The Egypt-European Union Partnership Agreement and the Egyptian Pharmaceutical Sector

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Abstract

Following the completion of the Uruguay Round and the institution of the World Trade Organization, Egypt has undertaken negotiation of a free trade agreement with the European Union. This paper examines the potential impact of these developments on the pharmaceutical sector in Egypt, focusing on the TRIPs and EU agreements, and seeks to draw conclusions about how to maximize benefits for the sector. The more important impact on the Egyptian pharmaceutical sector will be from changes to Egypt's legal regime governing patent protection, which shall emanate, not from the EU agreement, but from the Uruguay Round's Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPs).

This paper describes the main provisions of the TRIPs agreement that will affect Egypt's pharmaceutical sector, and outlines how patent protection generally affects developing countries such as Egypt. It looks at the additional obligations which the EU agreement will mean for Egypt, and examines options facing policy makers and the industry.

The paper concludes that, as the TRIPs agreement will force pharmaceutical producers to move away from imitation-based production, the competitive advantage in Egypt's pharmaceutical sector will shift to foreign companies whose production is based on research and development. Only a small share of the current market, however, will be thus affected.

ملخص

على إثر استكمال جولة أوروجواي وإنشاء منظمة التجارة العالمية، قامت مصر بالتفاوض على اتفاق للتجارة الحرة مع الاتحاد الأوروبي، ويتم في هذه الورقة فحص الأثر المحتمل لهذه التطورات على القطاع الدوائي في مصر، مع التركيز على الاتفاقات الخاصة بالنواحي التجارية المتعلقة بحقوق الملكية الفكرية والاتحاد الأوروبي، وهي في ذلك تحاول استخلاص نتائج عن كيفية تعظيم الفوائد التي تعود على هذا القطاع.

إن أكبر أثر على القطاع الدوائي في مصر سينشأ من التغيرات التي ستطرأ على النظام القانوني في مصر فيما يتعلق بحماية براءات الاختراع والتي لن تنبع من اتفاق المشاركة الأوروبية بل من اتفاق جولة أوروجواي الخاص بالنواحي التجارية المتعلقة بحقوق الملكية الفكرية. وتتناول هذه الورقة وصف النصوص الرئيسية في الاتفاق الخاص بالنواحي التجارية المتعلقة بحقوق الملكية الفكرية التي ستؤثر على القطاع الدوائي المصري، كما تبين الالتزامات الإضافية التي يعينها اتفاق الاتحاد الأوروبي بالنسبة لمصر، فضلاً عن الاختيارات المطروحة أمام الصناعة وواضعي السياسة.

وتنتهي الورقة إلى نتيجة مؤداها أن الاتفاق الخاص بالنواحي التجارية المتعلقة بحقوق الملكية الفكرية سيرغم منتجي الدواء إلى الابتعاد عن الإنتاج القائم، وأن الميزة التنافسية في القطاع الدوائي المصري ستنتقل إلى الشركات الأجنبية التي يقوم إنتاجها على البحث والتطوير، ومع ذلك فإن جزءاً بسيطاً من السوق الحالية هو الذي سيلحقه التأثير.

1. Introduction

As part of its efforts to integrate with the world economy, Egypt has undertaken to negotiate a free trade agreement with the European Union. This initiative follows close on the heels of the completion of the Uruguay Round and the institution of the World Trade Organization (WTO). At the same time, the Egyptian economy is poised to embark upon serious structural reforms that include privatization, deregulation, and reduction of general trade barriers. This paper seeks to examine the potential impact of these developments on the pharmaceutical sector in Egypt, focusing on, but not restricted to, the TRIPs and EU agreements. In view of the EU agreement's pre-nascent state, and insofar as it is not a fait accompli, the paper seeks to draw certain normative conclusions about what can be done in the agreement to maximize the benefits for the sector. More importantly, broader policy conclusions for this sector are drawn.

It is essential to clarify at the outset that the EU agreement *per se* will have limited incremental impact. The pharmaceutical sector is affected by international agreements of this ilk in two possible ways. First, there is the competitive impact that will result from the progressive elimination by Egypt of its trade, especially tariff, barriers. Tariff barriers in Egypt's pharmaceutical sector are very low and far more penetrable than those in the rest of the economy. This sector is already exposed to international competition from European and non-European sources of supply.[1] Furthermore, Egyptian exports of pharmaceutical products to the EU already benefit from duty-free access under existing arrangements, hence the proposed agreement will add nothing by way of additional access.

The second and more important impact will emanate from changes to Egypt's legal regime governing patent protection. However, here too the causation for change should be assigned not to the EU agreement, but to its multilateral forbear—the Uruguay Round's Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPs). The EU agreement will entail relatively few changes to Egypt's intellectual property regime. To understand the impact on Egypt's pharmaceutical sector, it is to the TRIPs agreement that we should turn.

[1] The time frame for the phase-out of tariffs on the imports of pharmaceutical products into Egypt has not yet been decided. Some indication of this can, however, be gleaned from the EU's agreements with Morocco and Tunisia, which have committed to eliminate tariffs on most pharmaceutical products over three years and five years, respectively.

This paper is organized as follows. Section 2 describes the main provisions of the TRIPs agreement that will affect Egypt's pharmaceutical sector. Section 3 outlines the main theoretical arguments related to patent protection, particularly as it affects small developing countries such as Egypt. Section 4 describes the structure of Egypt's pharmaceutical industry. Against this background, Section 5 assesses the short run, or more precisely the static, impact on Egypt's industry, while Section 6 assesses the long run or dynamic impact. Section 7 briefly looks at what the EU agreement will add to TRIPS by way of additional obligations for Egypt. Section 8 contains a normative analysis and examines various options facing policy makers in regard to the pharmaceutical sector, and options facing the industry. Section 9 concludes.

2. Changes in the Legal Regime Consequent to TRIPs [2]

The TRIPs agreement will have the following far-reaching implications for the legal regime governing the Egyptian pharmaceutical sector:

General obligations. The most important general obligation under the TRIPs agreement is national treatment, which requires all members to treat nationals of other countries no less favorably than their own nationals on all IP matters—standards, enforcement, and acquisition—subject to certain exceptions. However, this obligation is not likely to require legislative changes, as most countries, including Egypt, already grant national treatment in their domestic laws.[3]

Patents. Under TRIPs, no field of technology can be excluded from patent protection, effectively disallowing any exemption for pharmaceuticals from protection. The key advance here is that Egypt will have to grant protection for pharmaceutical products, and it will no longer be enough to provide process protection for pharmaceuticals.[4] Egypt will have to provide a minimum term of protection of 20 years from the date of filing of the patent application. Egypt cannot favor the pharmaceutical sector through permissive rules on "compulsory licensing."[5] Also, Egypt cannot stipulate that firms should produce the pharmaceutical invention locally rather than importing it.

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[2] This section draws heavily on Subramanian (1995a, 1995b).

[3] The second general obligation on innovation in the field of IP is that of most-favored-nation (MFN) treatment. This requires countries to treat nationals of any one country no less favorably than nationals of another country.

[4] Process protection provides limited exclusivity to the creator because a given therapeutic product can be produced by different processes.

[5] Compulsory licenses need to be distinguished from voluntary licenses that are negotiated between the patent owner and

While TRIPs does not specify the reasons for which a compulsory license may be granted, Egypt will have to comply with a series of stringent conditions when a compulsory license is granted (Article 31). Notable among these are requirements to establish that normal channels of obtaining a voluntary license have proved unsuccessful and that the patentee be provided adequate compensation for a compulsory license.

Finally, Egypt will have to ensure that all these obligations are enforced effectively, in the sense that patent owners can prevent unauthorized use of their patent rights and be adequately compensated in the event of infringements of their rights.

To comply with TRIPs, Egypt must undertake extensive reform of its patent laws in each of the areas described above to protect pharmaceutical products, increase the term of patent protection to 20 years, and eliminate discrimination in the system of compulsory licensing against pharmaceutical inventions and against imported patented products.

Transitional arrangements. Egypt, like all developing and less-developed countries, has had to implement the national treatment and MFN provisions beginning January 1, 1996. Other provisions of the agreement, including those on enforcement, have to be implemented by January 1, 2000. Patent protection for biotechnological products must be implemented by 2005. In the critical area of pharmaceutical product protection, the transitional provisions are complex (see the box below).

3. The Economic Impact of TRIPs: Theoretical Arguments

Economics of IPRs at the national level. The rationale for a system of IPRs, particularly patents, has to do with the "public good" nature of knowledge. Once created, the benefits from it can be relatively easily "appropriated"[6] by agents other than its creator. This in turn can blunt the incentive to undertake the effort to create the knowledge in the first place, leading to an underproduction of knowledge, from society's point of view. IPRs therefore represent an arrangement whereby society mitigates the appropriability problem and reduces the divergence between the private and social returns to knowledge creation. Although IPRs create a static distortion by reducing the degree of competition, it is assumed that the dynamic benefits from the incentives to R&D creation will offset the static efficiency losses.

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the agent who wishes to use that patent. A compulsory license is granted by the government to an agent other than the patent owner, permitting the use of the patent for a price that is usually less than what would have been voluntarily negotiated between the patent owner and user. The compulsory license results in the dilution of the exclusivity conferred on the patent owner.

[6] In more emotive language, "appropriability" goes by the names of "theft," "robbery," and "piracy."

Economics of IPRs at the international level. This rationale for IPR protection at the national level gets more complicated at the international level for a variety of reasons, empirical and theoretical, analyzed below (see Siebeck 1990).

(i) Small country/countries case, no R&D impact. Suppose, as is likely to be true of Egypt, that a country or a group of countries is predominantly a net importer of technology and maintains a low level of IP protection to facilitate cheap or costless imitation by indigenous producers in a highly competitive environment. In addition, if one postulates that the country in question is "small," in the sense that the level of IP protection has no appreciable effect on global R&D creation, then an increase in IP protection will displace local producers and render the market less competitive, leading to a rise in prices and a consequent rent transfer from local consumers and producers to foreign title holders. The absence of an appreciable R&D effect will mean that the country will not derive any dynamic benefits in the form of reduced costs and prices, so that in welfare terms the individual country will be worse off (Chin and Grossman 1988; Deardorff 1990, 1992; Helpman 1993; Maskus 1990).

(ii) Imitation and large country effect. On the other hand, in a country or a group of countries that is sufficiently large, the level of IP protection could have a significant effect on R&D. An example of this could relate to the development of drugs for the treatment of diseases specific to developing countries, or technologies, such as seeds and chemicals designed for agriculture in developing countries. The possibilities of ex post copying, in the absence of IP protection, could dent incentives to undertake R&D. This is essentially the case examined in Diwan and Rodrik (1991), showing that if the R&D inducement effect is strong enough, higher IP protection may lead to gains for individual countries and the world.

(iii) Technology transfer effect: Where an invention can be copied easily, for example through reverse engineering, it cannot be plausibly argued that patent protection is necessary for the transfer of technology (Subramanian 1990). Where, however, the assistance of the inventor is required, there may well be cases where patent protection creates the conditions for a voluntary transfer of technology which might not exist in the absence of a patent regime. The patent enables its owner to control the diffusion of the related secret know-how required to

utilize the invention protected by the patent. In the absence of the patent, there would be little legal means of preventing persons, once trained in the use of the know-how, from setting up competing units, leading possibly to an uncontrolled diffusion of the technology. While ex post such diffusion might be in the national interest, the risk of such diffusion would deter the technology owner, forestalling the technology transfer in the first place. Thus the country could lose out on the benefits to employment, skills, and growth by not providing a climate conducive to transfer of technology or foreign direct investment (Maskus and Konan 1994).

(iv) R&D effects. In principle, there are three distinct R&D effects—know-what, know-who and know-where—that could be occasioned by higher patent protection. Know-what effects relate to whether higher IP protection would lead to greater R&D on products consumed (actually or potentially) by developing countries (or on processes used in the production of products consumed in developing countries). For example, will higher pharmaceutical protection by developing countries lead to greater R&D on the range of diseases typically found in Egypt and other developing countries? Know-who effects relate to whether higher IP protection will lead to greater R&D by indigenous firms; and know-where effects relate to whether protection will lead to a shift in the location of R&D investment in favor of developing countries such as Egypt. These three effects determine the welfare calculus of higher IP protection in different ways. Know-what effects determine costs, prices, and product variety, thereby affecting consumer welfare. Know-who effects determine who—foreigners or domestic nationals—would appropriate the rents from successful R&D activity; and know-where effects have implications for the rent effects (if R&D takes place locally, rents can be taxed by the country), but arguably also for the extent of diffusion of technology; that is, the more R&D generated in Egypt, the more likely its economy-wide diffusion.

4. Structure of Egypt's Pharmaceutical Industry [7]

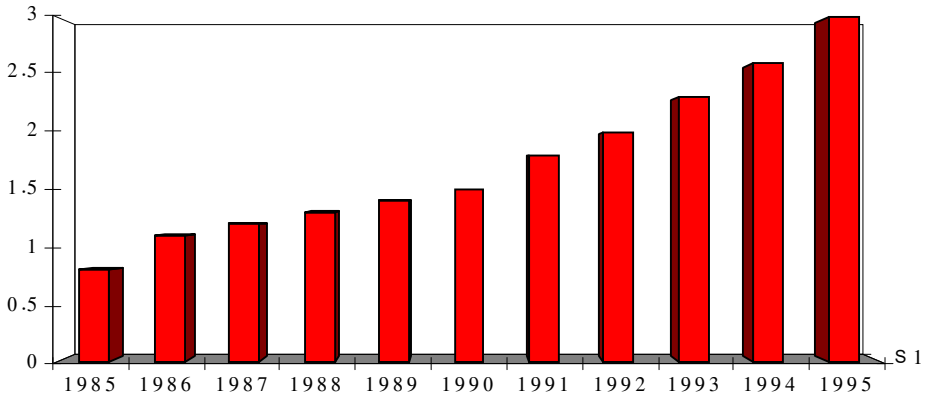
Aggregates. The market for Egyptian pharmaceuticals is estimated to be about LE 3 billion in 1995 and among the largest in the Middle East, accounting for about 20 percent of the Middle East market. The Egyptian market grew at an average annual rate of about 20 percent during 1985–95, with particularly rapid growth in the 1990s averaging close to 30 percent (Chart 1). These nominal growth rates signify a sharp increase in real consumption, especially

[7] This section is based on data compiled by the authors from the financial accounts of firms and obtained from interviews and responses to questionnaires. All these data are available from the authors upon request.

since the pharmaceutical sector has been subject to price controls. Accordingly, per capita expenditures on drugs reached LE 35 in 1994, compared with LE 7 in 1980.

The direct contribution of the pharmaceutical sector to the economy is relatively modest. The sector's value added represented less than 1 percent of Egypt's total GDP in 1995;[8] its exports constituted less than 1.5 percent of Egypt's non-oil exports in 1994; its imports in 1994 of final products accounted for about 1 percent of total imports, which increases to about 3 percent if import of inputs is taken into account; total sector employment is estimated at 50,000-60,000, less than 1 percent of Egypt's total labor force of 16 million.

Figure 1. Egyptian Pharmaceutical Market Evolution



Source IMS Q4 95

Ownership. The industry is comprised of three distinct categories of manufacturers, based on the ownership of production—the nine multinationals, (of which three are fully foreign owned and six are majority-owned); eight private companies, 11 public sector companies, and others. Over time, the shares of the foreign companies and especially the indigenous private sector have grown at the expense of the public sector. The shrinking pre-eminence of the public sector is reflected in the fact that its share in total production fell from 70 percent in 1984/85, to about 40 percent today (Table 1). The rest of the market is shared by the foreign companies and the local private sector. The industry exhibits a fair degree of

[8] Based on disaggregated data obtained from three enterprises, value added for the sector is estimated at about LE 1 billion, and nominal GDP at market prices at LE 212.8 billion.

concentration. In 1995, the top five firms accounted for 26 percent of market share, while the top 10 firms accounted for 43 percent.

Trade performance. At LE 94 million in 1994, exports accounted for a small share (less than 5 percent) of output, comprising mainly generic products and vitamins. However, exports have grown rapidly since the early 1980s, from LE 3.5 million in 1980/81 to LE 103.4 million in 1991/92, at an annual average rate of 27.7 percent (Table 2); exports as a share of total output grew from 1.7 percent in 1980 to 5.3 percent in 1993 (Table 4).

Table 1. Ownership Structure of the Industry: *values in LE millions*

	1984/85	1985/86	1986/87	1987/88	1988/89	1989/90	1990/91
Public Sector	304.0	331.7	370.1	442.0	520.6	553.8	628.3
Joint Venture	102.5	117.5	128.5	158.2	194.2	215.6	224.7
Private Sector	28.4	61.9	82.0	146.2	197.4	284.4	334.9
Total	434.9	511.1	580.6	746.4	912.2	1053.8	1187.9
Percent change		17.5%	13.6%	28.6%	22.2%	15.5%	12.7%

Ownership Structure of the Industry: Share percentages

	1984/1985	1985/1986	1986/1987	1987/1988	1988/1989	1989/1990	1990/1991
Public Sector	69.9%	64.9%	63.7%	59.3%	57.1%	52.6%	52.9%
Joint Venture	23.6%	23.0%	22.1%	21.2%	21.3%	20.5%	18.9%
Private Sector	6.5%	12.1%	14.1%	19.6%	21.6%	27.0%	28.2%

Source: Pharmaceutical Industry in Egypt (1980-1991) - A Case Study

Imports of final pharmaceutical products amounted to LE 405 million in 1994 and comprised 10 percent of final consumption. Imports have grown less rapidly than exports, from LE 49.4 million to LE 195.6 million in 1992/93, at an average annual rate of about 7 percent (Table 2). Imports, which accounted for almost 19 percent of consumption in 1980/81, now constitute about 10 percent of consumption, reflecting progressive import substitution over time.[9]

Imports of raw materials used in local production are estimated to be about 25 percent of total sales, approximately LE 750 million in 1995. The industry is estimated to import 80-90

[9] In part, this import substitution could reflect the choice of foreign suppliers to service the Egyptian market by locating within (i.e., through foreign direct investment) rather than exporting to Egypt.

percent of its total raw material requirements in the form of active ingredients. Local production of active ingredients is very small, a feature that distinguishes the Egyptian pharmaceutical industry from the more mature industries in other developing countries such as India. Thus, Egypt has consistently been running a trade deficit in pharmaceutical products (Table 2), which is substantially larger if imports of raw materials are also taken into account.

Protection. The simple average tariff for pharmaceutical products in 1994 was 8 percent, compared with 32 percent for the economy as a whole and 27 percent for the industrial sector. This pattern is found in most countries on account of governments' desire to maintain easy and cheap access to products that safeguard health and safety. Effective protection is not very high, owing to the low output tariffs and comparable tariffs on intermediate inputs.[10] Although there are no explicit quantitative restrictions or nontariff barriers, there could be de facto protection through the import licensing system implemented by the Ministry of Health.

Table 2. Pharmaceutical Sector Trade *In '000 LE*

Year	Exports	Rate of Growth	Imports	Rate of Growth	Balance (Deficit)
80/81	3,500	*(%)*	49,400	*(%)*	45,900
81/82	4,200	20	107,700	118	103,500
82/83	9,500	126	109,100	1	99,600
83/84	7,900	-17	131,600	21	123,700
84/85	8,600	9	150,800	15	142,200
85/86	10,400	21	161,300	7	150,900
86/87	12,600	21	191,800	19	179,200
87/88	25,800	105	163,400	-15	137,600
88/89	37,800	47	132,100	-18	94,300
89/90	29,100	-23	146,600	11	117,500
90/91	53,600	84	178,600	22	125,000
91/92	103,400	93	182,400	2	79,000
92/93	103,400	0	195,600	7	92,200

Source:: Scientific Research Institute 94

[10] Tariffs on the active ingredients that constitute the large bulk of inputs into production are 5 percent, while tariffs on imported packing materials range between 10 percent and 40 percent.

Table 3. Share in Consumption (%)

Year	Domestic	Imported	Total
1980	81.4	18.6	100
1982/83	77.6	22.4	100
1985/86	79.2	20.8	100
1987/88	85.1	14.9	100
1989/90	89.5	10.5	100
1990/92	90.0	10.0	100

Source: Pharmaceutical Industry in Egypt (1980-91) ACDIMA 1993.

Structural attributes. *A schizophrenic industry?* It is difficult to speak of the Egyptian pharmaceutical industry or generalize about the impact of international developments, because from an analytical perspective, there are at least two, perhaps even three, pharmaceutical industries in Egypt, with antithetical interests in relation to intellectual property protection.

Table 4. Share of Exports in Production

	1980	1985	1989	1993
Production				
Total	173.8	597.9	1059.9	1700
State	122.1	378	580.7	765
% Total	70.2	63.2	54.8	45
Private	51.7	291.9	479.2	935
% Total	29.8	36.8	45.2	55
Exports	2.9	10.2	51.4	90.4
% Export/ Production	1.7	1.7	4.8	5.3

Source: Egyptian Export Promotion Center

Licensing versus generics. The foreign-owned segment of the industry produces most or virtually all of its drugs under license from the parent companies. A large portion (about 70 percent) of these drugs are currently under patent in the industrial countries. On the other hand, the domestic private sector and the public sector produce only between 40-50 percent of

their products under license, with the remainder accounted for by generics (Tables 5 and 6).The latter offers a cheaper avenue of production because it avoids the payment of royalties that typically vary between 7 to 10 percent of sales. Production under license happens only because indigenous firms cannot buy the active ingredients from cheaper sources or because the technology and know-how are not easily available from other sources. A feature of significance from the perspective of assessing the impact of higher patent protection is that a growing share of generic production of indigenous firms is based on the use of inputs that would be deemed as infringements had Egypt observed high levels of patent protection.

Extent of "infringing" activity. An interesting feature of the market is that, historically, and even today, the share of infringing activity—or production based on imitation—has been low and is currently estimated at about 4 percent of total sales. In part this has reflected the embryonic state of the local industry, which needed the cooperation of the original drug producer in the form of inputs, technology and know-how transfer, to assist in production. Although the local industry is not geared to manufacturing the active ingredients, it has now matured enough to be able to produce generics without the help of foreign producers by importing the active ingredients. Correspondingly, the extent of "infringing activity" is expected to increase over the next few years and could account for 10−30 percent of the total market. This segment of the market will become vulnerable once the obligations of the TRIPs agreement have to be complied with.

Table 5. Financial Indicators for Representative Firms, 1995

	Private	MNCs	Public
Total Production	261,600	111,794	174,277
Sales:	249,911	154,119	167,508
Rate of Growth	18%	27%	2%
Wages & Benefits:	19,621	14,287	27,866
Rate of Growth	17%	23%	0%
% of Operating Costs	14%	16%	20%
% of Value of Production	8%	13%	16%
Operating Costs	141,017	88,182	137,866
Gross Margin	108,894	65,937	29,642
Gross Margin upon Sales	44%	43%	18%

Sources: Financial accounts of selected firms, and authors' calculations.

Who are the exporters? Interestingly, the contribution of the foreign-owned pharmaceutical manufacturers to total exports is minuscule, on account of restrictions imposed by the parent company on its Egyptian affiliates. Global marketing strategies, involving international market segmentation and consequential price variation according to a market's ability to bear, could explain this behavior.[11] About two-thirds of Egypt's pharmaceutical exports are accounted for by the private sector, and the remaining one-third by the public sector (Table 4). Exports consist of generics and other formulations such as vitamins, and are mainly destined for markets in the countries of the former Soviet Union, Eastern Europe, and some Arab countries.

Table 6. Economic Indicators for Representative Firms, 1995

	Private	MNCs	Public
Exports	31,200	0	16,865
exports % of sales	12.50%	.00%	10.10%
Number of products	157	87	210
generic products	107	0	141
under licence	50	87	69
Imports of RM ('000 LE)	63,541	64,516	55,204
imports % of oper. costs	45%	73%	40%
Wage rate/hour	6.01	7.87	4.75
$	1.77	2.31	1.40
rate of growth	14%	13%	9%
R&D (% of revenues)	1.50	n.a.	0.70
No. of employees	1547	860	2777
rate of growth	2%	9%	-8%
Value added	140,204	52,186	64,277
rate of growth	17.40%	29%	11%
Labor productivity[1]	90.63	60.68	23.15

Source: Financial accounts of selected forms, and authors' calculations.
(1) Defined as value added per worker.

[11] Foreign companies justify these export restrictions on the grounds that price restrictions in Egypt create artificial and unfair export opportunities.

Efficiency. The efficiency of the Egyptian pharmaceutical industry varies enormously across categories of producers. Predictably, the public sector lags significantly behind private and foreign-owned companies, as reflected in a variety of economic and financial indicators depicted in tables 5, 6, and 7.[12] The most profitable private company had a gross margin of about 44 percent in 1995, compared with margins of about 18 percent for the two best performing public sector companies, and 43 percent for the foreign company.[13]

Table 7. Financial and Economic Indicators
(Total Public Sector)

Financial Indicators: *Value in '000 LE*

	1992/93	**1993/94**	**1994/95**
Capital	202,200	229,300	331,280
Sales[1]	1,779,182	1,859,199	1,986,799
rate of growth		4%	7%
Wages and benefits	208,854	228,525	243,836
rate of growth		9%	7%
Net profit	-23,713	54,179	98,534
rate of growth		144%	82%
Net profit % of sales	-1%	3%	5%

Economic Indicators

	1992/93	**1993/94**	**1994/95**
No. of workers	29,608	29,247	28,485
rate of growth		-1%	-3%
Wage rate/hour			
LE	3.34	3.7	4.05
US$	0.98	1.09	1.19
rate of growth		11%	9%
Exports	n.a.	n.a.	63,606
exports % of sales	n.a.	n.a.	3%
Value added[3]	640,506	669,312	715,247
rate of growth		4%	7%
Labor productivity	21.63	22.88	25.11
rate of growth		6%	10%

Source: financial accounts and authors' calculations
(1) Official figures of sales are reduced by 10% to take account of revenues accruing from sales of non operational assets.
(2) Rate of growth using 1993/94 as a base year.
(3) Value added is calculated applying the value added to sales ratio for two public sector firms to sales of the entire public sector.

[12] Tables 5 and 6 contain data for three pharmaceutical firms, one each from the public, private and foreign sectors. The choice of firms was dictated by data availability, but they were all amongst the best performing firms in their respective categories, which provides a plausible basis for generalizing about the sectors. Table 7 depicts data for the 11 public sector pharmaceutical companies as a whole.

[13] The lower gross margin for the foreign company might give a misleading impression about profitability because of the possibility that imported raw material costs incorporate a margin of profit (see below).

Wage costs as a share of total operating costs were also lower for private and foreign companies (14 percent) than for public sector companies (20 percent). It is important to note that the pharmaceutical sector as a whole is not a labor-intensive industry, as exemplified in the low share of wages and salaries in operating costs and in value of production (about 11 percent for the three firms combined). This has implications for the extent to which Egypt can base its competitive advantage on its endowment of cheaper labor. [14]

Economic indicators paint a similarly stark picture. At 17 percent, value-added growth in the private sector was more robust than in the public sector, where growth was negative. Labor productivity as measured by value-added per worker was about four times higher in the private and foreign sectors than the public sector, which more than compensated the larger wages in the former sectors. The wage rate at US $ 1.77 per hour was slightly higher (by 26 percent) than the public sector's at US $ 1.40 per hour, the differential being more than offset by higher labor productivity. Employment growth was positive in the private sector but negative in the public sector.

The private sector exported more in absolute terms and as a share of total production. The share of imported raw materials in total operating costs tends to be substantially higher for the foreign companies, inviting the question of whether this is due to higher prices for patented products or to transfer pricing and an indirect mechanism for the transfer abroad of profits. R&D expenditures were higher in the private sector although the absolute levels remain low.

Research and Development. The extent of R&D activity carried out by Egyptian firms—foreign and local—is negligible, and less than 2 percent of revenue, compared with about 12-20 percent in industrial countries. While R&D can encompass a range of activities, in the case of Egypt there is more "D" than "R", and a fairly elastic definition of D is used to include activities such as training of physicians and participation of medical personnel in international conferences.[15] Overall, and at least for the moment, the Egyptian industry would not remotely qualify as an R&D-based industry.

Regulation. Concerns about health and safety contribute to extensive regulation of pharmaceutical sectors the world over, including Egypt. Two important aspects of Egyptian regulation are worth mentioning. First, prices of all pharmaceutical products are controlled and set by the government. In principle, pricing decisions are taken by a committee

[14] The comparable figure for the textile industry is about 21 percent.

[15] A small share of "development" includes conventional activities such as clinical trials.

comprising the ministries of Health, Economy and Finance, and industry representatives. Prices are apparently set according to a cost-plus formula (where costs are based on submission by the concerned manufacturer) with a mark-up of 10-12 percent earmarked for profits. There is no automatic adjustment to reflect cost inflation (or indeed deflation, for example when the prices of the imported active ingredients fall).[16] As a consequence, manufacturers frequently resort to product variation as a means of forcing a review of prices. In practice, the mechanism for price-setting is perceived as non-transparent and vulnerable to discretion.

The second aspect of regulation concerns product registration, a prerequisite for commercial marketing. Egypt, like many developing countries, does not have an independent and full-fledged system for regulatory approval of pharmaceuticals. Consequently, it relies on approval procedures in five other industrial countries; a product can be introduced in Egypt if it has obtained a "free sales certificate" in one of these five markets. Registration procedures in Egypt can be initiated only after this certificate is obtained, which results in a typical lag of two to three years between introduction of a product in an industrial country and its marketing in Egypt.

5. The Short-run Economic Impact of TRIPs

As explained above, the main impact of introducing patent protection for pharmaceutical products is that all activity that is based on imitation of patented products will have to cease or cede to license-based production. In the short-run, the effect of this is to lessen the degree of competition in the market—how much depends on the structure of the market, the demand and supply elasticities, number of competitors, etc.

Table 8 quantifies this impact for a number of alternative scenarios. The numbers in the table represent the annual price, welfare and profit effects consequent upon the TRIPs agreement.[17] Unsurprisingly, the short-term impact is negative: prices can be expected to rise,[18] economic welfare to fall, and profits accruing to patent owners—which in the case of

[16] Price controls were a particularly serious problem in the 1980s because of the frequent adjustments in the exchange rate which increased the costs of imported raw materials.

[17] The methodology used for these calculations is described in detail in Subramanian (1995a). In one set of calculations (Scenarios I and II in Table 8), the pre-TRIPs situation is modelled as being perfectly competitive and the post-TRIPs situation as a perfect monopoly. In the other set of calculations (Scenarios III and IV), the pre-patent situation is modelled as a duopoly with one foreign and one domestic duopolist; in the post-TRIPs situation, it is posited that the domestic duopolists costs go up because he has to "work around" his competitor's patent. Market demand is assumed to be linear and production is characterized by constant marginal costs.

[18] Of course, in a situation of binding price controls, the adverse impact will be felt through lower profitability of firms whose imitation-based production has been displaced.

Egypt are likely to be the foreign companies—to increase. As imitation-based production cedes to patent-based production, the share of indigenous firms will fall in total sales, while that of foreign firms located in Egypt and of imports will increase. [19]However, these numbers should be seen in the light of two important qualifications. First, as explained in the box, these effects will only be felt in 2015. Second, in view of the arbitrariness of the assumptions and the sensitivity of results to these assumptions, the numbers should be viewed as illustrative, suggesting broad indications rather than precise outcomes. Predictably, based on evidence for other countries (see Subramanian 1995a, 1995b), the effects of the TRIPs agreement on Egypt are extremely sensitive to assumptions made about the various market parameters.

Two parameters in particular drastically alter the nature of the conclusions. The first is the proportion of drugs in the future that will be patented. This is of course something that is impossible to predict since it will depend on the nature and rapidity of R&D over the coming years. According to data that we have collected, including interviews with industry experts, 15-30 percent of the market would be affected, because that is roughly the magnitude that would have been based on imitation had there been no patent protection. If 15 percent of the market is likely to be affected (Scenarios I and III), price rises of patented drugs could vary between 5 and 67 percent, resulting in an overall drug price impact of between 0.8 and 10.1 percent. In these cases, welfare losses to the country in the form of reduced consumer and producer surplus could vary between US$ 28 million and US$ 114 million; these losses are partially reflected in gains to patent owners (presumed to be foreign-owned companies) of the order of US$ 18 million and US$ 76 million.

The results are also sensitive to how competitive the market is assumed to be and what policies are followed after the TRIPs agreement. For example, in the limiting case where the pre-patent situation is perfectly competitive and the post-TRIPs regime is a perfect monopoly, the adverse impact is large (compare Scenario II with Scenario III in Table 7). This represents an upper bound to the economic impacts. If, on the other hand, the pre-patent situation is a duopoly with one foreign and one domestic producer, and the post-TRIPs regime is a monopoly with one foreign producer, the impacts become less adverse (this is the model analyzed in Chin and Grossman 1988, illustrated by a comparison of Scenarios II and IV).

[19] Imports of final pharmaceutical products are predominantly undertaken by the foreign firms.

Table 8. Impact of TRIPS on the Pharmacueutical Market in Egypt in 2015[1] (in US$ million at 1996 prices, unless otherwise stated)

	Elasticity		
	e = -0.75	e = -1	e = -2
Scenario I[2]			
Average price rise			
patented drugs	67.0%	50.0%	25.0%
all drugs	10.1%	7.5%	3.8%
Welfare loss	114	85	43
Profit transfer to foreign firms	76	57	28
Scenario II[2]			
Average price rise			
patented drugs	67.0%0%	50.0%	25.0%
all drugs	20.1%	15.0%	7.5%
Welfare loss	455	341	171
Profit transfer to foreign firms	303	227	114
	Elasticity		
	e = -2.5	e = -3	e = -5
Scenario III[3]			
Average price rise			
patented drugs	10.0%	8.0%	5.0%
all drugs	1.5%	1.2%	0.8%
Welfare loss	59	48	28
Profit transfer to foreign firms	36	30	18
Scenario IV[3]			
Average price rise			
patented drugs	10.0%	8.0%	5.0%
all drugs	3.1%	2.4%	1.5%
Welfare loss	117	96	113
Profit transfer to foreign firms	73	60	35
Memorandum item			
Annual sales of pharmaceutical products		1516	

Source: Subramanian 1995.
(1) 'e' refers to the price elasticity of market demand; in the case of a duopoly this translates into different perceived elasticities for individual duopolists. In all scenarios, marginal costs remain the same in pre- and post-patent. The theoretical models used for deriving these numbers are described in Subramanian (1995).
(2) Share of patented drugs = 15% in Scenario I and 30% in Scenario II. In both, pre-TRIPs market is perfectly competitive, and post-TRIPs is a foreign monopoly.
(3) Share of patented drugs = 15% in Scenario III and 30% in Scenario IV. In both, pre-TRIPs market comprises two duopolists, one foreign and one domestic, and post-TRIPs market comprises a foreign monopolist.

Box 1. Timing of Impact of TRIPs Provisions on Pharmaceuticals

It is important to understand *when* the economic effects, be they positive or negative, are likely to be felt under the TRIPs agreement, especially since the general impression seems to be that legislative changes and economic impacts will occur immediately.

Although developing countries appear to have a 10-year transition period for the introduction of pharmaceutical patent protection (Article 65.4), the effective period of transition will be determined by the combination of Articles 65 and 70.8. The latter effectively requires all patent applications filed after January 1, 1994 to be granted protection.[20] The chart below explains how these complicated transition provisions apply.

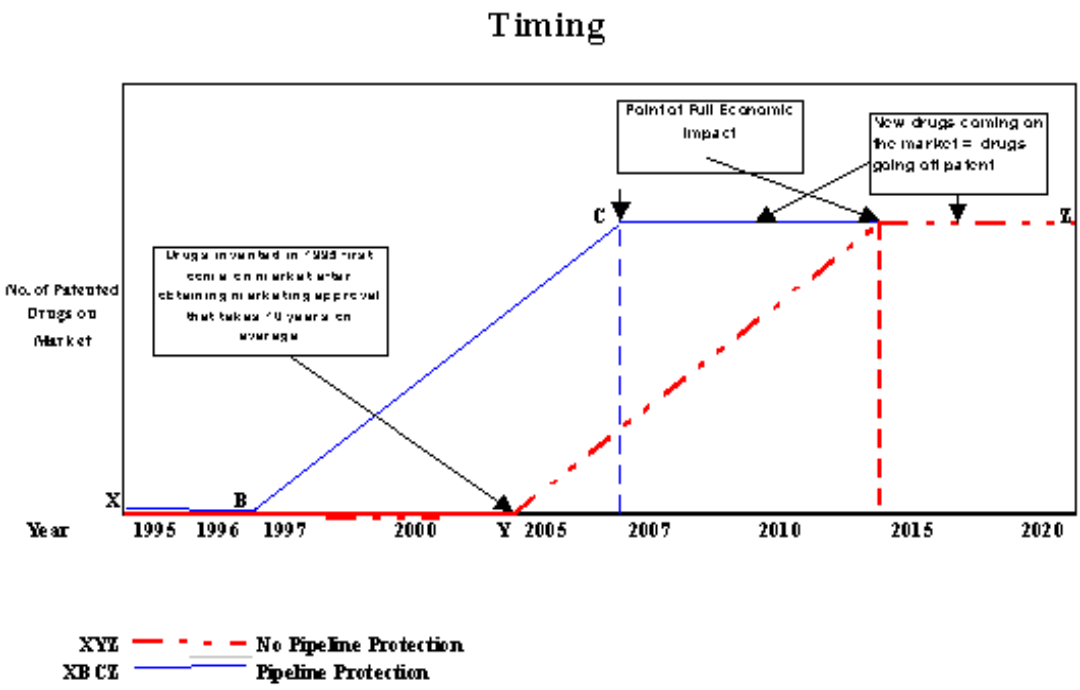
All patent applications for pharmaceutical products filed after January 1, 1995 will have to be put into a "black box" by countries that did not earlier grant pharmaceutical product protection. By 2005, countries will have had to pass legislation that would allow patents to be granted for such black box applications. However, no commercial benefits would have been lost during the 10-year interval because the products for which patents had been granted in industrial countries, but which were in the black box in developing countries, would have been going through the process of obtaining regulatory approval prior to commercial marketing. This process is estimated to take an average of 10-12 years for new chemical entities, giving each patent a commercial life of 8-10 years. This means that the patent applications that went into the black box in 1995 in Egypt would emerge in 2005; in 2005 the Egyptian patent authorities would have to examine these applications under the new TRIPs-consistent laws; concurrently, the drug would also be ready for commercial marketing in Egypt.

As the chart (line XYZ) shows, no patented drugs would be on the Egyptian market until 2005 and hence *no economic impact* of the TRIPs agreement would be felt until 10 years after the agreement. In other words, drugs that enter the market over the next 10 years, and certainly drugs already on the market, will be unaffected by the TRIPs agreement.[21] If 100 of the applications in 1995 were to be granted patents in 2005, these 100 patented drugs would be on the market in 2005. Assuming a uniform rate of successful drug patents, the number of drugs on the market by the year 2006 would be 200 (the 100 granted patents in 2005 plus the 100 in 2006), 300 in 2007, and so on. After 2015, the number of patented drugs on the market would be constant because the number of new drugs coming onto the market would be balanced by those going off-patent after the expiration of their 20-year patent term. Thus, **only in 2015, 20 years after the WTO enters into force, will Egypt have a full roster of patented drugs comparable with those in countries that currently provide patent protection.**

Finally, if pipeline protection were to be granted, say, for all inventions made after 1987, the effect would be to shift the graph from XYZ to XBCZ. The first impact would be felt next year and the full impact in 2007 instead of 2015. The consequences would be enormous, because essentially the economic impact would be shifted forward by seven years, leaving that much less time for domestic industry to adjust.

[20] Although the agreement requires patent applications made after January 1, 1995 to be accorded patent protection, patents filed in industrial countries after January 1, 1994 could in effect be eligible for protection because of the operation of the provision relating to the "priority date" of an application.

[21] The one significant caveat to this is that if regulatory approval for a drug takes less than 10 years, countries will still have to protect that drug by granting an exclusive marketing right, a patent by another name, until such time as they can receive formal patents (Article 70.9). Such drugs will enjoy a commercial patented life greater than 10 years, depending on how quickly they obtain regulatory approval.



However, if one posits, more realistically, that competition between patented therapeutic classes allows governments to use compulsory licensing to regulate a post-TRIPs pharmaceutical market, the adverse effects shrink further in magnitude. In Subramanian (1995a) this is modelled as a Bertrand duopoly in the pre- and post-patent situations, with one domestic and one foreign producer. The effect of the TRIPs agreement is modelled as forcing an increase in the cost of the domestic producer which can be interpreted as the royalty that he would have to pay to the foreign patent holder for the use—under compulsory licensing—of his patent. This model yields annual welfare losses price increases that are considerably less than the results shown in Table 6.[22]

6. Long-run Dynamic Impact

These calculations potentially ignore important dynamic benefits stemming from TRIPs-induced R&D effects. The evidence on these effects is unfortunately neither extensive nor systematic. A number of studies for industrial countries do, however, show that IP protection is important in R&D decisions in the pharmaceutical and chemical sectors, but less so in other sectors (Levin et al. 1987; Mansfield 1986, 1994).

[22] Maskus and Konan (1994) calculate the economic impacts under other scenarios.

In the case of Egypt, what are the prospects for the know-what, know-who, and know-where effects? Tables 5-7 shed some light on the know-who and know-where effects. Currently, there is very limited R&D in Egypt and very little by Egyptian firms; and as discussed above, the little that there is tends to be of a very special, limited nature. It could be argued, however, that this reflects in part the current legal regime that has not provided the incentives for R&D. On this view, future R&D activity cannot be extrapolated from current performance because of the regime shift that will occur. Even if this were true, the prospects for developing a genuine R&D based industry in Egypt in the medium-term are not very bright. To see why, the development of one new patentable drug today costs about US$ 250-400 million or about LE 850-1360 million, which represents almost half the revenues generated by the entire Egyptian pharmaceutical industry—an industry that is not even at a stage of development at which it manufactures the important active ingredients. Attaining R&D capability is therefore some time away.

This is not to say that certain kinds of R&D, such as clinical training and testing, cannot be carried out in Egypt, but attempts at assessing their magnitude are extremely speculative. Proponents of the view that R&D will be stimulated invoke the example of Italy, where it is claimed that patent protection improved the situation of local companies and encouraged R&D while at the same time keeping price increases restrained. On the other hand, the Canadian Drug Manufacturers Association argues that the promise of higher R&D after the strengthening of the patent law in 1991 was belied by subsequent experience. International evidence is too mixed to allow any easy generalization that would apply in the Egyptian case.

While the know-who and know-where R&D effects may not be promising at this stage, the same need not be true of the know-what effects. Improved patent protection in Egypt and other similar developing countries could stimulate R&D by foreign and local firms in finding cures for diseases found predominantly in these countries.

7. What Will the EU Agreement Add to TRIPS?

The draft agreement requires Egypt to provide protection for IPRs in line with "the highest international standards" and to adhere to a non-exhaustive list of multilateral conventions (Loutfi 1996). Although the deliberate ambiguity of the former requirement has raised some

concerns, it appears that neither of these two obligations will have any significant consequences for the pharmaceutical sector. [23]

However, another set of provisions may have some impact on the pharmaceutical sector, in particular on the ability of the government to regulate it. The draft agreement adopts the principles of competition policy that govern the free movement of goods within the EU. Once the agreement enters into effect, these principles would also govern the conditions of competition between the EU and Egypt. The implications, although uncertain at the moment, could be potentially significant, in terms of circumscribing the options that Egypt would otherwise have to regulate the pharmaceutical sector.

An example might help illustrate this point. Suppose that a European pharmaceutical company was charging a price that could be considered high or abusive under Egyptian competition law; however, under EU competition policy rules, such a price could be deemed normal. The question would then arise whether Egypt would be forced by the EU agreement to implement the latter standards. Another example relates to the freedom provided under the TRIPs agreement to use compulsory licensing to mitigate any abusive use of the patent right. Would the EU agreement's provisions on competition policy preserve or eliminate this freedom? These are uncharted legal waters that need to be carefully explored before Egypt undertakes commitments in the area of competition policy.

8. Policy Options for Egypt

Options for the Government

Pipeline Protection and Implementation of Legislation. The box indicates that the impact of the TRIPs agreement will be felt fully only in 2015—20 years after the implementation of the agreement—which should provide sufficient time for industries that are likely to be affected to adjust to the harsher environment. Two policy choices—neither of which is required by the TRIPS or EU agreements—confront the authorities: first, whether to grant patent protection for pharmaceutical products that have been invented prior to 1995 (the "pipeline protection" issue); and second whether to accelerate the domestic implementation of the patent laws from 2005 (the "black box" issue).

It is important to recognize that these are two distinct issues—the former will have a strong economic impact because it will shift forward by 7-8 years the effects described in the

[23] One of the conventions to which adherence is required, the International Convention for the Protection of Plant Varieties (1991), will, however, have important ramifications for the agricultural sector.

box; in other words, pipeline protection would disallow imitation-based production by local manufacturers from now onwards. [24]But economic logic suggests that pipeline protection may not have merit. Pipeline protection would induce the short-run economic impact of higher consumer prices and lower consumer welfare, but would not have any attendant dynamic benefits. Dynamic benefits arise when the improved IP regime induces greater R&D activity; but by definition the products that will be introduced have already been invented, so that there can be no incremental impact on R&D activity. The second advantage of not implementing pipeline protection is that it would afford a longer time period for local producers to adjust to the new patent regime, and to re-orient their production strategy from imitation-based production to license-based production.

On the other hand, the acceleration of the domestic implementation of laws (the black box issues) would have no economic impact; it would merely introduce transparency and certainty into the patent system and provide guarantees that from 2005 onwards, Egypt's patent protection for pharmaceutical products will be in line with international standards. [25]

Compulsory licensing: While the TRIPs agreement has significantly limited the use of compulsory licensing (which was, for example, the preferred tool in Canada for regulating drug prices), countries retain some margin of maneuver in using this form of regulatory control. In particular, it should be noted that two of the stringent conditions attached to compulsory licensing the need to demonstrate that the patent owner has refused to make available a voluntary license on reasonable commercial terms and conditions, and the criterion of adequate compensation can be waived if it can be shown that an IPR holder's actions have resulted in an anti-competitive practice. Hence, Egypt in its national competition law can specify standards of abuse, encompassing such outcomes as high prices. Egypt retains enough latitude—subject of course to the caveat that this might be circumscribed or eliminated by the EU agreement—in determining where these standards could be set, for example, the point at which a price would constitute an abuse of the patent right. In the event

[24] Egypt does not have the choice of not introducing patent protection. In fact, even if Egypt wished to renege on its international commitments, it will not be able to because it would not have access to the imported raw materials, which could not be legally produced in the country of origin, on which Egyptian imitation depends. The only real question is not whether but when to introduce such protection.

[25] According to legal experts, the TRIPs agreement is self-executing in Egypt in the sense that it has the force of domestic law overriding all previous relevant laws. However, there is still a need for domestic law if only to elaborate on and specify in greater detail the provisions of the TRIPs agreement.

that these standards are flouted, compulsory licensing could be used to redress the abuse and bring prices down to reasonable levels.[26]

However, in order to be able to implement compulsory licensing, Egypt needs to have a competition law in place that would allow explicitly for the regulation of the pharmaceutical industry. The current draft law, according to our understanding, does not provide for this possibility and needs to be remedied. In the long-run, it is probably preferable to regulate drug pricing through competition policy rather than through administrative fiat.

Price Controls: Neither the TRIPs nor the EU agreement would preclude the use of price controls already so pervasive in Egypt. Price control regimes co-exist with strong patent regimes in many developed countries, including those in Europe. If higher drug prices are a source of concern, the European model could serve as an exemplar; this policy, however, is a double-edged sword (see below).

Upgrading the Egyptian industry: This would require other policy efforts that are currently seen as hampering investment in and development of the industry. The first of these relates to price controls. Many countries regulate the prices of pharmaceutical products. However, successful regulation requires the institution of an independent body that takes into account and balances the interests of producers against the needs of the consumers, and that follows a transparent process which engenders confidence and credibility. While the current system of pricing has contributed to remarkable price stability, it has not necessarily been transparently done nor adequately reflected the needs of producers. This will need to change.

The second aspect of regulation relates to registration procedures. The current system, whereby registration in Egypt can only be initiated after a product has been marketed abroad, leads to a time lag of between two and three years before the drug is introduced in Egypt, depriving consumers of access to potentially life-preserving medication. This is just a deadweight loss to society. Registration procedures need to be speeded up through a transparent mechanism, possibly by the independent drug regulatory body.

Privatization: Finally, upgrading of the pharmaceutical industry also requires a careful review of whether the government has any comparative advantage in being engaged in the production of pharmaceuticals. The analysis in Section 4 demonstrated that the public sector has been underperforming. Its profitability has been low and lower than its private sector

[26] That the use of such compulsory licensing by governments can reduce the adverse impacts was noted above. In such a case, the adverse price and welfare effects are considerably less than those obtained under scenarios III and IV in Table 8.

competitors, and its efficiency as measured by labor productivity has also been poor. It is estimated that public sector companies receive about LE 150 million annually in subsidies from the government, and that in addition these companies carry "excess" (i.e. unserviceable) debt to the extent of LE 230-350 million. The question that needs to be debated is whether the legitimate regulatory and health concerns in the pharmaceutical industry require government ownership and management of the industry, or whether these objectives can be better accomplished through the combination of private sector ownership and management coupled with effective government regulation.[27] In other words, the government should reconsider its current strategy of restricting privatization in this sector to minority divestitures.

Some of the above options (especially the first three) are all damage-limitation options, stemming from the prior assessment that international developments are on balance likely to have a negative impact on the pharmaceutical industry. But there is a strong strand of opinion that views these developments as opportunities to be seized, rather than threats to be contained. From the point of view of the pharmaceutical companies, particularly those that currently thrive on the lack of patent protection, the need for adaptation is a reality that is imminent and that will have to be contended with. There is sufficient time—between 10 and 20 years—over which these adjustments can be made. The question is: What should they be?

Industry's Options: The Egyptian industry is what might be characterized as the equivalent of the CKD mode in the automobile sector. Essentially, all raw materials are imported, and Egypt serves as a base for mixing, packaging, and marketing, with very little R&D undertaken. From this base, a graduated approach to adaptation and upgrading could be considered. In the first phase, the industry would have to gear itself to acquiring capability in manufacturing bulk generic drugs. This may have to be done in collaboration with foreign companies through licensing of technology and know-how. Egypt's competitiveness in this phase would derive from its cheap and skilled pool of manpower;[28] lower marketing and packaging costs which are in turn also related to Egypt's cheap labor that allow for the replacement of automated processes by manual ones (see ERF 1996) and the relatively large size of its market compared with other markets in the region.

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[27] One of the arguments advanced against privatization is that it would lead to cessation of local production of certain essential product lines (e.g., insulin) that are unprofitable. However, even in this case, it is not clear why these products cannot be imported or sufficient incentives provided to private sector firms to produce them without increasing government subsidies.

[28] However, the competitive advantage derived from cheap labor should not be over-emphasized because labor costs account for a relatively small share (less than 10 percent) of the total costs of production.

Once this capability has been acquired, there could be greater scope for the Egyptian industry to invest in R&D. There are many facets to R&D. One immediate possibility would be to increase training and skill of personnel with a view to attaining manufacturing capability that complies with ISO-9000 standards. Another promising, if more distant, possibility would be the development of treatments for tropical diseases that are found in countries such as Egypt. The incentive to invest in finding cures for such diseases could be provided by the improved system of patent protection.

In building up its technological, marketing, and R&D capability, Egyptian companies could explore partnerships with foreign companies. Another possibility for deepening the R&D effort is for Egypt's science and technology institutes to collaborate more closely with local companies to identify areas of mutual interest and advantage. For example, these institutes could identify locally available natural products with medicinal properties, and help in supporting research related to diseases specific to Egypt.

9. Conclusions

The pharmaceutical sector in Egypt is entering a critical phase and confronting choices as a result of the confluence of a number of developments--external and internal. The most important external factor is the WTO's TRIPs agreement which will fundamentally alter the legal regime—and hence the nature of competition and market structure—and force producers to move away from imitation-based production. In Egypt, the balance of competitive advantage will shift away from indigenous private and public companies toward the foreign-owned companies that specialize in R&D-based production. Yet the magnitude of the impact should be kept in perspective—only a small share of the current market will be affected.

The current structure of the industry, which is segmented according to ownership, has the following characteristics:

- The domestic private sector and the public sector produce a much smaller fraction of drugs under licensing than the private sector
- These two sectors are most vulnerable to the TRIPs agreement because a small but growing share of their production is based on imitation.

- These two sectors account for virtually all exports.
- All companies invest relatively little in R&D and even the limited investment is of a fairly basic nature.
- All companies import virtually all their inputs of active ingredients.
- The industry as a whole is not very labor-intensive.
- Financial and economic indicators suggest that the public sector is highly inefficient compared with the other two sectors.

Against this background, the static impact of the TRIPs agreement will be negative for the economy—owing to higher prices and associated loss in consumer welfare; negative for the private sector and public sector whose imitation-based production will have to cease; and positive for the foreign-owned companies who will make larger profits. Imitation-based production by indigenous firms will be replaced by a combination of increased production by foreign companies and through increased imports. However, this static impact will be small in magnitude (because of the limited amount of imitation-based production) and backloaded in timing, with the full impact being felt only in 2015.

The dynamic impact is more uncertain, but the presumption is in favor of a limited rather than large impact. The prospects for greater and high-quality R&D by Egyptian firms and in Egypt appear limited at the present juncture. A possible exception is research on diseases prevalent in Egypt, which could be encouraged by the new legal regime.

Against this analysis, this paper offers the following tentative policy recommendations:

- The government should not introduce pipeline protection on economic grounds, and also to provide adequate time for affected industries to adjust to the new environment.
- The government should implement domestic laws and regulations consistent with—or more accelerated than—the TRIPs schedule, to remove uncertainty about the future legal regime.
- The government should also consider more seriously the possibility of using competition law—and compulsory licensing—to regulate a future pharmaceutical sector, in particular to redress abusive uses of patent rights. This would imply that the current draft competition law should be amended to encompass the pharmaceutical sector within its scope. 25

- A related point is that if the above avenue is to be used, care should be taken to ensure that the EU agreement's provisions on competition policies do not circumscribe Egypt's ability to use its competition policy appropriately.
- While equipping itself to more effectively regulate this sector in the future, the government should also take measures to foster the development of the industry. To this end, it should introduce greater transparency in regulating the sector, particularly as regards pricing. One possibility is the institution of an independent drug regulatory authority that could balance competing interests, namely legitimate health and security concerns and industry profitability.
- The government also needs to reconsider its engagement in the ownership and management of the industry in view of the financial unviability and economic unprofitability of the public sector companies. A superior alternative could be full privatization of these companies coupled with effective government regulation.

The option facing the industry is how to adapt to the changing environment over a sufficiently long period of time; a sequential strategy would focus initially on building a strong generic industry based on Egypt's labor cost advantage and comparative advantages in marketing; subsequently, a more R&D-based industry could be developed, including through cooperative links with foreign companies and local science and technology institutes.

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