
The TRIPs Agreement and Developing Countries: A Legal Analysis of the Impact of the New Intellectual Property Rights Law on the Pharmaceutical Industry in Egypt

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Summary

This paper seeks to highlight the impact that the new Intellectual Property Rights Law might have on the pharmaceutical industry in Egypt and on its population. It also seeks to provide a deep assessment of the law in considering the interest of Egypt’s pharmaceutical industry and the interest of Egyptians in general. The absence of product patents under the Old Patents Law might be one of the main factors that stand in the way of progress for this industry in Egypt. However, with the new IPR law coming into force, the industry is entering a critical phase. The law has made substantial changes in the levels of pharmaceutical patent protection. Therefore, it will force domestic industry to respect the monopoly of inventors on their drugs. As for the Egyptian population, it is expected that the law will have adverse effects, reflected in the potential increase in the prices of new drugs. This without doubt represents a real risk for all Egyptians.

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1- Introduction

In correspondence with Egypt’s commitment as a World Trade Organisation (WTO) Member, a new Intellectual Property Rights Law (Law No. 82/2002, Official Journal - ALWAKAA –AL MASREA, issue No. 22 bis, June 2, 2002, hereinafter ‘the new IPR law’) was enacted and it came into force on June 4, 2002. The law, aimed at the implementation of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPs Agreement), is Egypt’s maiden independent intellectual property rights law. It also represents the country’s first ever effort to combine all fields of intellectual property (except trade names) in one single Code.

This paper will firstly provide an outline of the TRIPs Agreement. It will then explore the position of the pharmaceutical industry in Egypt before examining the new IPR law, with special emphases placed on a comparison between the new and old provisions on patents. An overview of the Doha Declaration on the TRIPs Agreement and Public Health, which was adopted on November 14, 2001, is subsequently demonstrated. In the light of all these, an appraisal of the new IPR law is offered, alongside a number of recommendations that could be considered in future policy review.

2- The TRIPs Agreement: an overview

The TRIPs Agreement is one of the many agreements concluded in the Uruguay Round of Multilateral Trade Negotiations (1986-1994) which also created the World Trade Organisation. The Agreement of WTO entered into force on January 1, 1995 (for the legal texts of the results of the Uruguay Round, see The WTO: The Legal Texts, 1999).

The TRIPs Agreement is seen as the greatest achievement in the field of Intellectual Property Rights during the last century. The Agreement is based on certain international conventions
in the field of intellectual property, namely the Paris Convention,\(^1\) the Berne Convention,\(^2\) and the Rome Convention,\(^3\) as well as the Treaty on Intellectual Property in Respect of Integrated Circuits.\(^4\) It also provides other obligations additional to those stated in the above-mentioned conventions.\(^5\) The minimum standards of protection included in the Agreement are concerned with the availability of almost all categories of intellectual property rights and their enforcement (Correa, 2000, p.2).\(^6\) The Agreement furthermore regulates certain anti-competitive practices in contractual licences.

At first glance, those levels of protection embodied in the TRIPs Agreement mirror the existing standards in developed countries’ laws and regulations (Correa, 2000, p.3; South Centre, 1997, p. i (preface)). These are regarded by developing countries as exceptionally high (South Centre, 1997, p. i (preface)). It must be noted that all WTO Members are bound to include these standards in their own national laws. Non-compliance with such an Agreement will trigger the initiation of dispute settlement procedures (Gervais, 1998, p.249).

3- The Pharmaceutical Industry in Egypt

Medicines are of particular importance to Egypt. She is a developing country with a high level of classic problems related to such economic status (such as unemployment). The birth rate is considered the highest in the Arab region. As a result, Egypt was reluctant to swiftly implement the TRIPs’ levels of protection, despite the intensive pressures received from a number of developed countries in particular the USA\(^7\) and European Union countries. Recognising the large risk represented in providing patent protection for pharmaceutical products, Egypt has declared her intention to benefit from the additional grace period set forth in the Agreement (i.e. an additional five years over the regular period attributed to developing countries with regard to all aspects of IPRs).

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\(^2\) The Berne Convention for the Protection of Literary and Artistic Works signed in 1886. The Convention was reproduced in WIPO, *Berne Convention for the Protection of Literary and Artistic Works*, (Geneva: WIPO Publication No. 287 (E), 1992). WTO Members are required to comply with Articles 1 to 21 of the Convention as amended in 1971 and its Appendix. However, these Members do not have rights or obligations in respect of Article 6bis relating to moral rights or the rights derived therefrom (Art. 9 (1) of the TRIPs Agreement).


\(^5\) According to TRIPs Art. 2 (2), nothing in Parts I to IV shall derogate from existing obligations that WTO Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in respect of Integrated Circuits.

\(^6\) The only two categories of IPRs that are not included in the TRIPs Agreement are: i) utility models, and ii) breeders’ rights. Indeed, it has been stated that the absence of these two categories may be explained by the relative lack of interest on the part of the major industrialised countries (and the industrial lobbies that actively promoted the TRIPs negotiations), (South Centre, 1997). WTO Members consequently are not obliged by the TRIPs Agreement in formulating their domestic legislations on utility models and breeders’ rights (South Centre, 1997).

\(^7\) For example, the USTR 2001 Special 301 Report in which Egypt was placed on the priority watch list, as in the previous year, for not, among other things, providing patent protection for pharmaceutical and agricultural chemical products. The USTR 2001 Special 301 Report, available at: [http://www.ustr.gov/enforcement/special.pdf](http://www.ustr.gov/enforcement/special.pdf) (last visited August 17, 2003).
There is no doubt that patent protection is an important element of a ‘complex strategy developed by the R&D-intensive pharmaceutical drug companies to meet market competition’ (Nogues, 1990, p.102; Subramanian, 1995, 253). Patents are also said to be vital instruments for giving these companies effective opportunity to appropriate the returns from their inventions (Nogues, 1990, p.102).

Egypt has, since the early years, considered the improvement and growth of the national pharmaceutical industry as critical to its ability to provide quality healthcare to its population. Currently, not only does Egypt’s pharmaceutical industry provide nearly 93% of the current local consumption that totals approximately three billion Egyptian Pounds annually, it is also a major source of national income in the form of foreign currency derived from the export of its products (Federation of Egyptian Industries (FEI), 1997, p.1).

Within this sector, there are about 35 pharmaceutical factories, consisting of public sector, private sector, and joint venture (MFT study, 2001, p. 15). Furthermore, there are pharmaceutical companies that are subsidiaries of Multinational Pharmaceutical Companies (MNCs) (FEI, 1997, p.1). The existence of that variety of companies, particularly foreign companies, working within the drugs industry means that such an industry is open to pharmaceutical investors (whether national or multinational).

It is worth noting that drug prices in Egypt are one-sixth less compared to those of the MNCs. However, foreign pharmaceutical companies in Egypt set relatively high prices. These companies rely, to a greater level, on intensive advertising campaigns to promote their products (FEI, 1997, p.1). The importation of the specialised raw materials from the parent companies moreover accounts for the high-priced products of those companies functioning in Egypt, a fact that does not apply to the domestic industry (FEI, 1997, p.2). Generally speaking, Egypt imports an estimated 80-90 percent of its total raw materials in the form of active ingredients (Subramanian and Abd-El-Latif, 1997, p.7-8). Another special characteristic of this industry is that drug prices are governed by the Ministry of Health (MOH) and that no drugs can be circulated without such pricing controls (FEI, 1997, p.2).

Investments made in the pharmaceutical sector are very high in terms of the size of consumption and domestic demand. A large portion of the products (mainly generics drugs and other formulations such as vitamins) is therefore exported to Arab, African and East European countries (Saad, Ahram newspapers, 2003). The share of the foreign-owned pharmaceutical companies in total exports is minuscule, as a consequence of restrictions imposed by the parent company on its Egyptian affiliates (Subramanian and Abd-El-Latif, 1997, p11. The authors further refer to global marketing strategies, which involve international market segmentation and price variation, as reasons for such a policy). For that reason, the large share of Egyptian pharmaceutical exports is accounted for by indigenous private and public companies (Subramanian and Abd-El-Latif, 1997, p.11). It is worth mentioning that recent efforts to improve drug exporting activity are thus far promising (FEI, 1997, p.2).

4- Intellectual property rights law in Egypt (patents law)
4-1- The Old Patents Law

Before the new IPR law, Egypt’s patents system was carried out under Law No. 132 of 1949 concerning Patents and Industrial Drawings, Models (the Old Patents Law). According to this, patent protection was available for every invention (whether product or process) which met the three patentability criteria. Pharmaceutical chemical products and agricultural chemical products related to foodstuff were nevertheless excluded. 8 Under the aforesaid law, protection by way of process patent for pharmaceutical and agricultural chemical products was provided but only if such products were produced through new chemical processes.

The term of protection for all inventions was fifteen years, calculated from the filing date of the patent application in Egypt, and was capable of being renewed for another five years under some circumstances (Birairy, 2000, pp. 213-214). Nevertheless, for ‘process’ patents for pharmaceutical and agricultural chemical products the term was only ten years and was not eligible for renewal (Art.12 (4)).

Protecting Egyptian indigenous companies from powerful multinational competitors was the main purpose for eliminating patents protection to pharmaceutical products (Shaarawi, 1996, p.1). The designed objective of such a policy was to ‘encourage the development of the national pharmaceutical industry by opening the door to legalised copying of drugs. Out of this will emerge a strengthened national industry which will develop export business and, as a result of growing sales and profits, should eventually itself turn to original research’ (Shaarawi, 1996, p.1. The author further indicates- in p.2- the adverse impacts of denying patent protection to pharmaceutical products, such as the loss to national firms of their market share to multinational companies).

The position of the Old Patents Law was a common one in developing countries since a number of them provided (and still provide) very little or virtually no protection at all (Subramanian, 1995, p.253). At the start of the Uruguay Round, about 50 countries did not grant protection to pharmaceutical products at all, and some excluded pharmaceutical processes from protection as well (UNCTAD, 1996, p.30).

The insufficient and weak protection provided by process patents could explain why MNCs fought to introduce product patent protection. A process patent gives protection to a product only if it is produced with the patented process. Therefore, if minor modifications were made to the relevant formula, the chemical compound concerned could be produced by several means without infringing the patent (Nogues, 1990, p.83). It is worth noting that this was one argument of many made by MNCs in relation to why the TRIPs Agreement should be implemented in Egypt without benefiting from the additional grace period (mentioned in Abdul-Mawlaa, 1999, p.490).

Compulsory licences for patents were also allowed for both public interest and non-working reasons, provided a number of requirements were fulfilled (Art 30 et seq.). If the patentee did not work or insufficiently worked (exploit or insufficiently exploited respectively) the patent, a grace period –three years from the granting of the patent– was set forth under the law for

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8 Inventions, the exploitation of which might harm the morality or the ordre public, were also excluded under the law.

9 Or two consecutive years if the patentee suspended the exploitation of the patent.
this patentee before a compulsory licence was to be issued. However, if the Patents Office found that although the period stated above had expired, the non-working of the patent was due to external reasons and causes, it was permitted to grant the patentee another period (a maximum of two years) to work or exploit the invention (see also Birairy, 2000, p. 218).

The rationale underlying the previous Egyptian patent law in relation to compulsory licences was that the government gave exclusive rights to exploit an invention. In return for these, patentees had to work the invention in Egypt. The exploitation of the invention in Egypt facilitated the establishment of new industries and increased employment and capital. It seems that this rationale had been in the minds of the people responsible for the new IPR law (see below).

4-2- The New IPR Law

With the new IPR law in place, the above-mentioned situation will be totally changed. Patent protection is to be available for any invention, whether products or processes, ‘in all fields of technology’ (as required by Art.27 (1) of TRIPs). Moreover, patent rights are to be enjoyed without discrimination as to the field of technology. Accordingly, patent protection is to be granted for pharmaceutical products (in addition to processes).

A product patent ‘is the most desirable patent’ for the pharmaceutical industry (Lewis, 1996, p.842). Absent patent protection, imitators could freely ride on the protected invention and duplicate the compound for a small fraction of the inventor’s costs. In point of fact, imitation costs in pharmaceutical drugs are exceptionally low relative to the innovator’s costs for discovering and developing a new compound. In addition, the protection term is for 20 years to be counted from the filing date of a patent application in Egypt (Art.9 of the new IPR law). This Article corresponds to Art.33 of the TRIPs Agreement.

Under the law, compulsory licences are to be granted for many specified grounds including public interest and non-working. The non-working of an invention as a ground for granting compulsory licences has raised a number of concerns from some countries particularly the USA (see USTR 2003 Special 301 Report). Yet, Egypt sees such a requirement as consistent with both the TRIPs Agreement and the Paris Convention (Review of legislation IP/C/W/278 dated 12 June 2001, available at www.wto.org).

4-3- Pharmaceutical and Agricultural Chemical Products Protection (mail-box)

In accordance with Art 43 (1) of the new IPR law, the Patents Office is obliged to receive patent applications for pharmaceutical and agricultural chemical products that relate to nutrition. The Patents Office is also required to receive other applications concerned with the same types of products that were submitted from January 1, 1995 according to the established mail-box in line with the provisions of Art.70 (8) of the TRIPs Agreement. The Office will

\[10\] In this regard, see the complaint by the EC and its member States against India because the absence in India’s legal systems of patents protection for pharmaceutical and agricultural chemical products and formal regimes that permit the filing of patent applications for pharmaceutical and agricultural chemical products and that provide for the grant of exclusive marketing rights for such products, see
have to keep these applications until January 1, 2005, the date on which the examination of these applications will begin.  

The delay in the examination of such applications means that Egypt has taken advantage of Art.65 (4) of the Agreement, under which developing countries that did not grant product patent protection in certain areas of technology on the general date of application of the TRIPs Agreement in those countries (i.e. January 1, 2000) are allowed to delay the application of patents provisions of the Agreement (see also Art.4 of the issuance articles of the new IPR law).

If a patent is to be granted to inventions concerning the aforesaid products, its term of protection will commence from the day of grant until the end of twenty years counted from the submission of the application to the Patents Office (Art.43 (2) of the new IPR law). This is a clear implementation of Art.70 (8) of TRIPs.

### 4-4- Exclusive Marketing Rights

If a patent application is related to pharmaceutical and agricultural chemical products that concern nutrition, the applicant is permitted to request from the competent authority (the Patents Office) a grant of ‘exclusive marketing rights’ (EMRs) in Egypt for his product (new IPR law Art. 44). To be granted EMRs, the applicant must fulfil the following conditions:

- (a) submit a product patent application to the Patents Office, which operates the created mail-box since January 1, 1995;
- (b) present a copy of the patent that was granted for the same product in another WTO Member in accordance with an application for obtaining the patent in that Member, which was filed on or after 1 January 1995;
- (c) submit certified evidence of the marketing approval of the same product in the same WTO Member, as issued by the responsible authority, with effect from January 1, 1995 or later; and
- (d) obtain acceptance from the relevant Ministry approving the marketing of that product in Egypt.

The Patents Office will grant an Exclusive Marketing Right Certificate after approval by the ministerial committee formed by a Prime Minister’s decree (Art.44 (2) of the new IPR law). Upon the issuance of the marketing approval in Egypt, the applicant will enjoy exclusive marketing rights valid for a period of five years counted from the granting date or until a decision by the Patents Office to grant or reject the patent application, whichever period is shorter (new IPR law Art.44 (4)).

The meaning of ‘EMRs’ is not defined under either the new IPR law or the Prime Ministerial Decree that deals with the same topic. Even TRIPs is silent on the scope and content of such

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11 The number of patent applications related to pharmaceutical or agricultural chemical products which have been dealt with in the mail-box during the period January 1995/December 1998 is 439, see IP/C/W/136 dated 10 March 1999, available at [www.wto.org](http://www.wto.org).

12 See also the Prime Minister Decree Number 547 for the year 2000 which was issued to organise the implementation of Art.70 (9) of the TRIPs Agreement before the entry into force of the new IPR law and to specify the government body responsible for issuing the certificate of the exclusive marketing rights as well as the conditions and procedures necessary to grant this certificate.

a matter (Correa, 1998, p.221; Straus, 1996, p.214). However, it should not be understood as excluding others from marketing the product in question, like the case of patents, otherwise one has to question the benefits of the additional period granted under TRIPs for patents concerning pharmaceutical and agricultural chemical products (Correa, 1998, p. 221). Thus, ‘EMRs’ may be interpreted to mean ‘the right to receive a remuneration from those that commercialise the invention, rather than to forbid their activities’ (Correa, 1998, p.221. Cf. Daniel Gervais, 1998, p. 271, stressing that use of a non-commercial nature should only be allowed under the EMRs and not other activities).

It is to be noted that only one product benefited from EMRs, i.e., a court decision approved the granting of EMRs. The decision was based on an honest interpretation of the TRIPs Agreement, which comes in line with Egypt’s commitments under its constitution of 1971 ‘self-implementing provisions’. (see the decision of the Administrative Court of March 11, 2003 in the case No. 282 for the judicial year no.56).
### The Old Patent Law
- Patents protection was available for any invention (subject to the three patentability criteria).
- Patent protection for pharmaceutical and agricultural chemical products was excluded.
- Protection was only available for processes for pharmaceutical and agricultural chemical products.
- Relative novelty (time and place).
- Patent of addition was only available to the patent owner in cases of modification, improvement, or addition to an invention that was previously granted a patent.
- Protection term was 15 years (non-renewable 10 years for process patents for pharmaceutical and agricultural chemicals). This can be extended for another 5 years under certain conditions.
- Handful of exceptions to the rights conferred (such as prior use).
- Compulsory licences were set out for public interest and non-working.
- Required that a patent application have attached only a detailed description of the invention, without demanding the full statement of the subject matter and the best or preferred method (old patent law, Art. 16).
- Criminal sanctions were weak.
- no provisions on burden of proof in infringement suits over process patents that were to be reversed.
- No pre-examination system of the subject matter of patent applications.

### The New IPR Law
- Patents protection is available for any invention in all fields of technology (subject to the three patentability criteria).
- Patents protection is available for both products and processes.
- Absolute novelty (time and place).
- Patent is granted independently to a third party who has undertaken any of these activities.
- Protection term is 20 years.
- A full set of exceptions is included (such as scientific research, Bolar provision, prior use).
- Compulsory licences are set out for many specified grounds including public interest and non-working.
- Requires a full statement of the subject matter and the best or preferred method.
- Enforcement measures are more detailed
- Criminal sanctions are much tougher
- burden of proof in infringement suits over process patent that are to be reversed.
- Pre-examination system of patent applications.

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Table 1: A Summary of the Main Differences between the Old and New Patents Law.
5- The likely effects of the new IPR law on the pharmaceutical industry in Egypt

5-1- Prices of Pharmaceuticals

It has been argued that drug prices will increase as a result of introducing high levels of patent protection as embodied in the new IPR law. Some have made those claims without providing solid explanations (Abou-El-Enein, 1996, p.3, [stating that a 'dramatic rise' in prices of pharmaceuticals will occur as a result of the implementation of TRIPs]; Safadi and Laird, 1996, p.1235), but others have clarified their positions (MFT, 2001, pp.15-19; Subramanian and Abd-El-Latif, 1997, pp.14-18). With our belief that drug prices would (or might) increase as a consequence of introducing new standards of patents protection under the new IPR law, such an increase will not occur instantly but from the end of a period of 5-8 years, counted from the end of the additional grace period.

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14 The escalation in pharmaceutical drug prices has also been denied by Rozek and Berkowitz, (1998), p. 2. (The reasons for that, according to the authors, are the existence of therapeutic competition, monopsony buyers, pharmaceuticals price control systems, and that new IP protection laws do apply to existing products).
**Undisclosed Information Protection**

- undisclosed information is to be protected against unfair commercial practices, if the information is secret, has commercial value and is subject to steps to keep it secret.
- secret data submitted for the approval of new chemical entities for pharmaceutical and agrochemical products is to be protected against unfair commercial use and disclosure by government.

**Transitional Arrangement**

patent provisions relating to chemical products for foodstuffs, pharmaceutical chemical products, micro-organisms and other products that were not acceptable as subject-matter before the enactment of the new IPR Law, will not come into force until January 1, 2005.

**Protection of Existing Subject Matter**

- the patent term provided in the new IPR law will apply to all patents whose term has not expired when entering into force.
- all patent applications that have been submitted to the Patents Office and for which no patent has been granted before the date on which the law came into force, be dealt with in accordance with the provisions of the current law.

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**Table 2: Other Regulations Concerning Pharmaceuticals Under the New IPR Law.**

To understand why the increase in pharmaceutical drug prices will not be felt as soon as the law enters into force (January 1, 2005 for patent for pharmaceutical products) but rather at the END OF A PERIOD OF 5-8 YEARS, calculated as mentioned above, the following points should be taken into consideration:

- Egypt has benefited from the additional grace period provided for in Art.65 (4) of TRIPs. This means that Egypt will grant (i.e. the Egyptian Patents Office will have to accept applications in relation to pharmaceutical products) patent protection for pharmaceutical products from January 1, 2005.15
- The new IPR law sets out the criteria of patentability (absolute novelty, inventive step and industrial applicability). According to the novelty requirement, the invention must be new at the time of submission of the application to the Patents Office. Therefore, any patent applications related to drugs that currently are on the market or would be from now until that day (January 1, 2005), would not be new at the time of examination. Hence, these drugs would not be affected. For this reason, production (or importation or other activities) of such drugs is not (and will not be) incompatible with either TRIPs or the new IPR law and their prices would be the same without any changes.16

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15 The “mail-box” regulations, mentioned above, should be taken into account.
16 This can be understood under Art.3 of the new IPR law which sets out that the invention shall not be considered new if: i) a patent application has been submitted or a patent has been issued for all the invention or for part of it either in Egypt or outside of Egypt before the
It is generally acknowledged that the period needed for pharmaceutical drugs to acquire marketing approval (the period between submitting a patent application for a drug which involves preparing and putting all the necessary documents together and marketing it) is approximately 5-8 years (cf., Subramanian, 1995, p.258, stating that such a period is ten years). As a result, new drugs whose patent applications would be submitted on or after January 1, 2005, will not be marketed until the end of the said period.

5-2- Period of Protection

The period of patent protection under TRIPs and the new Egyptian law is twenty years with effect from the filing date of the patent application in Egypt. Under the Old Patents Law, the pharmaceutical industry benefited from the relatively short term of protection (10 years) that allowed it to produce products whose process patents protection had expired. (One should not repeat that such industry benefited totally from the non-product patents protection situation under the Old Patents Law). It is expected that the extension of the patent term in Egypt is likely to cause adverse effects through the ban of the possible use of the protected inventions before the expiry of the patent term.

Furthermore, the extended term of patent protection under the new IPR law would affect the price of pharmaceutical raw materials. Under the Old Patents Law, the use of such materials was allowed just after any process patent protection had expired (only 10 years). Alternatively, if Egyptian drug companies wished to use these materials during the patent protection term, royalties had to be paid to the owner of the patent. Under the new IPR law, however, the protection period has, as mentioned above, extended to 20 years, hence such use will not be permitted before the expiry of the term. This means, on the one hand, that payment of royalties by Egyptian firms will continue until the end of the 20 year term. On the other hand, the anticipated decrease of pharmaceutical drug prices, as a result of the expiry of the 10 years protection, had the Old Patent Law still been in force, would not occur until the end of the 20 years protection term.

6- The Doha Declaration: an overview

The Doha Declaration on the TRIPs Agreement and Public Health was adopted on November 14, 2001 as a result of the pressure received from a number of developing countries, supported by non-governmental organisations (NGOs). The main purpose was to clarify the rights of TRIPs Members particularly developing and least developed countries to use TRIPs safeguards (Ellen’t Hoen, 2001, p.11), such as compulsory licences and parallel imports, with a view to supporting and protecting public health through promoting both access to existing medicines and the creation of new medicines (for the importance of the use of compulsory licence to meet public health needs, see Abbott, 2002, p.15 et seq.). The use of these

| filing date of the application on this invention in Egypt; and ii) if the invention has been publicly used or exploited in Egypt or outside of Egypt or its description has been disclosed in such a manner that those skilled in the art could exploit it, before filing the patent application. Thus drugs that are covered by existing patent applications anywhere, or will be covered by applications before January 1, 2005, will not be regarded as new inventions, hence not affected. It is worth mentioning that the reason for that is that TRIPs does not provide for retrospective protection (pipeline protection as it is sometimes called) to patents for existing drugs, (Rozek and Berkowitz, 1998, p.2. |
measures, and others, by developing countries although permitted (and still so) under TRIPs, was to some extent hindered by a number of developed countries on the advice of their pharmaceutical companies. Therefore, the conclusion of the Doha Declaration was to reaffirm the rights of developing countries to use measures included within the Agreement (for a brief comment on the Declaration, see Pires de Carvalho, 2002, pp. 125-131). All the points clarified by the Doha Declaration were taken into consideration by the makers of the new IPR law.

Table 3: The Main Points of the Doha Declaration on the TRIPs Agreement and Public Health.

**7- The new IPR law: a reflection**

As stated above, the domestic pharmaceutical industry generates 93% of the current local consumption. With the new IPR law in place, new challenges and new circumstances have been created. Such challenges and circumstances pose, to a high degree, risks and harm to Egypt’s pharmaceutical industry, the people of Egypt and the national economy in general. Accordingly, work to develop the pharmaceutical industry has become an urgent priority, taking into consideration that such an industry depends heavily on imported raw materials.

The people behind the new IPR law have made significant efforts to limit and reduce the
potential adverse effects that would be faced by Egypt’s pharmaceutical industry and Egyptians in general. These efforts can be realised through the following points:

7-1- Limitation on Patentable Subject Matter

Pursuant to the TRIPs Agreement, the law excludes some subject matter from patentability. These include situations where the topic under consideration is concerned with: i) pharmaceutical products that are isolated or purified from biological materials or animals; ii) any manufactured drugs that are dependent on living organism, whether the living organism is a ‘whole’ or a ‘part’; and ii) any medicines produced by reliance on plants or animals. The patentability of micro-organisms must not be discounted here. However, this should be interpreted as applicable only to genetically modified or ‘transgenic’ micro-organisms, and not to those pre-existing in nature. A definition of micro-organisms should mean ‘any microscopical life form which is accepted by institutions for the deposit of micro-organisms, such as viruses, algae, bacteria, and even cells or cell lines’ (Correa, 1998, p.196).

It is assumed that the limitation on patentable subject matter under the new IPR law have been approved to serve the national pharmaceutical companies. These companies do not have the same resources and technologies the multinationals have.

7-2- Absolute Novelty

The law by employing the ‘absolute novelty’ standard (vis-à-vis ‘relative novelty’) has taken a highly appreciated stand. In line with the former ‘absolute novelty’ standard, novelty is lost by divulgence of an invention, whether oral, written or by other means, in a foreign country. This could be a useful tool for Egypt, as a developing country, to prevent or at least reduce so-called ‘bio-piracy’. This situation should be strengthened by the exclusion from patentability of any biological materials found in nature (new IPR law Art.2 (5)).

The case of bio-piracy has been a huge concern for developing countries, since their biological resources and traditional knowledge have been patented by multinational pharmaceutical corporations. Such a situation has led an author to urge the US (where many MNCs are located) to amend its law in order to ‘exclude patenting agricultural

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17 In order to draw attention to the issue of injustice patenting particularly the bio-piracy issue, ActionAid, a charity that mainly works to fight poverty worldwide, has filed an application to patent chips (as in “fish-and-chips.”); Gillian N. Rattray, 2002, p.1. See also www.actionaid.org, (last visited August 17, 2003).
18 Gillian N. Rattray, 2002, p. 11 (stating that “98% of Mexicans surveyed in the Northwest region eat yellow beans”, which has been granted a patent to a president of an US seed company. Despite the fact that such beans have been planted in Mexico for generations ).
19 See the case of the “Neem tree”. This tree has been used for many decades for a number of purposes, including medical. However, patents have been granted for some uses of this tree. On this issue, see for example, Shiva, Vandana, ‘The Neem Tree - A Case History of Bio-piracy’, available at: http://www.twnside.org.sg/title/pir-ch.htm (last visited August 17, 2003). The Technical Board of Appeal of the European Patents Office (EPO) decided that a patent granted to W.R. Grace (a multinational pharmaceutical corporation) for a fungicide derived from seeds of the Neem tree be revoked and struck off the Register since the invention in question was not new. For more detail, see Press Release, Neem Patent Revoked!!!-Major Victory Against Bio-piracy, International Federation of Organic Agriculture Movements (May 10, 2000, available at Error! Reference source not found.. (last visited August 17, 2003)). Another example of bio-piracy is the case of the US patent on the use of turmeric for healing wounds. For more details, see Shiva, Vandana, ‘The Turmeric Patent is Just the First Step in Stooping Bio-piracy’, available at: http://www.twnside.org.sg/title/tur-cn.htm. (last visited August 17, 2003).
biotechnology such as jasmine and basmati rice…. [and also to] exclude patenting resources that have rich cultural histories in [developing and] less-developed countries.’ (Woods, 2002, p.143. The author also indicates that if the US does not do so and the expropriation of indigenous knowledge continues, the products of its MNC may be boycotted (referring to what happened in Thailand and India).

7-3- Compulsory Licensing

Under the new IPR law, compulsory licensing for drugs will be available in some cases particularly in circumstances relating either to drugs (quality, quantity, prices), or to patents that are granted for a number of serious illnesses, or to drugs cases. Despite the fact that there were no cases for compulsory licensing in Egypt under the Old Patents law, it is good that the new IPR law has opted to include provisions on compulsory licences. The possible use of such licences in future has in fact met the interests of the drugs industry in Egypt. These interests are reflected in the fact that: i) the possible use of such licences could be an incentive (obligation) for any foreign IPR right-holders to use (work) their patents in Egypt, and ii) the use of such licences could prevent IPR rights-holders, especially foreigners, from using their rights in a manner that might restrict trade or adversely affect transfer of technology. The opportunity to grant or use compulsory licences has indeed been described as ‘equivalent to reducing the strength of the exclusive rights conferred by a patent’ (Subramanian, 1995, p.257.). It is without doubt that such compulsory licences system would help to make drugs available to the public in Egypt at affordable prices.

7-4- Exhaustion of Rights

The new IPR law has adopted the principle of international exhaustion of rights. In supporting the Egyptian stance in this regard, it is suggested that parallel importation will be accordingly allowed, thereby inventions related to drugs would be available on the national market at cheaper prices which is beneficial to Egyptians. Also, allowing parallel imports of pharmaceuticals could be considered an effective tool forcing IPR right-holders to sell their protected pharmaceuticals at reasonable and affordable prices.

7-5- Protection of Public Interest

Protecting the public interest, by laying down a number of restrictions that limit the potential increase in prices or in case the protected products are not sufficiently available or available only under unacceptable conditions, have been considered by the Egyptian law makers. The same could be said in specified circumstances aimed at preventing the abuse of IPRs by right holders. In such circumstances, the grant of compulsory licences (new IPR law Art. 23) is permitted and the patent may even be revoked if it is obvious that such licences are not sufficient to remedy or overcome the adverse effects that have been caused to the national economy because of the abusive activities by the patentee in exercising his rights (new IPR

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20 The possibility of granting compulsory licences in this case is being condemned by a number of developed countries particularly the USA, see the USTR 2003 Special 301 Report, available at: [http://www.ustr.gov/reports/2003/special301.htm](http://www.ustr.gov/reports/2003/special301.htm), (last visited August 17, 2003).
7-6- Scientific Activities

Under the new Egyptian law, use of the protected product is permitted in all scientific activities without considering these activities as infringement. This is a very important provision since the pharmaceutical companies could use it to undertake research and analysis for the protected pharmaceutical products to obtain better results.

7-7- Regulatory Exception (Bolar Provision)

Under the law, pharmaceutical firms are, furthermore, permitted to make, construct, use or sell the protected product during its protection period for the purpose of obtaining a marketing approval, provided that such marketing is not to be carried out until the expiry of that period (new IPR law Art 10). The provision is without doubt of interest to the drugs firms. It is essential to note that this exception is allowed in a number of countries, such as the USA (Correa, 2000, p. 77 illustrating that in USA, the Drug Price Competition and Patent Term Restoration Act permits testing to establish the bio-equivalency of generic products before the expiration of the relevant patent. Cf. Kolker, 2000, p.29 expressing the view that such act would not be allowed.). It has been recently decided by a WTO panel that stockpiling of pharmaceutical products during the patent term for purposes of sale after the patent expired is not allowed under the TRIPs Agreement. (This is the decision of the WTO panel in relation to the dispute between the EC and Canada.)

7-8- Term of Protection

Despite the fact that the issue of extending the patent term for products where commercialisation is delayed due to lengthy regulatory procedures was raised in the TRIPs Agreement negotiations (Pharmaceutical Patents and the TRIPs Agreement, p.3), neither this Agreement nor the new IPR law involves any provisions requiring the introduction of such a regime. Such an issue is already dealt with in the USA, Europe and other countries (for the situation in different countries, see Watal, 2001, pp.116-118). In the United States protection for such products may be extended subject to a number of limitations. In Europe, with the approval of the Council Regulation of June 1992, up to five years of additional protection may be granted for medicinal products.

From the perspective of Egyptian interests, the stance taken by the new IPR law is most satisfactory. The law, by not providing for such extended protection has taken into account the public interest of Egyptian pharmaceutical manufacturers, who seek to produce the protected drugs soon after the expiry of the protection term. In addition, the interest of Egyptians in obtaining cheaper drugs has been taken into account by the law. Furthermore,

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21 This exception has been allowed by a WTO panel concerning a dispute brought by the EC against Canada WT/DS114/R, dated 17 March 2000. See the report of the panel in this dispute at. For a discussion of the panel report, see Mathews, 2002, p.100.
22 These limitations, as cited in Watal, 2001, p.116, are: i) that such extension cannot exceed five years; and ii) that the total period of patent protection cannot exceed fourteen years from the date of drug approval.
the Egyptian law is completely consistent with the TRIPs provisions which, as mentioned above, do not incorporate obligations to the effect. It has been predicted that such questions could be set forth in the agenda of future TRIPs reviews (Watal, 2001, p.116).

7-9- Deposition of Micro-organisms (Micro-biological)

If a patent application relates to micro-organisms (micro-biological) then the applicant is obliged to disclose such micro-organisms and deposit a viable culture with the authority determined by the executive regulation (new IPR law Art.13 (4)). It is worth mentioning that the use of the deposited sample of the micro-organism is widely known in the pharmaceutical industry particularly after the expiry of patent term or even during its life through compulsory licences. The deposition requirements therefore form a significant tool in disseminating, promoting, and practising new technology.

7-10- Disclosure Condition

Under the new Egyptian law, it is required that a patent application be attached with a detailed description of the invention including a full statement of the subject matter and the preferred method that enables a person skilled in the art to carry out this invention in respect of each product and process of the subject matter of the application. Since disclosure makes publicly available significant technical information which may be of use to others in advancing technology in the area, even during the patent term, it represents an essential element of the social contract that the grant of a patent constitutes (Pharmaceutical Patents and the TRIPs Agreement, p.2). Furthermore, disclosure aims at ensuring that, after the expiry of the patent term, the invention truly falls into the public domain because others have the necessary information to carry it out (Pharmaceutical Patents and the TRIPs Agreement, p.2).

7-11- Expropriation of Patent Ownership

In line with the Paris Convention, it is permitted under the new IPR law to expropriate the ownership of a patent: i) for reasons related to national security (defence); and ii) in conditions of extreme necessity in which compulsory licensing is not sufficient to overcome such circumstances. In our view, these cases may give rise to questions about new IPR law-TRIPs consistency, on which basis the decision of expropriation of patents shall stand.

It is to be noted that under the Old Patents Law, it was permitted for the government to expropriate patents on grounds of public interest or national defence (Old Patents Law Art.33; Yusuf, 1995, p.271).

7-12- Drug Prices Council

The law contains vital provisions relating to drug prices. In accordance with this law, a council that balances drug prices was created in order to achieve health development and to
guarantee that drug prices will not be affected by any changes (Prime Ministry Decree No.1216 for the year 2002, Official Journal-ALWAKAA –AL MASREA No.160, July 15, 2002 p.3).

7-13- Drug Prices Control

Because of the socio-economic implications of pharmaceutical drug prices, Egypt has a binding price control system for drugs. The prices are controlled by the government (Ministry of Health (MOH)). Accordingly, no drugs can be circulated without such pricing controls. In the event of violation, both the producer and the retailer would be subject to severe punishment. This is a vital guarantee that the prices of drugs, whether produced nationally or imported from outside Egypt, will not increase unless the Egyptian government (represented by MOH) accepts to do so. Furthermore, it is permitted for Egypt to refuse the registration of any drugs that are seen as extremely expensive or unaffordable.

The drug prices control system is consistent with the TRIPs Agreement (Art.8 (1)), which allows TRIPs Members to adopt measures necessary to protect public health and nutrition.

7-14- Pre-examination System

Unlike the Old Patents Law, the new IPR law provides, for the first time, for a substantive examination of the patent application before granting the patent. The adoption of the pre-grant examination system is a significant advance in the patents regime in Egypt. The significance of this new development can be appreciated through looking back at our analysis relating to the likely increase in pharmaceutical drug prices. Above we concluded that these prices would increase but not dramatically as has been argued. Our conclusion depended (and still depends) upon the long time that exists between the start of granting product patents protection (January 1, 2005) and when the increase in pharmaceuticals prices is felt. The long period is needed for pharmaceutical drugs to acquire marketing approval.

Furthermore, it is expected that the Patents Office’s function will change. Under the new system, the Patents Office will be responsible for ensuring that an invention is absolutely and truly new and not similar to any previously granted patent, whereas under the old Patents Law, the Patents Office’s chief role was to examine applications only for sufficiency of disclosure and clarity, definiteness and accuracy of the claims and formalities (Goans et al., 1994, p.30).

It is interesting to mention that Egypt recently decided to join the Patent Cooperation Treaty (PCT) (see the Presidential Decree No.303 for the year 2002). It deposited its instrument of ratification at the World Intellectual Property Organization (WIPO) on June 6, 2003. The Treaty will enter into force for Egypt on September 6, 2003 (Press Update 197/2003, WIPO, Geneva, June 16, 2003).

The ratification by Egypt means that in any international application filed on or after September 6, 2003, applicants may designate Egypt and also that nationals and residents of Egypt may themselves file PCT applications as of that date. As Egypt will be bound by
Chapter II of the Treaty, it may also be elected for the purposes of international preliminary examination (Personal communication from WIPO (e-mail) dated June 17, 2003).

8 Recommendations

The new IPR law, as it stands now in relation to patent protection of pharmaceuticals, represents a significant development as far as Egypt’s pharmaceutical industry and the public interest are concerned. Nevertheless, a number of recommendations particularly in the areas of drugs definition, use of expired patents, among others, are thought to be important.

8-1- Drug Definition

It is hoped that a broad definition of drug is to be adopted. Any definition of drugs should include not only medicines that are necessary to cure people from diseases, but also any other materials that are to be used to prevent such diseases. Furthermore, it is advisable that such a definition should comprise materials that might be used to improve public health, such as vitamins and cosmetics.23

8-2- New Use for a Known Substance (or drug)

The new Egyptian law, following TRIPs, has no provisions dealing with the patentability of new uses of known substances or products, especially second or subsequent therapeutic uses for known pharmaceutical products, e.g. an anti-cancer drug with a new and widely accepted use for treating HIV/AIDS (Watal, 2001, p.104; Correa, 1998, p. 201). It could be concluded that the second use of known substances, which are already in the public domain, should be excluded from patentability (new uses of old substances particularly second and subsequent medical uses of a known product are patentable subject matter under both the European Patents Convention (EPC) and the UK Patents Act, see Bently and Sherman, 2001, pp. 426-436). The search for newer and more effective treatment of diseases must, however, be taken into account. Therefore a balance between these two factors should be considered (Watal, 2001, p.105).

8-3- Use of Expired Patents

It is vital to highlight the increased importance of making use of inventions that have entered the public domain. The use of these inventions would be free of charge. To put such a suggestion into effect, it is necessary to know and recognise which patents have entered into the public domain. Accordingly, it is recommended that an authority, either governmental (such as the Patents Office) or non-governmental, be created or be given sufficient competence to search for expired patents and then declare that such patents are freely available to interested parties who would be able to use and exploit them. Such an authority should cooperate with other regional or international organisations (such as the World Health

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23 As suggested by Dr. Ahmed Mosa Soliman of the University of Cairo in a personal communication with the first author.
Organisation) in order to achieve the greatest possible effect.

8-4- The Patents Office

It is important to consider improving and developing the Egyptian Patents Office to be able to consider the requirements of the new IPR law (implementing TRIPs), along with providing the Office with the needed experience, equipment, and references to examine the submitted patent applications. One should mention that some developments have been made in the Egyptian Patents Office with a view to presenting a quicker and a better service to inventors. One of these developments is reducing the period of the examination of patent applications from six to three years (Habib, 2003, p.3).

8-5- Policy for Research and Development (R&D)

It is highly recommended that an on-going policy for R&D based on domestic raw materials and traditional plant varieties be adopted. In this regard, it is important to establish new scientific research centres with a view to taking part in modernising the domestic drugs industry and in creating new pharmaceuticals to be available for the public at reasonable prices (Abd-elaziz, 2002). Furthermore, the Egyptian Prime Minister has called for the establishment of a council consisting of Ministry of Health officials and owners of drugs companies to be responsible for improving Egypt’s drugs industry, increasing its exports and limiting its imports (Abd-elaziz, 2002).

8-6- Policy for Health Care

A comprehensive policy for health care especially through a strong system of medical insurance should be adopted. Donors are invited to contribute in this system by paying the premiums on behalf of persons giving less than one hundred 100 US$ per month.

8-7- System for Selling Pharmaceutical Products

Establishing an effective system that allows the selling of pharmaceutical products by dosage and not by boxes, is considered to be important. Such a system will contribute in minimising the cost of new drugs for the individual.

8-8- No Protection for Disclosed Information

Non-acceptance of using the system of undisclosed information as a ‘back door’ to allow extending monopoly on expired patents. No protection should be granted to disclosed information in any part of the world, the concept of novelty to the domestic market is not valid as the system of protection of undisclosed information is based on an international instrument i.e. the TRIPs Agreement. Such an Agreement was adopted to exclude the
concept of relative novelty as a basic criterion in granting patents in all fields of technology including pharmaceuticals.

9- Conclusion

The new IPR law presents a significant development in the search for an appropriate balance between the interests of IPR owners and pharmaceutical users. By providing protection to pharmaceuticals (seen as an incentive for R&D), the law does consider the interests of the rights holders. On the other hand, the interests of the users of protected products and the public generally are taken into account through the disclosure provisions, limitations and exceptions that are allowed under the law.

The exact implications or impacts of the new patent protection for pharmaceutical products are difficult to predict. As patent protection is a very important instrument for industries like pharmaceuticals (Mansfield, 1994, pp. 22-23), it is hoped that by providing such protection, the flows of foreign direct investment (FDI) will be more located in Egypt and technology transfer will increase. Furthermore, R&D directed at the specific needs of Egypt (certain diseases) will flourish. It remains to be noted that Egypt has competitive advantages as far as R&D is concerned, since it has ample local talent and a reasonable infrastructure offering research prospects at considerably lower costs than in developed countries (Shaarawi, 1996, p.10).

With regard to pharmaceuticals prices, the improved levels of patent protection will not lead to ‘dramatic’ increase in drug prices. The new patent protection will have no impact or effect on existing drugs (understood as those which were marketed before the implementation of the TRIPs Agreement in Egypt). The increase in prices will not be felt until the end of a period of 5-8 years, counted from the day the new IPR law enters into force in relation to protection for patents for pharmaceutical drugs products (i.e. January 1, 2005).

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