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THE PHARMACEUTICAL INDUSTRY IN THE ESCWA MEMBER COUNTRIES

Technological Responses to Global Challenge

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This paper is based on studies conducted within an activity carried out by ESCWA with the aim of assessing the implications of WTO rules and related agreements on intellectual property rights (IPS) for selected sectors in the ESCWA member countries. Part of the afore-mentioned activity was directly concerned with the pharmaceuticals industry in these countries. In particular, contributions made by an international consultant, C. M. Correa and two experts from the region, B. E. Fayez, from Egypt, and Z. Fadloun, from Syria, constitute the basis for what was written about the pharmaceuticals sector within the above-mentioned activity. The technological needs of this sector in the ESCWA member countries were paramount in all three studies. Highlights of the conclusions reached by these studies concerning technology transfer, R and D and, generally, technological capacity building measures in this industry are briefly discussed below.

I. The world pharmaceutical industry

The global industry: its size, growth rate and main actors:

Production of pharmaceuticals is a sizeable global industry. It is largely concentrated in a relatively small number of countries. In 1994, companies based in only seven industrialised countries,[1] supplied the global pharmaceuticals market with more than 84 percent of its total value, estimated at US $ 237 billion.[2]

The global pharmaceutical industry has been growing at an annual rate of around 10 percent. On the basis of available figures for 1994, its value must now exceed the US $ 300 billion mark.

Multinational companies (MNCs), operating mostly in the developed countries, play a predominant role in the production of pharmaceuticals.

Consumption of pharmaceuticals is also largely concentrated in the developed countries. These countries, including the countries Eastern Europe and Russia, accounted for 81.1 percent of the world's consumption. Production and consumption, in the developing countries are estimated at around 18 and 19 percent respectively.[3]

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[1] France, Germany, Japan, Sweden, Switzerland, the United Kingdom and the United States.

[2] The figure for 1995 was US$ 286 billion.

Innovation in the world pharmaceuticals industry:

Pharmaceuticals production is a science and technology (S and T) intensive industry, comparing well to aerospace, computers and electronics in terms of research and development (R and D) expenditure. Information on R and D spending in a number of leading countries in the field is provided by figure (1). World R and D expenditure on pharmaceuticals was estimated to be around US $30 billion in 1991. R and D expenditure in the OECD countries alone is reported at around 9% of the industry's output in these countries.

R and D expenditure in the pharmaceutical industry is highest in a small number of developed countries. Innovation in pharmaceuticals is largely dependent upon the discovery and the introduction of new chemical entities (NCEs) that emanate directly from formal R and D efforts. High R and D expenditure is reflected in a country's contribution to NCE development. Thus, the development of around two thousand NCEs, between 1950 and 1989, was carried out in only thirteen industrialized countries, with the United States alone accounting for 40 percent of all NCEs developed during this period.

New discoveries in microbiology and genetics are constantly being investigated with a view to providing the industry with routes for synthesising new drugs. Innovations in computer technology have also been instrumental in providing pharmaceuticals research with powerful new tools for molecular modelling, the design of complex synthetic routes as well as the simulation of drug interactions.

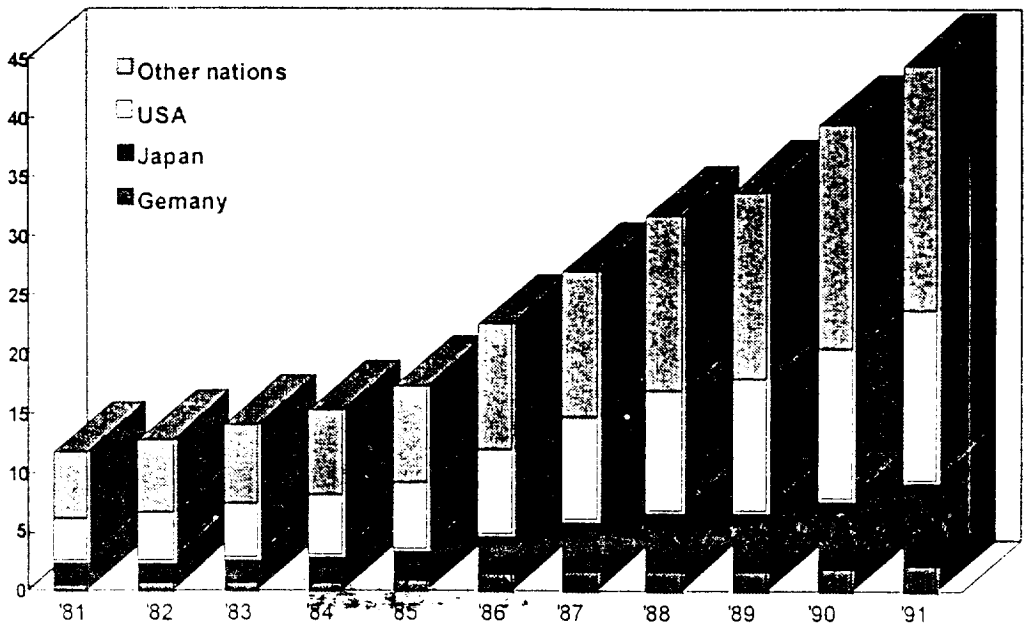
While the acquisition of powerful computer facilities and other prerequisites for effective R and D capabilities are certainly quite expensive, it should be mentioned that emerging drug development paradigms based on novel discoveries in the life sciences will eventually render the activity of drug design and interaction less costly and thus more accessible.

MNCs dominate innovative activity in the industry. Nevertheless, innovative activity by small research-based firms has been on the increase in selected areas, such as biotechnology and genetic engineering.

A strong relationship appears to exist between firm size and R and D capabilities. Schwartzman states that "the costs of drug research are so large ... that they exclude small firms from engaging in R and D on a sufficiently large scale to expect success". [1]

The fact that the costs of developing an entirely new drug are estimated as exceeding U$S 300 million, renders this relationship self evident. According to Raggett, some pharmaceutical companies concentrate on research projects that are likely to result in revenues of over U$S 500. [1]

Figure (1); Annual pharmaceutical R and D expenditure in 11 leading nations, 1981-1991, United States $ billions [6]



Other nations are: Belgium, Denmark, France, Italy, the Netherlands, Spain, Switzerland and the UK.

Little "globalization" of R and D appears to have taken place in the pharmaceuticals industry. Although the industry tends to engage in foreign R and D to a larger extent than other sectors, pharmaceutical firms conduct very little research and basic clinical evaluation outside their home countries. Only around 3 percent of R and D expenditure by U.S pharmaceutical companies abroad is reported as being carried out in developing countries. Several Latin American countries may be among the more prominent beneficiaries.

The pharmaceuticals industry is, thus, characterised by high costs at "both ends of the business system." [1] Economic and regulatory pressures faced by the global industry, are reported as having constrained their growth and as having provoked increasing merger and acquisition activity. This has resulted, in the smaller producers becoming more vulnerable and less capable of matching the innovative prowess of the industry's giants.

For several reasons which fall beyond the scope of this paper, the rate of discovery of NCEs experienced considerable reductions during the past two decades. This has tended to slow down the rate of new drug entery into the market. Further, increasingly stringent preclinical and clinical testing of NCEs before allowing them onto the market, has resulted in reduced effective patent lives and, hence, profitability.

On the other hand, innovations in targeted delivery/packaging systems and in the development of entities that embody modifications to previously successful chemical entities have been in ascendence.

Governments and the pharmaceuticals industry:

In discussing the pharmaceutical industry, it is essential to appreciate the important role played by governments in determining the status and future prospects of this sector. Thus, governments, particularly in the developed countries, play an important role in the operations of pharmaceutical firms and hence in their ultimate profitability. Products need approval prior to commercialization. Governments in most countries are involved in specifying laboratory testing procedures and protocols for conducting clinical trials leading to the certification of the use of drugs in human and veterinary applications. Many governments are also involved in setting maximum consumer and public sector prices in order to keep treatment costs under control.

Governments' role in pharmaceuticals, however, is not only regulatory. In some countries, governments play an important role in providing a variety of incentives for R and D and facilitate the transfer of knowledge from academia to private companies. More importantly, for the purposes of the present study, governments are also important actors in the sphere of

intellectual property rights.

Summary:

The world pharmaceutical industry is going through what might be termed a rough period on account of reduced profitability, declining rate of NCE discoveries.

Targeting innovative drug delivery, formulation and packaging systems of both new drugs, as well as generics, are among survival strategies being sought by the industry. Smaller producers have tended to adopt niche positions, focusing on a more limited set of therapeutic classes or methods of drug delivery.

Tighter protection of patents and intellectual property rights, at the global level, are among measures sought by multinationals with overt support from their home governments to derive maximum benefits from their established positions of technological superiority.

II. The pharmaceuticals industry in the ESCWA member countries

Pharmaceuticals production in the ESCWA member countries is a young and a dynamic industry. Thus, with the exception of Egypt's pharmaceuticals industry, most other countries in the region initiated their own pharmaceuticals operations during the sixties and seventies. The pharmaceuticals industry in the region has recently exhibited and continues to show considerable growth rates.

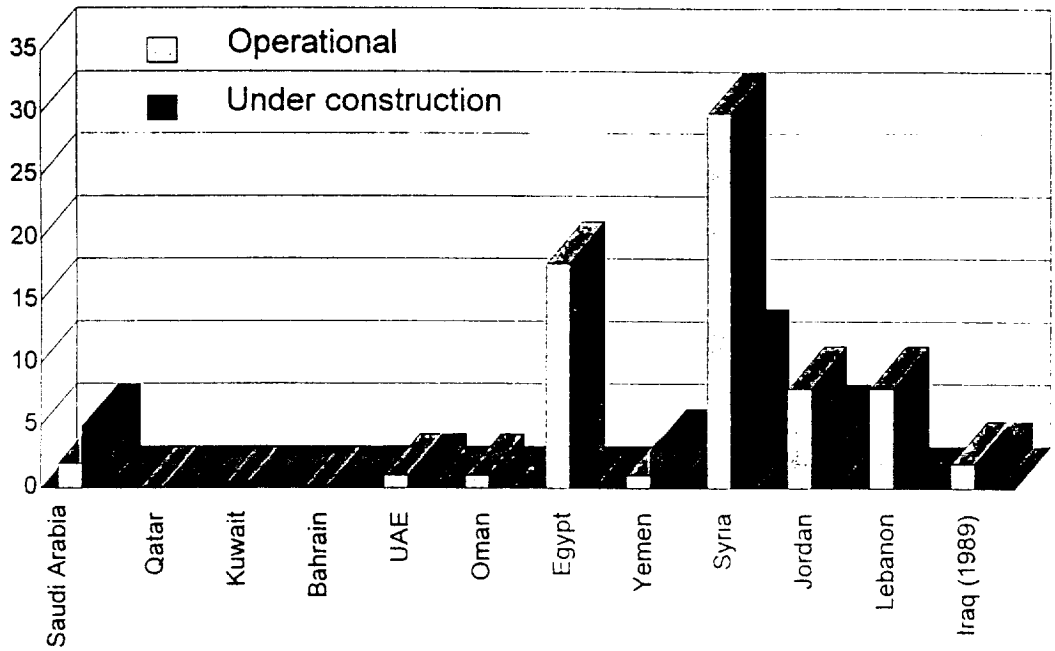
Pharmaceuticals production in the ESCWA member countries:

Over 120 pharmaceutical factories are presently reported as being in operation throughout the region, thirty new factories are under construction in only twelve countries. See figure (2). The Saudi, Syrian, and Jordanian industries appear to have undergone remarkable expansion during the past few years. Around 27 pharmaceuticals factories have been set up in Syria since 1990. In Jordan, the first pharmaceuticals producer, the Arab Pharmaceuticals Manufacturing Company Limited, set up business in the early sixties. Three companies followed suit in the seventies. Five more producers were established in the eighties and early nineties and a further five should start production in 1997.

In Egypt, the share of the principal private sector producers of local production capacity has witnessed a dramatic increase. Private sector producers have also been responsible for a good deal of advanced inputs into the industry, particularly in terms of manufacturing and management systems.

Figure (2)

Pharmaceuticals production facilities in operation and under construction in ESCWA member countries, 1994 [1]



ESCWA pharmaceuticals producers are for the most part small- to medium-sized firms that specialise principally in packaging and distribution. Formulation activity, largely based on imported active ingredients, is carried out by an increasing number of producers, particularly in Egypt, Jordan and Syria. [1] The spectrum of pharmaceuticals produced by local industry in the Arab countries tends to be largely confined to generis. Egypt's pharmaceuticals producers, in particular appear to cover a more comprehensive range of products.

The number of locally produced pharmaceuticals has grown considerably throughout the region. The number of brands manufactured in Syria, for example, grew from around 350 in 1983 to about 600 in 1990. An even higher rate of growth was witnessed during 1995 and 1996,[3] so that nearly 2,500 brands are now produced by Syria's pharmaceutical industry which covers an estimated 75[4] percent of this country's needs.[4] Nearly 260 production lines are said to be in operation in a total of 44 plants belonging to both the public and private sectors. [3] Established Jordanian pharmaceuticals manufacturers produce around 345 brands.

The combined local pharmaceutical industries in the Arab countries are valued at an estimated US $ 1.8 billion. Taken together, the national industries of Egypt, Morocco, Iraq, Syria and Jordan comprise more than 80 percent of the overall size of local Arab pharmaceuticals industries.

The relative size of the industry in comparison to other sectors of the economy in some of the countries of the region, particularly Jordan, is considerable. Thus, the combined capital of all fourteen registered companies in Jordan is estimated at around US$ 150 million. Furthermore, the pharmaceuticals industry in Jordan has become an important source of export earnings with revenues amounting to US $ 125 million in 1995. [1]

Value added by local producers is considered to be on the low side. In the case of the Egyptian industry, for example, it is estimated to be about 35 percent. This is primarily due to the fact that little if any of the industry's raw materials are produced locally and that the majority of production and packaging equipment, in deed a large proportion of packaging and auxiliary materials as well, are imported.

On the issue of technology acquisition through operations by MNCs the opinion is that these enterprises generally [2] failed to transfer production technologies pertaining to the manufacture of basic chemicals for pharmaceuticals. The argument

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[3] The number of drugs registered with health authorities in Syria exceeded 20,000 in 1963. These drugs were imported from producers all over the world. This figure was brought down to about 3,800 by 1973.

[4] Higher estimates have been reported, for example, by Fadloun [3].

put forward by MNCs is that pricing regulations and economies of scale render such activities of little interest.

Consumption levels and local industry sizes:

Consumption levels and local industry sizes in some of the Arab countries of the Middle east and North Africa are presented in figure (3).

Total consumption of pharmaceuticals in the Arab countries is estimated at US $ 3.8 billion. The 1994 market figures quoted by Correa for the countries of the Middle East and the Gulf countries amount to around US $ 3 billion or 1.5 percent of the world market.[5] Consumption in only six of these countries, namely, Saudi Arabia, Egypt, Iraq, Morocco, Algeria and Syria, amounts to nearly three quarters of the total. The cost of Syria's pharmaceuticals import bill is estimated to be close to US$ 600 million. [3] On per capita bases consumption ranges from US $ 50 in Saudi Arabia to around US $ 12 in Egypt. [2]

The public sector represents more than 60 percent of the total market in a number of Gulf countries, e.g. Kuwait, Oman and Qatar. The share of this sector is, however, much smaller in other countries such as Egypt and Syria, where it is close to 20 percent. The public sector and the large private-sector hospitals in Jordan account for 30 percent of the pharmaceuticals market.

Ownership patterns:

Different patterns of ownership of production enterprises may be observed in the countries of the region. Public and private sector enterprises predominate with the share of the latter generally expanding in favour of the latter. Multinational producers (MNCs) also operate in the region. In Egypt the market share of public-sector producers was around 41 percent, while the private sector produced around 34 percent of market needs. Joint-venture production with MNCs constituted around 20 percent of the local pharmaceuticals market.[6] Eight public-sector manufacturing enterprises are in operation, some established as early as the thirties.[7] Seven companies manufacture a variety of pharmaceuticals while the eighth produces bulk chemicals for the

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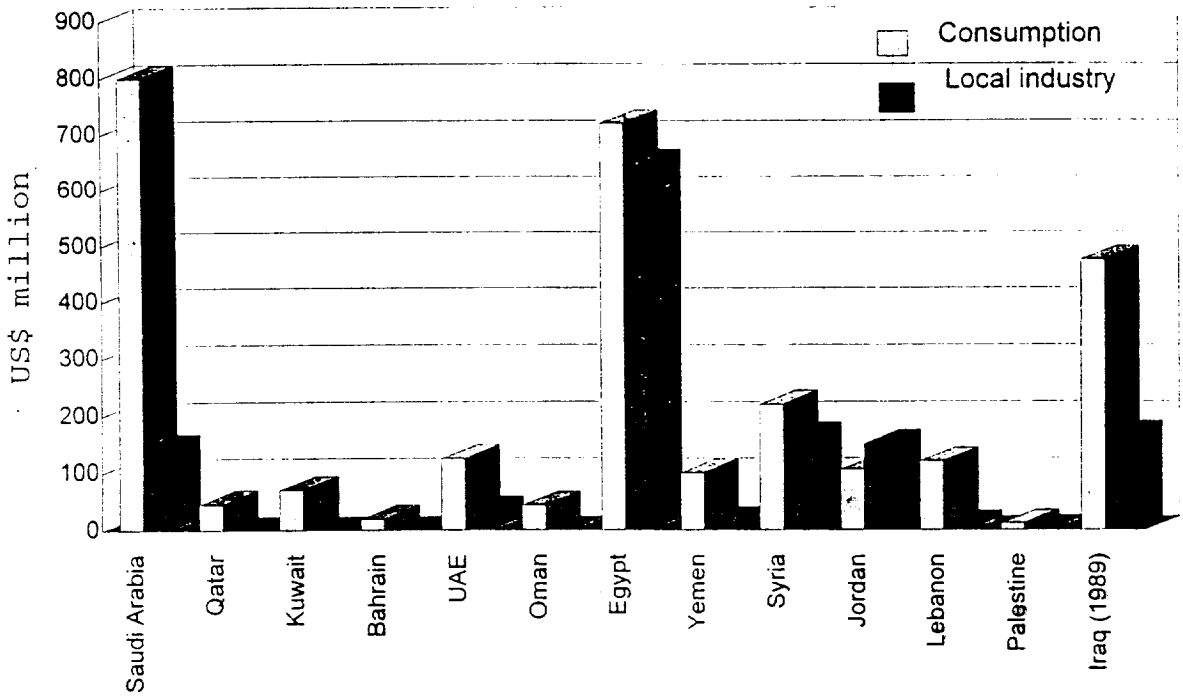
[5] The value of the Saudi market quoted by this author, US $974 million, is considerably higher than that quoted by a recent study of Jordan's Industrial Development Bank [4]: US $800 million. [4]

[6] Six firms in this group operate production plants based on foreign-sourced bulk materials.

[7] Additionally two public sector firms in Egypt specialise in trade, presumably mainly in the importation of pharmaceuticals.

Figure (3)

Consumption and local industry production in pharmaceuticals for ESCWA member contries, 1994 [4]



industry.[8] In all, locally produced pharmaceuticals in Egypt account for nearly 94 percent of local consumption in terms of value.

In Syria, prior to 1988, two public-sector factories covered around six percent of the needs of the local market, eight private-sector firms covered an additional two percent while remaining demand was met by imports. Today the pharmaceuticals industry in Syria is largely dominated by private-sector enterprises, whose number was estimated as exceeding 40 in 1996. [3] Jordan's pharmaceuticals industry, on the other hand, is totally dominated by private sector enterprise. [4]

The pharmaceuticals sector has received significant support from respective governments. Examples of this may readily be found in Syria and Egypt. Privatisation of public-sector enterprises has actually taken place in the latter country. Efforts aimed at liberalisation, particularly with respect to price controls and the ending of state subsidies have are faced with resistance on several fronts. State protectionism as applied to the pharmaceutical sector in Egypt, for example, is rooted in the fact that the industry is the sole source of inexpensive drugs for large segments of limited-income populations. [2]

Export versus local market orientations:

Production of pharmaceuticals in most countries of the region is geared principally towards local market needs. Jordan is the notable exception with export sales approximating 75 percent of total sales. In Egypt, exports of pharmaceuticals, led mainly by private-sector producers[9] are said to have grown rapidly from very low initial proportions. Export sales include generic products such as acetyl salicylic acid preparations (aspirin), antibiotics, dermatologicals, geriatrics, cough preparations, among others. Prospects exist, however, for expanding sales of both generic and licensed drugs in Arab and the African countries as well as the East European and the former Soviet states.

Licensed production of pharmaceuticals:

Licensing in the pharmaceuticals industry is generally sought in order to:

- produce drugs still under patency protection;
- ensure know-how for high-quality production of drugs which

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[8] Local production of pharmaceuticals in Egypt is largely based on imported chemical ingredients. However, a recent report [Aboulenein 1996, quoted by Correa 1997] states that around 10 percent of bulk chemicals used by the industry is produced locally by two local firms.

[9] More than two-thirds of total pharmaceutical exports are estimated to be due to the private sector.

may be no longer protected by patents;[10]

- establish reliable links to sources of high-quality raw materials;

Detailed information on licensing arrangements made by manufacturers in the region is generally unavailable. Yet it appears that all of the above-mentioned objectives are sought in the variety of licensing arrangements concluded by producers in the region.

Variations apparently exist with regard to the degree of dependence upon licensing in the manufacture of pharmaceuticals from one country in the region to another.[11] There is also evidence to suggest that variations do exist at the national and the regional levels with regard to technology transfer provisions included in licensing agreements. Some licensing agreements concluded in the early nineties stipulated sharing responsibility for production quality, e.g. Eli Lily and Alpha, in Syria. Other cases, such as the ferrous preparation produced by Shifa, also in Syria, did not reflect such arrangements. [3] In other cases, licensing arrangements were merely aimed at acquiring the brand name by the recipient company. Examples of comprehensive technology and human skill transfer may, nevertheless, be found in some of the new production plants, e.g. in Syria, Jordan and Egypt.

Analysis of the spectrum of products manufactured under license in some countries with respect to their therapeutic applications indicates that product groups are targeted on the basis of economic considerations. Furthermore, a considerable number of drugs are produced by more than one firm in a given country with consequent profitability losses for the national industry at large.

In some countries, a trend is observed towards initiating licensed production of drugs for which manufacturing capabilities were already in place without the benefits of licensing. This reflects the wish to capitalise on an existing need in the local market which was not being adequately met in terms of product quality. Instances are also met where licenses have been obtained for products which were nearing the end of their patent lives.

Examination of the spectrum of licensed drugs produced in Syria at the moment, for example, indicates that none of these drugs will be under protection in late 1997 or early 1998. Thus,

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[10] Examples of such arrangements do exist in which the licensee seeks to produce a well-known drug under the name of the original maker with clear economic benefits in mind.

[11] Only 2 percent of all drugs produced in Jordan, for example, are licensed. [4] In Egypt, on the other hand, around 54 percent of drugs are produced under license. Reference: Aboulenein 1996, as quoted by Correa [1]

licenses in these instances were not in fact sought in order to acquire a foothold in a new field. In certain instances, Syrian producers appear to have acquired licenses to produce the very drugs which the public-sector pharmaceuticals importing organisation imported for the Syrian market. While this must have made extremely good economic sense[12] it has not helped guide producers towards acquiring some of the more advanced production techniques.[3]

Generally, licensing by the pharmaceuticals industry in some countries of the Middle East and North Africa may have been of limited benefits on account of the following:

- technology transfer has not been extensive and has tended to concentrate in traditional areas of production technologies;
- a combination of regulatory measures and licensing arrangements governing raw materials sourcing practices and prices has negatively affected drug pricing and may also have indirectly impacted export possibilities;
- licensing arrangements concluded in the past have been devoid of provisions for significant research and development activity.[13]

Quality considerations:

One of the positive effects of licensing in the pharmaceuticals industry may have been to accelerate the adoption of good manufacturing practices (GMP) at the national level. Stipulations put forward by foreign companies, concerning the production environment and methods used to guarantee quality, as part of licensing arrangements, may have catalysed moves on the part of the health authorities to develop, adopt and enforce national GMP codes.

Quality assurance aspects in the pharmaceuticals industry throughout the region are reported as having undergone significant improvements during the early nineties. Producers in several countries in the region are reported as having made commitments towards obtaining ISO certification. Some have already acquired ISO 9002 certification. This will, however, reflect on performance rather than technology standards.

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[12] Syria's general practitioners were by and large accustomed to prescribing these drugs and demand for them had reached a mature stage.

[13] Industrial operations covered by such licensing arrangements generally involve traditional operations within mature production environments.

Research and development activity in the ESCWA pharmaceuticals industry:

With the exception of reports on R and D activities in Egypt, mostly targeting the extraction and packaging of active material extracts from naturally occurring substances in endogenous plants, little or no R and D appears takes place in the region that is of direct benefit to the industry.

Summary:

Box (1) summarises some of the main difficulties encountered by local pharmaceuticals manufacturers in the region. In summary, although the pharmaceuticals industry in the ESCWA member countries may be said to have performed an important socio-economic function, small and fragmented markets as well as lack of synergy both within the industry and with governments exert limits on its mastery of underlying technologies and innovative capabilities.

Box(1); Difficulties encountered by local pharmaceuticals manufacturers in the region

- High levels of local competition and replication within confined therapeutic categories;
- Lack of cooperative activity among pharmaceuticals producers in strategic production planning and marketing;
- Emphasis on short-term investment based on low-barrier products with limited technology inputs targeting low-income consumer groups;
- Government regulations that rightly target pricing with welfare considerations in mind but do not accord sufficient attention to securing long-term technology needs of the industry;
- Lack or weakness of intellectual property regimes in the region may have discouraged greater involvement by MNCs with consequent long-term impacts on product quality;
- Difficulties due to limited market sizes, further deepened by lack of national and regional coordination, have resulted in excess capacity and low profitability;
- Although significant efforts have been made towards the adoption and application of GMP standards in many countries in the region a good deal of effort is still needed in order to achieve internationally acceptable standards.

III. WTO/TRIPs and the pharmaceuticals industry

The World Trade Organisation (WTO) which evolved from the General Agreement on Tariffs and Trade (GATT) came into being on January 1, 1995. WTO reduces tariffs and does away with import

restrictions.[14]

WTO applies the most-favoured-nation principle in accordance with which signatories may not discriminate among members on the basis of tariffs. The WTO simplifies or eliminates licensing rules and customs procedures and converts non-tariff barriers into tariffs which are earmarked for downward revision. Developing countries are allowed grace periods as well as more leeway in the extent of tariff liberalization.

WTO, which monitors trade relations among some 120 signatories, further incorporates agreements covering trade in services, trade related investment and intellectual property rights (IPR). It is principally with the latter issue, which constitute the focus of the agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs), frequently referred hereafter as the "Agreement", that we are concerned.

WTO and trade in pharmaceuticals:

The following sections briefly discuss the main outcome of the Uruguay Round with regard to trade, investment and technology in relation to the pharmaceutical industry.

The multilateral rules that constitute the outcome of the Uruguay Round will have wide reaching impact on trade throughout the world. The effects of these rules on developing countries will vary from one sector to another. The direction and the severity of the impact on developing countries will depend on a number of factors including the degrees of trade liberalization; the kind of products and services involved and; in particular, the comparative advantages possessed by a given country, or group of countries in terms of access and capacity to use up-to-date technologies.

In pharmaceuticals production the main impact is not likely to stem from tariff-related considerations. Rather they will be firmly related to rules relating to the industry's technological capacity, quality standards and investment flows.

Globally, pharmaceuticals exports approximated $ 40 billion in 1991. Only North America, China and Japan are effectively self-sufficient. The rest of the world, notably the developing countries, depend more or less heavily on imports. [1]

The following categories of products are involved in pharmaceuticals trade:

a) Primary materials and intermediates for the production of active ingredients. These are

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[14] Thus, 44 percent of goods being traded on the international market, including pharmaceuticals, construction equipment, toys, wood and iron, will have their tariffs rescinded.

mostly produced by the world chemical industry and include commodities such as chlorine, nitric acid, aromatic hydrocarbons, etc.;

b) Active ingredients including, for example, antibiotics, vitamins, etc., which are produced in large quantities and sold on the open market

c) Speciality active ingredients, not covered by patents, generally produced in relatively small quantities and more or less accessible on the market;

d) Speciality active ingredients covered by patents, produced by specialized pharmaceutical firms and commercialized through subsidiaries or under exclusive agreements;

e) Finished, i.e. formulated and packaged pharmaceuticals.

Trade in pharmaceutical primary materials, intermediates, active ingredients and finished products have generally undergone significant liberalization. Nevertheless, significant variations still exists in the average rates applied by different countries.[15]

Additionally, as a result of the Uruguay Round, tariff rates on chemicals have been considerably reduced. For example, reductions reached, 48,4% in the case of Canada, 60,9% in Japan and 39,7% in United States.

In general, however, it is difficult to estimate the impact of tariff reductions resulting from the Uruguay Round, on trade in pharmaceutical-related products.

In a recent study carried out for ESCWA, Correa [1] discusses a number of economic models that have been used more or less effectively to predict the impact of the WTO rules on trade in pharmaceuticals. Box (2) includes a summary account excerpted from this study.

In summary, it may be said that trade in pharmaceuticals and pharmaceutical-related products may benefit more from the application of internationally agreed standards that facilitate trade, such as the WHO "good manufacturing practices (GMP)", and the elimination of obstacles created by registration procedures for the commercialization of pharmaceutical products, than from any tariff reductions obtained as a result of the Uruguay Round.

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[15] A number of mostly OECD countries agreed during the Uruguay Round to eliminate customs and all other duties and charges on imports of certain pharmaceutical products from any origin, such as all pharmaceutical active ingredients bearing a World Health Organization (WHO) international nonproprietary name. The zero tariff list includes around 7.500 pharmaceutical products and chemical intermediates. 17 countries agreed during the Uruguay Round to conduct a review of the list once every three years to identify products to be added to the list.

Box(2), Economic models proposed/used in the analysis of the implications of WTO on trade in pharmaceuticals [1]

The general implications of the Round on trade may be examined under various types of econometric models. Applied general equilibrium models, in particular, will permit estimates of the likely quantitative effects of trade liberalization on wages, employment, welfare and other important variables. In most of these models, premised on perfect competition of a static nature, technology is assumed as providing constant returns to scale. Dynamic models have also been developed and applied, however.

Modelling the implications of trade liberalization is based on quite straightforward assumptions. Exporters widen their access to foreign markets and may exploit economies of scale; consumers widen their range of options and may get lower prices. In exchange, governments loose some tariff revenues (but may benefit from increases in domestic activity) and previously protected producers may lose market share due to enhanced competition.

The models applied to forecast the effects of the Uruguay Round indicate a gradual increase in international trade and world GDP, but their findings differ considerably regarding the extent of this increase and the distribution of their resulting gains within and among countries. In addition to a number of conceptual and methodological limitations, most modelling studies analyze trade at a very broad level of aggregation, which precludes any meaningful sector-specific analysis.

The impact of the Uruguay Round on trade in pharmaceuticals might be estimated on the basis of models as noted above. It should be added, however, that the main obstacles to trade in pharmaceutical-related products are likely to emerge from the wide array of regulations (such as, registration procedures, quality and manufacturing standards, technical barriers, etc.,) that are applied for the commercialization of pharmaceuticals, rather than from tariff barriers. It should be also noted that an important portion of trade in pharmaceuticals essentially involves intra-firm activities, i.e., trade between parent companies and their subsidiaries.

WTO and foreign investment in pharmaceuticals production:

Foreign direct investment (FDI) is an important channel of internationalization in the pharmaceutical industry. The larger pharmaceutical companies appear to opt more for FDI than for straight forward exporting. This is attributable to two factors:

a. differences that exist in medical practices and consumption patterns;
b. the importance of maintaining a local presence for successful pharmaceuticals marketing and distribution.

FDI flows in pharmaceuticals have been extensive in developed countries. FDIs flowing into the developing countries have been less significant in volume terms. Nevertheless, an important amount of FDI in pharmaceuticals has also taken place

in these countries. Thus, foreign-owned firms account, on average, for about two-thirds of all pharmaceuticals produced in developing countries. [1]

The agreement on Trade Related Investment Measures (TRIMs), one of the outcomes of the Uruguay Round, aims at preventing the adoption and utilization of investment measures (legislative or otherwise) with the purpose of causing "trade restrictive and distortive effects". TRIMS, therefore, should have the effect of facilitating FDI by limiting the freedom of the host country to impose "trade-related investment measures such as performance requirements." The TRIMs Agreement does not include precise definitions or criteria that determine the admissibility of certain TRIMs articles under the substantive obligations. [1]

The possibility of establishing foreign subsidiaries or other forms of affiliated companies is, thus, of special importance in the pharmaceutical industry. FDI in pharmaceuticals generally takes place on the basis of the establishment of wholly-owned subsidiaries. Less, commonly, in some countries, joint-ventures with local companies are also established.

In general, TRIMS have not been as common in pharmaceuticals as in other industries, such as electronics and automobiles. The Uruguay Round, hence, may contribute to a consolidation of current patterns of FDI in pharmaceuticals, but it is generally judged by as "unlikely to substantially alter such patterns in any significant way." [1]

Box(3), Modelling the impact of TRIMs on FDI in pharmaceuticals. [1]

The possible impact of TRIMS (and of the related limitations imposed by the Uruguay Round) may be estimated drawing on a model from P. Krugman that illustrates a public perspective for oligopolistic industries with increasing returns to scale.

The model may be used to demonstrate that there is a substantial dimension of rent-and-producer surplus (gains for infra-marginal workers and suppliers) which any given host and all other potential hosts have an interest in procuring for themselves. To pursue a development strategy to capture this rent-and-producer surplus, domestic content and export-performance TRIMS are probably not the first and best tools. However, an approach using TRIMS may have special advantages when dealing with international investors with high exit costs in the home country.

WTO and technology transfer in the pharmaceuticals industry:

In the pharmaceutical industry, and particularly insofar as

the developing countries are concerned, WTO rules are likely to exert profound influences through technology-related considerations.

This is essentially due to the central role of patents and patenting in pharmaceuticals production. The importance of patent protection, to the pharmaceutical industry is self-evident. The implications of the Uruguay Round with respect to technology access and use, must, therefore, focus in large measure on the "likely impact of the introduction or strengthening of patent protection in developing countries." [1]

Patents and patent protection in pharmaceuticals has been the subject of a large number of recent studies. See box (3). Nevertheless, drawing general conclusions from these studies, is fraught with difficulties due to their varying perspectives, underlying assumptions and methodologies.[16]

Correa concludes, that the impact of technology-related rules of the Uruguay Round in pharmaceuticals, and particularly of the new standards on IPRs, will have to be assessed on the basis of "a variety of approaches and models, depending on the objectives of the research" in mind. [1]

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[16] A comprehensive literature review on the matter was produced by the World Bank. [1]

Box(4), A literature survey of the implications of WTO/TRIPS on the pharmaceutical industry. [1]

In examining the "welfare economics of patent protection" in a trading environment, Chin and Grossman conclude that "IPRs do enhance global efficiency at least for substantial innovations, but the South would incur losses that the North should be able and willing to compensate." [1]
Other studies relate the impact of patent protection measures stipulated by WTO/TRIPs to the levels of development of the countries where they are being applied. Thus, Deardoff has found that, the poorest countries could not be expected to gain from protection. On this basis he has advocated that they be exempted from any new agreement that is made to extend patent protection. [1]
The "small country" case was considered by Subramanian. He found that "in welfare terms the individual country will be worse off, because there are no dynamic benefits (such as an appreciable effect on R and D) to offset static efficiency losses." [1]
Evenson, however, argues that stronger IPRs "can aid poor countries to move forward in the technology draft" and that the case for these countries is "actually stronger than for the drafting (pirating) countries". He stressed the need to "address the balance between IPR protection for mainline and derivative inventions" and that "utility model protection and possible design patent protection, could be used to stimulate adaptive invention" .[1]
Primo Braga has addressed the impact on the larger developing countries with particular reference to newly industrializing countries (NICs). He argues for the existence of a "development threshold" after which protection of IPRs will generate net welfare gains. [1]
"Global gains as well as benefits for individual countries" are predicted by Diwan and Rodrik, on the other hand, when R and D promotion induced by IPRs is sufficiently strong. [1]
In more general terms, Nogués concluded that lower R and D productivity pertaining in the developing countries suggest that "patent protection should not necessarily be as strong as in high productivity competitive economies". He concluded that "patents should be strengthened once economies have stabilized and restructured" . [1]
The likely implications of IPR protection on trade in have also been investigated. The effects found by Maskus and Penaburti, applying a model developed by Helpman and Krugman, are ambivalent. The net effect is the result of the interplay of two conflicting factors: "the reduction of elasticity following the enhancement of IPRs holders' market power, and the displacement of imitators." [1]
In general, the studies referred to above suggest that patents will inter-alia limit access to technology and generate price increases in developing countries. Price, and hence welfare, effects are found to be negative, essentially for small developing countries, though given the transitional periods provided for by the Agreement and the extensive time required for the approval of a medicine, those effects would not be felt some years hence.[1]

The TRIPs Agreement:

The TRIPs Agreement is the most ambitious international instrument to date on IPRs. It is widely expected to influence future global developments in this field. Reforms introduced in

the US, Japan and other developed countries, serve as an indication of the extensive impact of the Agreement on IPRs standards.

Through the transitional periods provided for in the Agreement the developing countries may be able to gain the time needed for adjusting relevant national legislations and enforecement measures.

Strengthening of intellectual property protection in pharmaceuticals was one important issue in the negotiation of the TRIPS Agreement. Several provisions in various parts and sections of the Agreement are relevant for the consideration of this issue.

Objectives and principles of TRIPs:

Article 7 indicates that "[t]he protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations".

This Article provides a general framework for the interpretation of the TRIPS provisions. It aims at balancing the interests of the various stake holders, including innovators, producers and consumers in a manner that enhances "social and economic welfare". [1]

Article 8, which outlines the "Principles" of the Agreement specifically refers to the protection of "public health". This is regarded as an essential element for consideration in the formulation and amendment of national legislation and the design of enforcement measures in accordance with the provisions of the Agreement. The same Article also addresses the adoption of measures to prevent the abuse of IPRs or resorting to practices that may "unreasonably restrain trade or adversely affect the international transfer of technology".

Section 5, Part II, of the TRIPS Agreement addresses minimum national standards in regard to patents. See Box (5).

More specifically, Article 27.1, stipulates that Member countries are bound to grant patent protection for pharmaceutical processes and products alike. In this respect, it is useful to recall that, at the beginning of the Uruguay Round, legislation in at least fifty countries did not grant protection to pharmaceutical products, and that some, e.g. Brazil, excluded pharmaceutical processes from protection altogether.

Box (5); TRIPs Provisions on patent rights [1]

- Definition of subject matter, including criteria for granting patents and possible exceptions. Patents shall be granted in all fields of technology. No discrimination is allowed with respect to the place of the invention or based on whether the products are locally produced or imported (article 27)
- Rights conferred in the case of product and process patents (article 28), subject in the case of imports to the principle of exhaustion (article 6)
- Conditions for the granting of patents, particularly disclosure (article 29)
- Exceptions to the exclusive rights (article 30)
- Conditions for granting other uses without the authorization (compulsory licenses) of the patent holder (article 31)
- Revocation/forfeiture (article 32)
- Term of protection, which shall be at least twenty years from the date of application (article 33)
- Reversal of the burden of proof in civil proceedings relating to infringement of process patents (article 34)

It may also be noted that article 27 contains two possible health-related exceptions to patentability. Thus, under article 27.2, Members were allowed to exclude from patentability inventions the "prevention within their territory of which is necessary to protect... health". Article 27.3.b, on the other hand, allows the exclusion of diagnostic, therapeutic and surgical procedures for the treatment of humans. None of these provisions, however, authorize prevention of patentability in relation to pharmaceutical processes or products, nor of medical devices and other products for use in diagnostics, therapeutical and surgical applications.

In addition to extending protection to pharmaceuticals products, the TRIPS Agreement strengthens the rights conferred to the title-holder. In the case of product patents, Article 28.1.a of the Agreement stipulates that patents be applied in a manner that would prevent third parties not having the patentee's consent from "making, using, offering for sale or importing for those purposes the product" in question.[17]

As for process patents, Article 28.2.b provides for the extension of the protection conferred on a process to the product "obtained directly by that process". This must be viewd in relation to the principle regarding the reversal of burden of

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[17] Some ambiguity pertains with regard to the right to import a pharmaceutical product. Thus, while Article 28.1.a considerts importation an exclusive right of the patent holder, a footnote to the same article refers to article 6 of the Agreement, which allows Members to provide for "parallel imports" under the principle of "international exhaustion of rights", subject to the national and most-favoured-nation treatment.

proof.[18] When thus combined this Article imparts considerable strength to patent rights derived from process inventions.

Undisclosed information:

Article 39.3 specifically refers to pharmaceutical products, in dealing with the approval of their commercialization. It requires that data provided as a precondition for approving the marketing of pharmaceuticals including NCEs be protected by the Members against unfair commercial use.[19]

Anti-competitive practices in contractual licenses:

Anti-competitive practices are dealt with in Section 8 of the Agreement. Article 40.1 recognizes that certain licensing practices pertaining to intellectual property rights would restrain competition and "may have adverse effects on trade and impede the transfer and dissemination of technology".

Article 40.2 allows the adoption of measures that effectively limit or eliminate such licensing practices. While doing so, however, it establishes limits for national action. Three questions must be considered in establishing whether a particular practice is restrictive, in the sense alluded to above,essentially the practice in question must:

a) be assessed in reference to particular cases;
b) constitute an "abuse" of IPRs;
c) have an "adverse effect on competition in the relevant market".

Transitional periods:

Article 65 discusses transitional periods to which developing countries may avail themselves thereby delaying recognition of pharmaceutical patents for up to ten years from the date of entry into force of the TRIPS Agreement (i.e. 1.1.1995). Least developed countries, are allowed transitional periods of up to eleven years (until year 2006), which may be extended upon application to the Council of TRIPS.

Articles 70.8 and 70.9 discuss with specific reference to

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[18] Article 34 provides for the reversal of burden of proof in civil litigation involving process patents. This significantly increases the legal powers inherent in process patents. Authorities may "order the defendant to prove that the process to obtain an identical product is different from the patented process". A similar faculty is allowed under article 43 of the Agreement, Part III on "enforcement". Article 34, further stipulates that "any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process".

[19] Exceptions are provided which allow members to disclose such information in cases where it may be necessary to protect the public.

pharmaceutical products the procedures to be followed by Members applying for transitional period under article 65 of the Agreement.

According to these Articles the transitional periods are applicable once decision by the Member is taken in this regard. Thus, no notification or declaration by the concerned Member country is needed. Members applying transition periods are, however, bound to recognize "exclusive marketing rights" under the conditions established by article 70.9. A source of difficulty in this respect is that the Agreement does not specify the scope and extent of such rights.

Implications of the TRIPs Agreement for ESCWA Member countries:

The TRIPs Agreement will most significantly impact the pharmaceutical industry in the ESCWA region through patent protection regimes for medicaments.

In accordance with TRIPs, countries applying for transitional periods can delay the introduction of pharmaceutical patents as indicated by articles 65.4 and 66. They are, however, then obliged to accept, since the general date of entry into force of the Agreement (1.1.95), the filing of new applications relating to pharmaceutical product patents, and to eventually grant exclusive marketing rights (EMRs).[20]

In general, the impact of introducing pharmaceutical patents will vary on account of:

1. the length of the transitional period applied;
2. the date of granting a patent and the scope of EMRs eventually conferred. [1]

The implementation of the TRIPS Agreement will require changes in the accepted durations of patents in the countries acceding to the agreement.

Exceptions to the exclusive grants should be consistent with Article 30 of the Agreement. This Article allows Members limited exceptions under a set of specific conditions. These include, for instance, the need to infringe patents with the aim of carrying out research and experimentation.

Changes are also expected in national legislation dealing with compulsory licensing. Conditions for the granting of compulsory licenses, rather than the grounds on which such licenses are granted are expected to be the focus of such changes. TRIPs does not constrain national legislation with regard to these grounds, provided that conditions set forth in

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[20] One of the difficulties which may arise in this respect is that the agreement does not clearly spell out issues relating to EMRs.

Article 31 are met. In particular, TRIPs allows compulsory licenses in cases of "refusal to deal" and to avoid anticompetitive practices . [1]

Impact of pharmaceutical patents:

Assessing the likely impact of changes in patent law on pharmaceuticals as a result of TRIPs is constrained by a number of issues. Firstly, there is the difficulty in estimating the market share corresponding to products that would be under patents had the latter been recognized at the present time.[1]

Second, the dearth of information on price elasticity of medicaments will tend to hinder estimates on welfare effects.[21]

Third, assumptions about the homogeneity and stability of products which would be essential for building adequate models may only be applicable under a limited set of conditions.

Fourth, the characterization of pre-TRIPs market structure, as essentially competitive or duopolistic, and post-TRIPS period, as basically monopolistic, may be a gross oversimplification. This is particularly the case where substitutes to patented medicaments are available.

Fifth, as mentioned above, TRIPs provides for the possibility of compulsory licensing. This may well favour access to technology by local firms, and would thus lead to lower prices in comparison to situations of full monopoly by the patent-holder.

It is ultimately difficult to single out the effects of patents from those due to other variables, such as changes in living standards altered income distributions, impact of new health policies and consumption patterns, e.g. due to demographic changes, among others.

Impact on technology transfer:

A definitive assessment of the implications of patent protection on technology transfer is curtailed by a rather meagre body of information on the subject. An essential argument is that protection of IPRs will encourage product and process innovators to license the results of their travails. An issue that is still in need of closer consideration is whether the IPR protection would increase international technology flows. On this score, it may be argued that patent holders may prefer to directly exploit their invention, in which case technology flows would be greatly restricted.

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[21] Medicaments are generally considered to possess relatively low demand elasticity.

Factors which may favour a more restrictive stance with respect to technology transfer include the following:

1. Developments in information technologies facilitate and cheapen the cost of intra-firm communications, coordination and management control and are thus widely predicted to enhance the advantages of internationalization by MNCs.
2. Policy changes in a number of developing countries aimed at encouraging FDI will tend to reduce the cost of international operations by technology holders.
3. High development costs and short life-cycles constitute further inducements for innovator firms to secure rapid returns through simultaneous international operations.

At any rate, it is expected that should technology be transferred, the improved bargaining position of the technology holders is likely to lead to high royalty rates[22].[1]

In addition, it should be mentioned that access to scientific knowledge is probably becoming increasingly difficult. The growing economic relevance of scientific research "increases pressures to limit the free dissemination of research results and to constrain the traditional openness of university laboratories where most basic research is performed in Western countries".

Impact on innovation:

Domestic R and D efforts in pharmaceuticals are not expected to be enhanced due to the recognition of product patents. [1]

A general assumption is that the development of new chemical entities (NCEs) will be out of the reach of pharmaceuticals producers in al but a few developing countries.

The impact of the extension of patent protection on R and D undertaken by multinational drug companies has recently been analyzed by Scherer who found that developing countries might be better off if extra profits conveyed to drug firms led to the development of more new, and hence more effective drugs, and. Scherer's observes that multinational drug companies already have substantial operations in least developing countries LDCs[23], yielding profits, despite weak IPR protection. Scherer further

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[22] This effect will be strongly dependent, however, on patent granting modalities, the availability of measures to combat restrictive practices in licensing agreements, and of use without the authorization of the right holder, for instance, in cases of refusal to deal.

[23] Developing countries account for around 20 percent of world consumption. Additionally, many of them already recognize patent protection. Thus, further expansion of patent protection under TRIPs in these countries is likely to provide patent owners with only limited returns.

concludes that, a three-fold increase in the development of new drugs would be needed before citizens in the developing countries can feel the positive effects of introducing patent protection in terms of improved medicaments. Considering this increase rather unlikely, Schererconcludes that the developing countries are unlikely to benefit.[24]

To sum up, the introduction of patent protection is unlikely by itself to lead to substantial changes in pharmaceutical R and D activities in the ESCWA region. Other policies should be devised if local R and D capabilities are to be established or reinforced.

A possible model may be the programme initiated last decade in Spain. Thus, in order to strengthen the Spanish pharmaceutical industry before the introduction of product patents (decided in 1986 but effective as of 1992), subsidies for R and D were granted, particularly to co-finance the development of new chemical entities. In addition, participating firms received a special treatment for the registration of products and the determination of their prices subject to government's control. More than 30 patents had been obtained in 1990 as a result of the programme. [1]

Enforcement:

The TRIPS Agreement includes detailed consideration of the "enforcement" of IPRs. This can be particularly relevant for the pharmaceuticals sector.

Summary:

In conclusion, strengthening intellectual property protection in pharmaceuticals was a principal concern in negotiations of the TRIPS agreement during the Uruguay Round, it continues to be the object of many post-TRIPS multilateral and bilateral discussions.

Anxiety, in the pharmaceuticals industry circles in the developing countries, is often expressed regarding:

- pressure exerted by some MNCs supported by their home governments for the immediate introduction of the TRIPS standards;
- frequent calls for the application of the TRIPS standards retroactively and for the prolongation of the term of protection, beyond the 20 years required by the Agreement in relation to certain pharmaceutical products.

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[24] According to Scherer, the increase in the number of new drugs would more likely be of the order of 20 percent, assuming diminishing returns in either the production function or the quasi-rent function or both.

- the need to attract FDI and encourage effective technology transfer in particular areas of the pharmaceutical industry with the aim of import-substituting as well as export-oriented manufacturing.

By and large, the stance taken by the industrialised countries in relation to IPR protection strongly supports powerful local pharmaceuticals manufacturers as well as multinationals based within their boundaries. Critics of the position taken by these countries argue that it will ultimately be detrimental to public health and to industrial development in other countries. Thus, in negotiations over GATT and in bilateral trade negotiations, the United States, for example, has supported policies which would lead to considerable enhancement of the level of protection for intellectual property rights enjoyed by pharmaceutical producers. It is noteworthy that the position taken by the developed countries vis-a-vis IPR protection does not enjoy unanimous support even within these countries. Several consumer groups and NGOs concerned with development issues have voiced strong criticism of the industrialised countries' policies in relation to WTO and IPR protection measures. Constant debate over a number of important intellectual property rights issues goes on. Protests by agricultural experts over an excessively broad patent awarded for genetically altered cotton are just one example. The US Patent and Trademark Office's (PTO) decision to grant patents for new life forms created by genetic engineering has engendered, and continues to create, heated controversy revolving around the ethics owning life.[5]

At any rate the pharmaceuticals industry in the Arab countries, in deed in most developing countries, have been unanimous in demanding maximum possible delays in the application of TRIPS provisions to the production of pharmaceuticals.

Compliance with TRIPS provisions entails drastic revision of intellectual property rights legislation in the Arab countries. While appearing to be biased towards immediate concerns of the industrialised countries, this may be in the long-term interest of all operators. On the other hand, joining the TRIPS agreement and the development of reliable means for the enforcement of its provisions will, naturally, not be sufficient to guarantee a rosy future for the industry. It will additionally be essential to synchronise such activities with measures aimed at reviewing technology transfer and development policies and practices.

Several Arab countries are in the process of developing or revising legislation aimed at the protection of intellectual property rights (IPR).

The oldest system of patent laws in the region is probably that applied in Egypt. It dates back to 1949 and excludes from patentability chemically prepared substances designed for use in

food or medicine. The current patent law in Jordan does not allow patentability of pharmaceuticals products but extends protection to processes used in the manufacture of pharmaceuticals. The GCC Secretariats has pledged priority attention to the issue of intellectual property rights. A new patent law was passed in 1989 in Saudi Arabia. IPR laws in the UAE do not provide cover for pharmaceuticals products but grants production processes a 10 year protection term. The situation in Kuwait is rather similar to that in Egypt in that its patent law excludes certain chemicals used in food and medicine from patenting. Protection terms of 15 years are, however, generally granted. Apart from the state of IPR legislation, it may confidently be stated that measures designed to enforce whatever laws that do exist are in need of attention. Efforts will have to be made by the Arab countries at the policy, legislative and enforcement levels if greater compliance is to be achieved with WTO/TRIPS.

IV. The Future

T need to recognize the opportunities presented, as well as the challenges posed, by recent international agreements will be an essential prerequisite for future action on the part of the industry and concerned authorities alike. In essence, the issue is that of identifying appropriate policy measures to maximise benefits and diminish harmful impacts.

Drug consumption in the region is destined to rise due to population growth and enhanced health standards. Qualitative changes in consumption patterns will also be fuelled by socio-economic and demographic changes in the region. Major expansion into new therapeutic categories is contingent upon local developments with respect to IPRs regimes and compliance with TRIPs regulations.

In the mean time, the viability of numerous operators in the region, hinges upon a multitude of factors. The stance adopted by foreign patent holders, as well as the bargaining position of domestic producers, will be instrumental in deciding the fate of production activity that is unprotected by licensing agreements. Otherwise, an ability to switch to alternative product repertoires will be paramount in determining chances of domestic industries' survival. This, in turn will be contingent upon the acquisition of more advanced technological capabilities in production, packaging and distribution. Additionally, R and D capabilities will be of the utmost importance for securing the long- term future of the pharmaceutical industry in the region. Initiating R&D and distribution alliances with established international operators, difficult as it certainly is, will also be of considerable benefit in improving the industry's chances for survival.

Endogenous industry-specific R&D capabilities, in the region,

need to be created and strengthened with emphasis on adaptive R&D endeavour. Limited original activities on natural products, and NCEs derived therefrom, could produce longer term dividends. Conducting such activities in alliance with established R&D partners, both in and outside the region, should produce decided benefits. To this end, emphasis needs to be placed upon R&D cooperation at the national, regional and international levels and fresh government/industry initiatives have to be launched. Box (6), includes a list of R&D priorities for the pharmaceutiacls industry in the region.

Box (6); R&D priorities for the pharmaceuticals industry in the region

- Adaptive R&D activity aimed both at formulations and active material development and modification. R&D in the latter category may be aimed at the introduction of incremental structure changes into molecules of known physiological properties with a view to altering its side-effects, absorption characteristics, etc.
- Adaptation of new delivery systems and new modalities for administering.
- Safety and preservation studies, as well as packaging and site-specific delivery systems constitute other related areas of activity.
- Production process improvements targeting generic drugs and their raw materials, including the introduction of higher degrees of automation and computerisation in production and quality control.

Establishing modern distribution networking on the basis of regional and sub-regional industry alliances may well be rewarded at two levels: greater complementarity at regional and sub-regional levels, as well as possibilities for interfacing with larger global networks, thus, facilitating and reducing the cost of both import and export of pharmaceuticals.

References

[1] "Implications of the WTO for Technology Transfer in the Pharmaceutical Industry in the ESCWA Member Countries", by C. Correa, University of Buenos Aires, April 1997.

[2] "Implications of WTO Rules for Technology Transfer to the Pharmaceutical Industry in the ESCWA Member Countries with Emphasis on the Case of the Arab Republic of Egypt", by M. Fayez, Cairo

[3] "The Impact of GATT/WTO on Technology Transfer in the Pharmaceutical Industry in Syria", by Z. Fadloun, Syria, May 1997.

[4] Industrial Development Bank -" Study for the pharmaceutical industry in Jordan", MMIS and A.T.Kearny Inc., Jordan, May 1997.

[5] Nader 1996: "Ralph Nader and James Love, to Michael Kantor on Health Care and IPR;" Ralph Nader, P.O. Box 19312, Washington, DC 20036. James Love, Consumer Project on Technology, P.O. Box 19367, Washington, DC 20036. Comments or corrections to James Love <love@tap.org>; Consumer Project on Technology Home Page.

[6] "Another look at the world's pharmaceutical industry;" R. G. Halliday and S. R. Walker, International Journal of Pharmaceutical Medicine, 1997, 11:29-36.