as long as there is no discrimination against the local companies affecting their competitive ability. It has to be noted, however, that differential pricing may be controversial with the rising international scrutiny of prices. Also, with growing access problems in the developed countries,¹⁰² differential pricing may be politically harmful. The WHO and WTO Secretariats asserted in their meeting in Norway on April 8-11, 2001,¹⁰³ that whenever differential pricing is used, it is important to clarify that lower prices for the developing countries do not mean higher prices for the developed countries. The Meeting also touched upon concerns relating to creating an anti-dumping effect on the local industries of the developing countries.

C. *Parallel Imports of Cheaper Pharmaceuticals*

Parallel imports are products made and marketed by a patent owner in more than one country, which are later imported into one of these countries without the authorization of the patent owner. This is based on the legal principle of "exhaustion of rights," which provides that once a patent owner sells its product

101. See Fouad Benghalem, *Financing and Differential Pricing of the Essential Medicines for Developed and Least Developed Countries*, IOMS CONFERENCE, available at <http://www.islamset.com>.

102. An example is the United States where the elderly's access to medicines is increasingly diminishing, thereby raising public health concerns.

103. See World Trade Organization, *WTO, WHO secretariats workshop on affordable drugs*, available at <http://www.wto.org> for a list of final reports and discussions.

in one country, its patent is exhausted and it has no more rights or control over the product. Article 6 of TRIPS clearly excludes from its dispute settlement power such disputes relating to provisions in domestic laws of Members that allow parallel imports.¹⁰⁴ The significance of this for pharmaceuticals comes up in situations where the same product is sold at considerably different prices in two countries, the product is imported into one of the countries by a third party and offered for sale at a reduced price, thereby affecting the patent owner's ability to maintain the higher price in the second country. It is not clear if Egypt would use this method to provide affordable pharmaceuticals, but it is certainly a solution that may be used, given that it is permitted under the new law.

D. *Monetary Fund To Stabilize Prices*

Both, the WHO/WTO Meeting and the Commission on Intellectual Property Rights ("CIPR"), formed by Clare Short, the British Secretary of State for International Development,¹⁰⁵ addressed the option of providing developing countries with financial aid, or the creation of a global fund, to deal with the problem of access. CIPR argues that providing adequate access to essential pharmaceuticals should be part of the commitment of the international community to reduce the proportion of people in poverty by half in the year 2015. There has been no global fund established for that purpose to date.

The WHO, however, has prepared a list of 100 essential medicines needed to treat diseases of major populations, and lobbied governments and NGOs to provide donations and financial assistance in this respect. From 1998 to 2001, pharmaceutical companies and NGOs in the United States alone provided more than U.S.\$1.9 billion in financial assistance and donated medicines. NGOs, e.g., the Donation Program for River Blindness, the Global Alliance for Vaccines and Immunization, and the Accelerated Access Initiative, have played critical roles in solving access problems in twenty-three countries.¹⁰⁶ Despite these efforts, the WHO stresses that this is hardly a long-term

104. See TRIPS, art. 6.

105. See CIPR, *supra* n.93, at 8.

106. See Statement delivered by Dr. Harvey Bale, Jr., IFPMA, on behalf of the research-based pharmaceutical industry at the 55th World Health Assembly, Geneva (May 17, 2002), available at <http://www.ifpma.org>.

solution to the problem. Doctors Without Borders have also strongly criticized these programs for “attaching conditions, limiting the scope of donations, and taking too much time to implement.”¹⁰⁷ There seems to be a lot of global pressure on the developed countries to seriously address this problem, which is currently under consideration by the TRIPS General Council.

The new law does address this problem briefly, providing in Article 18 that a fund shall be created to adjust the prices of pharmaceuticals that are not subject to export, with the main purpose of stabilizing prices.¹⁰⁸ The Minister of Health shall oversee the operation of the Fund while the President shall determine its financial resources. Article 18 provides further that any financial assistance granted from other governments or organizations shall go to the Fund. It is not clear what the needs are that the Fund will try to satisfy or the level of its financial resources.¹⁰⁹

E. *Pooled Procurement*

Pooled procurement entails the coming together of the developing countries to negotiate reduced prices for essential pharmaceuticals with pharmaceutical companies. There are a number of concerns with this solution relating mainly to quality issues, and the fact that the national populations of countries in the MENA region are too small to secure desirable prices.¹¹⁰ There are also solutions that address the access problem on the surface without dealing directly with the root causes relating to infrastructure.

F. *Developing Infrastructure and the Competitive Landscape*

Poverty is the main manifestation of a weak economic and healthcare infrastructure. It does not only affect pharmaceutical prices, but also the ability of the local producers to effectively compete, and the feasibility of directing R&D expenditures to finding cures for local diseases. The R&D and the manufacturing deficiencies that Egypt, among other developing countries,

107. See Doctors Without Borders (“DWB”), *World AIDS Day Teleconference Transcript* (Nov. 28, 2000), at www.dwb.org/news/wad2000_transcript.htm.

108. See Law No. 82, art. 18 (author’s trans.).

109. *Id.*

110. See Nerozzi, *supra* n.10, at 629.

suffers from are very prevalent. The developing countries produce less than one tenth of pharmaceuticals' output while having over 75% of the world's population.¹¹¹ Looking at the bigger picture, Egypt faces challenging economic times, as its local industry struggles to compete in the global pharmaceutical industry. In addition to the Trade Law No. 17 of the year 1999, which encourages technology transfer,¹¹² Egypt adopted a number of economic policies to promote public/private development agreements. An example is the agreement between the Egyptian Government and Siemens, whereby Siemens will invest £E 1 billion (250 million Euro) for design, construction, and commissioning of a new pharmaceutical plant to be implemented in phases from 2003 to 2005. Siemens will also provide technology transfer training and development of Egyptian employees and will aim at exporting.¹¹³

CONCLUSION

The Egyptian pharmaceutical industry is the largest in the MENA region, and it is currently undergoing a number of changes. The main change relates to extending patent protection to pharmaceuticals pursuant to the TRIPS Agreement. TRIPS provisions, however, include exceptions to patent rights, which may be invoked by Members in a number of cases. In implementing the provisions of TRIPS, Egypt tried to strike a balance between its economic reform policy and the responsibility to provide its poor masses with adequate access to essential medicines. Taking these and other considerations into account, Egypt passed a new law to provide patent protection for pharmaceuticals, while at the same time, providing for exceptions in cases of emergencies. The most controversial exception is related to the use of compulsory licensing for the economic development of the local industry. Although there is great doubt that this provision will be invoked, the possibility still exists.

There is a strong possibility that the Egyptian government

111. See Bale, *supra* n.97, at 10.

112. On file with author.

113. See Siemens, Press Release, *Siemens has been awarded a contract to build a pharmaceutical and petrochemical factory in Egypt* (Sept. 20, 2002), available at <http://www.is.siemens.de>. See also Siemens, *Siemens in Egypt*, at <http://www.siemens.com.eg>.

will avoid stringent price controls, resort to compulsory licensing in cases of emergency, and negotiate with multinationals wherever possible for affordable prices. On the global level, Egypt will probably continue to lobby with other developing countries for the creation of a global fund addressing the access problem, while at the same time procuring grants to the local fund established under the new law.

What is more interesting and promising is Egypt's opting not to control prices and instead, creating a fund for their stabilization. In addition, other methods may be used, e.g., directly negotiating reduced prices with pharmaceutical companies. Overall, there is much promise in the Egyptian pharmaceutical industry, although it remains to be seen how and whether Egypt will use exceptions to patent rights in tackling the formidable challenges posed by trade globalization.