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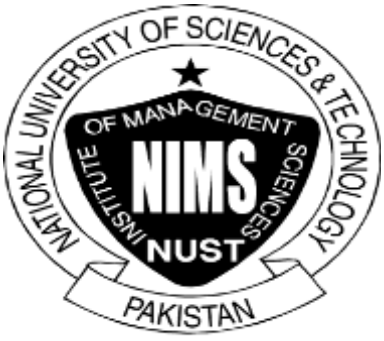

MBA Final Thesis

(Initial Draft)

WTO & Its Impacts on Pakistani Pharmaceutical Industry

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EXECUTIVE SUMMARY

Globalization is a reality, not a choice. Globalization is here and inescapable, because it corresponds to the present phase of historical development and because it has the power to fulfill many human wants" (Chen & Berlinguer 2001).

Despite the running battles in downtown Seattle, the back streets of Davos or the plaza in Genoa, the ongoing debates between the supporters and opponents of globalization are a testimony to the fact that we live in an increasingly shrinking world. Whether we like it or not, we do live in a global village with vastly increased opportunities for sharing information, communication between individuals and societies.

This research paper is all about the impact of Globalization their step that is WTO. The beginning pages of the paper are about salient features of WTO & Pakistan's agreement with the organization and its consequences that is opportunities, threats and benefit. The paper specifically focuses the impact of WTO on Pakistani pharmaceutical industry.

Michael Porters five forces Model has been applied to scan real situation of domestic pharmaceutical industry. This explains different market forces which affects the pharmaceutical industry. To get the true picture of the pharmaceutical business scenario real industry examples have been discussed in the analysis of the Model. SWOT analysis explains the coming threats to the pharmaceutical industry after non-quota regime that is implementation of WTO in 2005. It also focused on the available opportunities as well.

The analysis part of the paper gives overview of Global & Regional pharmaceutical industry and its impact on the Pakistani pharmaceutical industry. The domestic pharmaceutical industry analysis explores all areas which are related to pharmaceutical industry. It also discusses current industry problems and WTO's impact after its implementation.

The concluding part elaborates the overall result of analysis and recommends certain strategies which will help the Pakistani pharmaceutical industry to cope with WTO regime that has yet to come in near future. The papers also include international recommendations that will greatly help Pakistani pharmaceutical industry in framing policies and boost export.

CHAPTER #1

1.1: INTRODUCTION

Pakistan became the member of the World Trade Organization (WTO) in January 1995, as a result of the Uruguay Round (UR) of trade negotiations (1986-94). The purpose was to extract gains from implementation of the new regime of multilateral trade liberalization like other countries, under the scope of the WTO. Since then, their [3]had been an unparalleled range of debates and deliberations among the intelligentsia of the country about its impacts and applications.

During the 1990s, Pakistan opted for economic liberalization, not as a policy generated indigenously, but largely as an obligation under the conditional ties imposed by the IMF and the World Bank through their Structural Adjustment Program. Presently, Pakistan's trade and investment regimes are fairly liberal due to the continuous liberalization process the country undertook during the 1990s.

However, as is the case for many other developing countries, the implementation process of the WTO involves, significant challenges for the socio-economic development of Pakistan, reason being the overall lack of technical capacity and the accepted lower level of economic development in such countries.

Recent economic research provides powerful evidence that the trade liberalization is associated with increased growth and development, which was proved by the unprecedented global growth, since the 1970s. However, the evidence of positive relationship between trade liberalization and economic growth is not as convincing in the case of a majority of developing countries as it is in the case of developed countries. Pakistan's economic and trade liberalization during the 1990s, though initiated largely under the IMF pressure, has not been fruitful in improving its social and economic

[3] www.wto.org

development; almost all socio-economic indicators were reversed by the end of the 1990s. This particular aspect further intensifies the WTO's implementation-related challenges for Pakistan, as its obligations not only include a further reduction of trade barriers, but also to implement significant reforms both in trade procedures and in many regulatory areas.

The implementation of these agreements involves significant financial costs, raising the question of the future productivity of these expenses and opportunity costs. In addition to the financial cost, the social cost of the implementation in the form of rising unemployment is there (although the impact cannot be calculated precisely in various sectors at this initial stage). Thus it is to be especially noted, since the implementation of WTO agreements would not only affect trade-related sectors of the economy but would have indirect effects on non-trade sectors of the economy.

Using the results of country's liberalization reforms of 1990s as the background, this research paper makes an attempt to focus upon the possible future impact on pharmaceutical industry in Pakistan, with the implementation of the WTO provisions. For the purpose of analysis, the economy has been divided into three major categories i.e. agriculture, industry and services on the basis of their share in the GDP of Pakistan. However, due to the broad spectrum of the subject, the study is restricted to the pharmaceutical sector only.

In doing so, an attempt will be made to address the following questions:

- Do the WTO agreements correctly diagnose the development problems and prescribe appropriate remedies?

- What regulations would be imposed over the pharmaceutical industry of Pakistan under WTO agreements and what steps have been taken to coup with it?

- What are the costs/gains associated in terms of socio-economic development of the country, with the implementation of the WTO agreements?

- Does the implementation of the WTO agreements imply that Pakistan would be able to increase its share in foreign markets and thereby transfer the stated welfare and developmental benefits/gains to the various sectors within its economy? Especially in manufacturing and pharmaceutical sectors?

- A brief study of the agreements related to pharmaceutical and manufacturing.

- Effect of the biased policies in the past years on the foreign direct investment in the manufacturing area and FDI's importance in WTO w.r.t to pharmaceutical sector.

- Overall Concerns of Pakistan on WTO with focus on manufacturing and pharmaceutical sectors.

- The implications of Pakistan's entry to WTO on its trading partner.

Salient Features of the WTO

Location: Geneva, Switzerland
Established: 1 January 1995
Created by: Uruguay Round Negotiations (1986-94)
Membership: 145 countries (As Of 5th February 2003)
Budget: 154 million Swiss Francs for 2004
Secretariat staff: 550
Head: Supachai Panitchpakdi (Director-General)

Principle Functions:

• Administering WTO trade agreements

•Forum for trade negotiations

• Handling trade disputes

• Monitoring national trade policies

• Technical assistance and training for developing countries

• Cooperation with other international organizations.

BRIEF HISTORICAL OUTLOOK

It all started during the 1930's, when the world suffered from the unprecedented Great Depression (Global economic recession) and the World War II, which lure to the creation of many international organizations like the UN. Amid them, a need for some system in order to trade among the nations was greatly felt. So, in order to cope with the 1923 Stock Market crash and WWII, 23 nations of the world sat together in Geneva in 1948, and formulated a General Trade Agreement On Tariff and Trade (GATT). The first round resulted in 45,000 tariff concessions, affecting about 10 billion$; till today , the GATT and WTO have helped to create an affluent strong trading system, contributing to the unexampled growth in the trade , which can be well seen from the fact , that the total trade in2003 was about 23 times that were in 1950.

1.2: STRUCTURE OF WTO

The WTO is a rule-based, member-driven organization_ all decisions are made by the member governments, and the rules are the outcome of negotiations among members. Thus, it is a leading global organization that governs the world trade. There are about 140 members, and 32 observer governments (most of which have applied for the membership). The members represent over 97% of the world trade. Decisions are made by the entire membership, typically by consensus. The WTO continues to apply many of the principles that were originally in the GATT. All WTO members may participate in all councils, committees, etc, except Appellate Body, Dispute Settlement Panels, Textiles Monitoring Body, and Plurilateral Committees.

The main structural body of the WTO is the MINISTERIAL CONFERENCE, which constitutes the trade ministers of all the member countries. It is the WTO's top-decision making body. It plays a pivotal role in the policy making of this organization. It performs its session once in a two year.

The other main body of the WTO is the General Council. It inspects day-to-day operations of the organization. It administers policy making in

- Trade in services
- Trade in goods
- Trade related aspects of intellectual property rights (trade marks, copyrights, and patents).

It is a day-to-day decision-making body meets regularly, normally in Geneva. It constitutes of ambassadors and heads of delegation in Geneva, but sometimes officials sent from members' capitals also participate. It meets several times a year in the Geneva headquarters. The General Council also meets as the Trade Policy Review Body and the Dispute Settlement Body.

At the next level, there is the Goods Council, Services Council and Intellectual Property (TRIPS) Council, which report to the General Council.

Numerous specialized committees, working groups and working parties deal with the individual agreements and other areas such as the environment, development, membership applications and regional trade agreements.

The first Ministerial Conference in Singapore in 1996 added three new working groups to this structure. They deal with the relationship between trade and investment, the interaction between trade and competition policy and transparency in government procurement. At the second Ministerial Conference in Geneva, in 1998, ministers decided that the WTO would also study the area of electronic commerce, a task to be shared out among existing councils and committees.

1.3: MAIN OBJECTIVES OF WTO

The prime objective of WTO is to create a liberal and free trading system, under which business enterprises from respective member countries can trade with one another in an even-handed and undisclosed competitive system, with an agenda of:

- Optimal utilization of world resources,
- Enhancing the standard of living of the developing nations,
- Guarantee ample and steady growth volume of the real income and ensure full employment,
- Expansion in the production and exchange of goods.

Thus, the absolute goal of the WTO can be categorized, as to help the producers of goods and services, exporters and importers conduct their business in a particular formal manner. And the objectivity of the goal is enhanced by the fact that the application of the GATT rules led to a total trade growth of about 23 times, as to that of 1950.

1.4: BASIC TRADING PRINCIPLES OF WTO

The WTO constitutes a coherent and democratic working structure and a number of laudable principles:

a) Domestic Industry Protection

- GATT obligates the member countries to protect their domestic industry through tariffs only.

- WTO prohibits the use of quantitative restrictions, except in restricted number of cases.

"In sectors where specific commitments are undertaken, each member shall ensure that all measures of general application affecting trade in services are administered in a reasonable, objective and impartial manner."{Article VI; Part II; GATS: Uruguay Round Agreement}

b) Bidding of Tariffs

- The member countries are influenced to abandon protection to their domestic industry /manufacturing, through reduced tariffs and removing other barriers, to trade in multilateral trade negotiations.

- The reduced tariffs are constrained against further increases by listing them in each country's national schedules. And the schedules are an integral part of the GATT legal system.

"Members recognize that, in certain circumstances, subsidies may have distortive effects on trade in services. Members hall enter into negotiations with a view to developing the necessary multilateral disciplines to avoid such trade-distortive effects." {ArticleXV; PartII; GATS: Uruguay Round Agreement}

c) National Treatment Rule

- It forbids the member countries from discriminating between the imported products and domestically manufactured goods, in the matter of internal taxes and in the application of internal regulations.

"A member shall not accord recognition in a manner, which would constitute a means of discrimination between countries in the application of its standards or criteria for the authorization, licensing or certification of services suppliers, or a disguised restriction on trade in services."{ArticleVII; PartII; GATS: Uruguay Round Agreement.}

d)Most Favorite Nation Treatment:

This rule lays down the principles of non-discrimination among the member countries:

- ❖ Tariff and other regulations should be applied to imported or exported goods without discriminating among the countries.

- ❖ Exception to the rules i.e. regional arrangements subjected to preferential or duty free trade agreements, General System of Preferences (GSP), where developed countries apply preferential or duty free rates to imports from the developing countries.

"With respect to any measure covered by this agreement, each Member shall accord immediately and unconditionally to services and service suppliers of any other Member treatment no less favorable than that it accords to like services and service suppliers of any other country."{ArticleII; PartII; GATS: Uruguay Round Agreement}

Trade Rounds of Negotiations
In pursuance of the objective of expansion and liberalization of trade, series of multinational negotiations (so far eight) known as "trade rounds" were undertaken since 1947. The earlier rounds were focused on reduction of tariffs but the later ones were more comprehensive encompassing non-tariff barriers and other areas as well.
[4]

GATT Trade Rounds

Year	lace Name	Subject Covered	Participating Countries
1947	Geneva	Tariffs	23
1949	Annecy	Tariffs	13
1951	Torguay	Tariffs	38

[4] www.wto.org

1956	Geneva	Tariffs	26
1960-61	Geneva(Dillon Round)	Tariffs	26
1964-67	Geneva (Kennedy Round)	Tariffs and anti-dumping	62
1973-79	Geneva (Tokyo Round)	Tariffs non-Tariffs, treatment agreement	102
1986-1994	Geneva (Uruguay) 8th Round	Tariffs non tariffs rules, services, intellectual property, dispute settlement textile, creation of WTO etc.	123
2001-2005	Geneva (Doha Development Agenda)	Intellectual property continuation of ongoing work service, market access trade and environment	184

Source: WTO www.wto.org

1.5: WTO AGREEMENTS

Practically the agreements of WTO constitute of about 60 complex agreements, decisions and understandings. But for simplicity the agreements are classified into three broad categories.

I. Firstly, the agreements for Goods and services in the form of GATT and GATS, which now also include TRIPS, the agreement for intellectual property.

II. Second are some extra agreements and annexes dealing with the special prerequisites of specific sectors or issues.

III. Third type of the agreements constitutes of broad and lengthy agreements by specific countries.

The WTO rules& agreements are the results of the negotiations among the members. The current set of regulations was the outcome of the 1986-94 Uruguay Round negotiations, which included a major revision of the General Agreement on Trade and Tariff (GATT).

GATT is now the WTO's principle rulebook for trade in goods. The Uruguay Round also created some new regulations pertaining to the trade in services, relevant aspects of intellectual property, dispute settlement and the policy reviews. The complete set runs to some 30,000 pages consisting of about 30 agreements and separate commitments (called schedules) made by individual members in specific areas such as lower custom rates and services, market –opening etc.

1.6 WTO OPERATING SYSTEM

The WTO members operate in a non-discriminatory trading system that spells out their rights and their obligations, with the help of agreements. Each country receives guarantee that its exports will be treated fairly and consistently in other country's market. The system also gives developing countries some flexibility in implementing their commitments.

1.6.1: GOODS

It all started with trade in goods. From 1947 to1994, GATT was the forum for negotiating lower customs duty rates and other trade barriers; the text of General Agreement indicated important rules, particularly non-discrimination. Since 1995, the updated GATT has become the WTO's umbrella agreement for trade in goods. It has annexes dealing with specific sectors such as agriculture and textiles, and with specific issues such as state trading, product standards, subsidies and actions taken against dumping.

1.6.2: INTELLECTUAL PROPERTY

The WTO's intellectual property agreement signifies the rules for trade and investment in ideas and creativity. The rules state how copyrights, trademarks, geographical names used to identify products, industrial designs, integrated circuit layout-designs and undisclosed information such as trade secrets" intellectual property" should be protected when trade is involved.

1.6.3: SERVICES

Banks, insurance firms, telecommunications companies, tour operators, hotel chains and transport companies looking to do business overseas can now enjoy the same principles of freer and fairer trade that originally only applied to trade in goods. These principles appear in the new General Agreement on Trade in Services (GATS). WTO members have also made individual commitments under GATS, stating which of their services sectors they are willing to open to foreign competition, and how liberal those markets are.

1.6.4: DISPUTE SETTLEMENT

The WTO's procedure for resolving trade quarrels under the Dispute Settlement Understanding is vital for enforcing the rules and therefore for ensuring that trade flows smoothly. Countries bring disputes to the WTO, if they think their rights under the agreements are being violated. Judgments by specially appointed independent experts are based on interpretations of the agreements and individual countries' commitments. The system encourages countries to settle their differences through consultation. Failing that, they can follow a carefully mapped out, stage-by- stage procedure that includes the possibility of a ruling by a panel of experts, and the chance to appeal the ruling on legal grounds. Confidence in the system is borne out by the number of cases brought to the WTO 267 cases by March 2003 compared to some 300 disputes dealt with during the entire life of GATT (1947–94).

1.6.5: POLICY REVIEW

The Trade Policy Review Mechanism's purpose is to improve transparency, to create a greater understanding of the policies that countries are adopting, and to assess their impact. Many members also see the reviews as constructive feedback on their policies.
All WTO members must undergo periodic scrutiny, each review containing reports by the country concerned and the WTO Secretariat. Over 54 members have been reviewed since the WTO came into force.

1.7.1: MAJOR AGREEMENTS OF THE ROUND.

The Uruguay round of multilateral trade negotiation launched in 1986 covered a wide range of subjects, which went even beyond the traditional field of trade in goods covered by the GATT. These negotiations continued for over seven and a half years and culminated in a number of agreements in Marrakesh in 1994. These agreements are known as the final act embodying the results of the Uruguay Round of multilateral trade negotiations. The agreements include

I) Agreement establishing the Multilateral Organization (WTO).
II) Agreements on Trade in Goods, including:
a) General Agreement on Tariffs and Trade 1994 (i.e. GATT 1947 and understandings on interpretation of some of its articles agreed in Uruguay Round.
b) Uruguay Round Protocol GATT 1994 (relating to the agreed schedules of tariff reductions)
c) Agreement on Agriculture
d) Agreement on Sanitary and Phytosanitary (SPS) Measures.
e) Agreement on Textiles and Clothing
f) Agreements on Technical Barriers, Investment Measures, etc.

III) General Agreement on Trade in Services (GATS)
IV) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs).

1.7.2: THE TEN BENEFITS OF WTO

The following are defined as the most outstanding benefits, which the countries would be enjoying after joining WTO with its true spirit:

1) The system helps to promote peace.
2) Disputes are handled constructively.
3) Rules make life easier for all.
4) Free trade cuts the cost of living.
5) It provides more choice of products and qualities.
6) Trade raises incomes.
7) Trade stimulates economic growth.
8) The basic principles make life more efficient.
9) Governments are shielded from lobbying.
10) The system encourages good governance.

1.8: THE DOHA DEVELOPMENT AGENDA

The WTO Ministerial Conference has met for four times since 1995. The Conference at its last session held in Doha in November 2001 agreed on launching the new round of trade negotiations to be concluded not later than I January 2005. A Trade Negotiation Committee supervises the overall conduct of negotiations. The next Ministerial Conference scheduled in Mexico in November 2003 will review the progress of negotiations. When the results of the negotiations in all areas are established a special session of the Ministerial Conference will be held to take decisions regarding the adoption and implementation of the results.

Areas of Doha Round

The negotiations will cover:

1. Implementation related issues and concerns: (i.e. implementation of WTO Agreements)

2. Agriculture: Negotiations already initiated in early 2000 under Agreement on Agriculture will be integral part of the new Round. The aim is substantial improvement in market access reduction/phasing out all sorts of subsidies.

3. Services: Work already initiated in special session of the Council on Trade in services: Participants are required to submit initial requests for specific commitments by 30 June, 2002 and offers by 31 March 2003.

4. Market Access for non-Agricultural Products: Negotiations shall aim at reduction/elimination of tariff peaks, high tariffs and tariff escalations as well as non-tariff barriers in particular on products of export interest to developing countries.

5. TRIPS: Continuation of ongoing work in pursuance of TRIPS Agreement. A separate declaration on TRIPS and public health was adopted agreeing that TRIPS Agreement does not prevent members from taking measures to protect public health.

6. Relation between Trade and Investment: Negotiations will be initiated after the fifth session of the Ministerial Conference in 2003. In the meanwhile the work will focus on clarification of issues.

7. Interaction between Trade and Competition Policy: Negotiations will be initiated after the fifth session of the Ministerial Conference in 2003 on the basis of a decision to be taken in that Conference.

8. Transparency in Government Pronouncement: Negotiations will be initiated after the fifth session of the Ministerial Conference.

9. Trade Facilitation: Negotiations will be initiated after the fifth session of the Ministerial conference on the basis of decision on modalities of negotiations to be taken at that Session.

10. WTO Rules: Negotiations will aim at improving disciplines under Agreements on Implementation of Article VI (relating to anti-dumping) and on Subsidies and counter-veiling measures.

11. Dispute Settlement Understanding: Negotiations will aim at improvement and clarification of the Dispute settlement understanding.

12. Trade and Environment: Continuation of the ongoing work of the Committee on Trade and Environment, which is also mandated to suggest future action, including desirability of negotiations.

The Conference also took decisions in respect of other issues like continuation of work on electronic commerce, small economies, trade, debt and finance, trade and transfer of technology, technical cooperation and capacity building of developing countries, and special and differential treatment to developing countries.
[5]

[5] Source: www.wto.org

CHAPTER # 2

PAKISTAN & WTO

2.1: DEVELOPMENT AND TRADE

Over three-quarters of WTO members are developing or least-developed countries. Special provisions for these members are included in all the WTO agreements. They include longer time periods for implementing agreements and commitments, measures to increase trading opportunities for these countries, provisions requiring all WTO members to safeguard the trade interests of developing countries, and support to help developing countries build the infrastructure for WTO work, handle disputes, and implement technical standards. In 1997, a high-level meeting on trade initiatives and technical assistance for least-developed countries brought their concerns to centre stage. The meeting involved six intergovernmental agencies and resulted in an "integrated framework" to help least-developed countries increase their ability to trade, and some additional preferential market access agreements. A committee on trade and development, assisted by a sub-committee on least-developed countries, examines the developing countries' special needs. Its responsibility includes implementation of the agreements, technical cooperation, and the increased participation of developing countries in the global trading system

The WTO organizes around 100 technical cooperation missions to developing countries annually. It holds on average three trade policy courses each year in Geneva for government officials. Regional seminars are held regularly in all regions of the world with a special emphasis on African countries. Training courses are also organized in Geneva for officials from countries in transition from central planning to market economies. In 1997/98, the WTO set up reference centers in over 40 trade ministries in capitals of least-developed countries, providing computers and Internet

access to enable ministry officials to keep abreast of events in the WTO in Geneva through online access to the WTO's immense database of official documents and other material.

The developing countries now form a majority of WTO members. However, it is clear that not all developing countries are in an equal position to benefit from the trade liberalization process promoted by WTO. There is a growing sense among nations, that they are not getting equal benefits from the multilateral trading system. As a consequence, the multilateral system may loose essential support, and together with trend in developing countries, this may led to revert to a new era of protectionism.

As regards the developing countries, two principles should be adhered to:

a) Ensure that they do not lose from the trade liberalization, and

b) That they eventually gain from it.

The developing countries joined the WTO in the expectation of certain benefits. Broadly speaking, the benefits that were being envisaged by the developing countries included increased market access for their goods and services, plus the phased integration of their economies into the global economy, in a manner that their domestic production base was strengthened and not overwhelmed by more powerful competitors. Are these, eminently reasonable, expectations being met? An objectionable analysis does not give reason for much cheer.

WTO is under fire from all sides, North and South. WTO is not a conspiracy of industrialized/developed countries as some in developing countries perceive. Demonstrations in the Seattle during WTO Ministerial Conference in 1999 proved that the people of the North are also afraid of the trade with developing countries. They think that WTO opens their markets to low-wage products and their high skilled jobs are threatened. On the other hand we feel that our industries are exposed to very severe competition and our

enterprises will go down. So WTO is neither a conspiracy of developed nor that of developing countries.

2.2: CONCERNS OF DEVELOPING COUNTRIES INCLUDING PAKISTAN

2.2.1: MINIMAL TECHNICAL ASSISTANCE

The commitments in the Uruguay Round Agreements regarding technical (and even financial assistance, e.g. as provided for in Article 67 of the TRIPS Agreement) have not been implemented to the required extent. This could partly be due to the fact that unlike obligations in other areas, which are precisely worded, the obligations to assist developing countries are couched in general terms.

2.2.2: PERSISTENCE OF TARIFF BARRIERS

A major benefit of the Uruguay Round Agreements was supposed to be a significant increase in market access through the lowering of tariff barriers. The results of the URA belie this expectation. There is:

(i) An absence of tariff reductions on 22% of dutiable imports which include products of particular interest to the developing countries, such as items in the leather, rubber, footwear, and travel goods category.

(ii) A relatively high degree of tariff escalation in most product groups, again particularly those of export interest to developing countries, including tropical and natural resource based products.

(iii) A persistence of peak tariff on sensitive products such as textiles, leather, footwear and fish products.

2.2.3: EMERGENCE OF NEW BARRIERS

There is a danger that social and environmental concerns could be used for protectionist purposes, thereby damaging the multi-lateral trade régime. In addition, possible new barriers for many developing countries may emerge due to certain operations of the regional trading arrangements.

2.2.4: EROSION OF PREFERENTIAL ARRANGEMENTS

In the post Uruguay Round period, there has been an unfortunate weakening of schemes that favored the developing countries, notably the GSP scheme.

2.2.5:IMMEDIATE/IMMINENT LOSSES DUE TO IMPLEMENTATION OF URAS

Certain losses due to implementation of the Uruguay Round Agreements are undeniable, e.g. those faced by the food importing countries. There are other losses that can be easily anticipated, for example those, resulting from the implementation of the TRIPS Agreement. Studies show that the prices of the pharmaceutical products will register a rise, and developing countries will also have to pay increased prices for high technologies products as a result of stronger patent protection.

2.2.6: EXCESSIVE ADMINISTRATIVE REQUIREMENTS

The notification and legislation requirements of the URAs impose massive demands on the administrative as well as on the financial capacities of the developing countries, e.g. Bangladesh would have to incur recurring cost of $750,000 per annum for the implementation of TRIPS Agreement alone.

This is in addition to, of course, to the initial costs of establishing judicial, administrative and enforcement frameworks, including the setting up of customs and border control machinery.

2.2.7: SENSE OF EXCLUSION

There is a growing sense of non-participation, among developing countries, from, negotiations on important issues. This was seen at Singapore especially in regard to the negotiations on ITA. There is an apprehension that this mode of negotiations may be repeated in other critical areas, e.g. investment.

On the whole it can be said that WTO has two major effects on Pakistan. It has necessitated changes in existing laws or promulgation of new national laws. These include antidumping, countervailing, safeguards, copyright, patent laws. The second is reduction in custom duties and binding of tariffs

Further, it can be concluded that WTO is working to remove trade barriers, prevent discrimination among participants in the world trading system, and resolve specific trade disputes. As the volume of international trade increases, both in absolute terms and as well as a percentage of total production, the role of WTO will continue to grow.

2.3: Pakistan's Apprehensions over Trade Negotiations

Pakistan joined with the governments of the developing countries from Latin-America, Asia, and Africa in endorsing a broad proposal aimed at improving the positions of the poor countries, vis-à-vis rich ones, in the WTO. Separate provisions would tighten the restriction on anti-dumping rules, allow developing countries flexibility in retaining export subsidies for the purpose of "industrialization and diversification," and loosen the intellectual property commitments of the Uruguay Round.

In a separate proposal submitted to the WTO with the Caribbean and Central American developing governments, Pakistan called for special provisions to

be made for food-importing, developing countries, which face the gravest economic disadvantages and social dangers. The proposal establishes the right of the developing countries to consider non-trade factors when creating domestic agricultural policy; factors such as food security and employment levels. At the same time, this joint proposal calls for operating special market access for their exports. In essence, Pakistan and its allies accept the argument commonly made by the EU and Japan that agriculture has social consequences justifying special considerations. However, they argue that, therefore international trade rules should be made to favor poor countries, where the externalities of the rural demise are worst.

In its own communication to the WTO, Pakistan displays a particular displeasure with what it sees as unfair advantages enjoyed by the developed countries. Pakistan has whipped out as what it sees as inadequate efforts by the EU and the USA to liberalize their textile industries. In addition, Pakistan has submitted a detailed proposal to modify the dispute settlement rules, with most provisions geared toward improving developing countries' access to dispute settlement process and reducing the dispute settlement panel's ability to enforce social regulations such as environmental standards.

Within our own borders, Pakistan has had some difficulties in implementing policies that liberalize trade. Foreign investors are frustrated with the endless and sometimes contradictory policies and the government's uneven record when it comes to complying with agreements with foreign investors. Beyond investment concerns, there is a general lack of transparency in government decisions. Many of these problems are due to the fact that Pakistan has largely been preoccupied with carrying out the IMF reform program of OCT 1997, which requires Pakistan to reduce its external current accounts deficit, raise its annual GDP growth rate, and reduce inflation.

2.4: BRIEF OUTLOOK OF TBT AGREEMENT W.R.T PAKISTAN

The agreement on Technical Barriers to Trade (TBT Agreement) aims to ensure that WTO members do not use domestic regulations, standards, and testing and certification procedures to create unnecessary obstacles to trade. The TBT Agreement was designed to prevent arbitrary standards from being used to protect domestic industries from foreign competition.. It encourages countries to use international standards where appropriate. Such harmonization of standards is expected to facilitate trade by reducing the variety of different, sometime incompatible, standards that producers must comply with to gain access to different markets. This would be specifically beneficial to countries, like Pakistan. The TBT Agreement covers a wide range of domestic measures including many taken to protect the environment .It divides these measures into two categories: "technical regulations" and "standards".

Technical regulations are laws requiring mandatory compliance, including regulations regarding product specifications, labeling, packaging and other "technical" issues, as well as mandatory GMO labeling. Standards, by contrast, are non-binding rules, and may include voluntary labeling schemes. The TBT Agreement includes obligations relating to the preparation, adoption, and application of technical regulations and standards, and the procedures for assessing whether the product conform to these regulations and standards. Many of these obligations are set out in a Code of Good Conduct that may apply to private, non-governmental bodies.

The TBT agreement commits WTO members to two main obligations:

a) The Non- discrimination obligation: and,
b) The obligation to ensure that measures are" not more trade restrictive than necessary"

The TBT "non-discrimination" obligation Article2.1 states:

"Members shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favorable than that accorded to like products of national origin and to like products originating in any country."

{**Source**: The Consumer Choice Council, "An Activist's Handbook On Genetically Modified Organisms And WTO", By Mathew Stillwell and Brennen Van Dyke.

Center for International Environmental Law, July 1999.}

In the context of above rules during Multi Trade Negotiations under the Uruguay Round of Talks (1984), Pakistan received requests from the following countries for reduction/ binding in tariff rates:

Sr. No.	Country	Product	No. of Items
1.	Canada	Iron ore, tallow, wood pulp and paper products, coal, wheat, wool, zinc and zinc alloys.	794
2.	Australia	Agricultural products, casein, caseinates, hides and skins, iron ore, tallow, wood pulp and paper products, coal, wheat, wool.	189
3.	USA	Cigarettes, non-alcoholic beverages, medicaments, rubber and steel, iron ore, tallow, wood pulp and paper products, coal, wheat, wool.	30
4.	EC	Pharmaceutical products and machinery etc.	25
5.	Switzerland	Chemicals, textiles machinery and watches, trucks, vehicles for transport of goods.	20
6.	New Zealand	Agricultural products, casein, hides and skins, iron ore, tallow, wood pulp and paper products, coal wheat, wool.	17
7.	Japan	Machinery and equipment and other miscellaneous goods.	257
8.	Korea	Footwear and other miscellaneous goods.	98
9.	Sweden	Agricultural Machinery	50

	Total		1390

Further, Pakistan bound about 25% of its Tariff Lines. Sector wise bindings are given below:

Sr. No.	Sector	Reduction in Tariffs / Bindings	Current/Applied Tariff (2002-03)
i.	Agriculture	100%	25%
ii.	Textile	20% – 50%	25%
iii.	Pharmaceutical	50%	25%

The Reduction / Binding of Tariffs in 1992-93 were based on:

- Protection levels required by various industrial sectors of Pakistan
- Improved cascaded tariff structure
- Review of Para tariffs and their phasing out
- Gradual withdrawal of tariff concessions/exemptions and translation of concessionary tariff regime to statutory tariff regime
- Tariffication of non-tariff barriers except those which were applied on account of religion, security and health
- Pakistan's commitments to IMF, World Bank, Asian Development Bank
- Preferential tariff rates under GATT Protocol relating to the trade negotiations among developing countries
- Existing GATT bindings in respect of certain commodities.

Pakistan needs to draw up a strategy to make use of the forth coming market accesses negotiations under the new round of talks as decided in the Ministerial Conference held in Doha (2001). Some suggestions are set out below:

- Take into account the obligations under the GATT / WTO Rules and assess the current position of tariffs.
- Review the existing bindings and assess the possibilities of reducing the bound levels to the proposed levels given below:

Sr. No.	Sector	Reduction in Tariffs / Bindings	Current/Applied Tariff	Proposed Levels
i.	Agriculture	100%	25%	75%
ii.	Textile	20% – 50%	25%	50%
iii.	Pharmaceutical	50%	25%	50%

- Develop the following two lists:

  i. Export interest list consisting of fifty major items of exports from Pakistan.

  ii. Import interest list consisting of fifty major items of imports to Pakistan.

- Identify twenty major trading partners each in respect of exports as well as imports.

- Classify items of the abovementioned two lists in terms of:

  a. Textiles and clothing
  b. Agriculture
  c. Pharmaceutical

- Identify country-wise, the tariffs and non-tariff measures which hinder our market access both in terms of exports as well as imports

- Proceeds

a. Address requests from individual countries; and
b. Formulate our counter-requests.

2.5: BRIEF OVERVIEW OF MAJOR ECONOMIC ISSUES OF PAKISTAN

In recent years Pakistan has faced severe macro-economic imbalances, declining economic growth, rising poverty, and poor social indicators. Crisis management of public finances and external balances, dominated the economic policy agenda in Pakistan during the 1990's.However, despite all efforts, and three international Monterey Fund (IMF) programs between 1988 and1999, little progress was made in addressing the macroeconomic imbalances. The result was decade of stop-go stabilization policies, with the attendant negative impact on growth, but without the desired improvement of macro economic fundamentals.

Table 2.1: Growth Rates Of Various Sectors Of Pakistan (percent)

Item	1980s	1998-99	1999-00	2000-01	2002-03	2004-05
REAL GDP (At cost factor)	6.5	3.5	4.2	3.9	2.6	5.1
Agriculture	5.4	4.5	2.0	6.1	-2.5	3.8
pharmaceutical	8.2	6.1	4.9	-0.1	4.2	8.7(LSM)
Services	6.7	1.6	5.0	4.8	4.4	5.2

Source: Economic Survey 2003-04, Economic Advisor's Wing, Finance Division, GoP 2004

2.5.1: POPULATION, EMPLOYMENT AND POVERTY

The population growth is estimated to be 2.3 percent and total population at 160 million in 2003. The urban population, according to 1998 census, is 33.4 percent of the whole but this is generally assumed to be underestimated. A large number of areas, urban in nature but not in the purview of any municipality or corporation are excluded from the urban population.

Pakistan's labor force is growing at a rate of 2.5 %. With the declining rate of economic growth, except this year, the capacity to generate employment has also fallen. With an economic elasticity of around 0.4, the growth in productive jobs during the last three years may have been no more than 1.4 percent per year. As a result, 1.5 million pupils may have been added to the ranks of unemployment. The unemployed rate in the 1998-99 was already around 6%, and this did not take into account the very large number of workers who were not fully occupied. Unemployment in the urban areas was higher (8%), and, while gender –desegregated data is not available, some surveys show that unemployment rate is higher among females than, males.

Falling growth rates, accompanied by rising income inequality and increasing unemployment, have resulted in increasing poverty during the 1990s

Since 1998-99, economic growth has slowed further, the fiscal squeeze has intensified, development spending has declined, and the country has experienced a severe drought; therefore, the incidence of poverty in Pakistan today is likely to be significantly higher than it was in 1998-99.

CHAPTER # 3

PAKISTAN AND WTO/ GATT

3.1: INTRODUCTION

Pakistan was one of the twenty-three founders of the GATT. It actively participated in GATT forums since its inception in 1947. It has been involved in the Uruguay Round that resulted in the creation of the WTO and conclusion of the final Act of WTO in 1994. Pakistan had closely collaborated with other developing countries, in particular on matters relating to export of textiles and clothing.

It is of interest to know that one of the initial disputes taken up by GATT related to Pakistan and India. After independence in 1947, Pakistani and Indian rupees were at par and mutually freely convertible. In September 1949, Indian rupee was devalued against US Dollar by 19% in line with pound starting. Pakistan however maintained the parity of its rupee. Consequently exchange rate of Pak and Indian rupees changed. India refused to accept the new rate, suspended trade relations, and lodged a complaint with GATT that Pakistan was discriminating against it. India lost the case as being a sovereign state, Pakistan had the right to fix its own exchange rate.

Pakistan's position in respect of selected areas is discussed in the following section:

3.2: MARKET ACCESS FOR NON-AGRICULTURAL PRODUCTS:

Predictability and reciprocity are among the basic principles of WTO/ GATT. Another principle is that only tariff be used for regulating imports (non-tariff barriers should be discouraged). Each member is required to have a schedule of concessions in identifying the products and import charges thereon and the member is bound not to increase duties beyond the indicated levels. These concessions are based on the principle of reciprocity i.e. each contracting party has given this commitment to others. There are

however exceptions and conditions for relaxation of these principles (temporary waivers on account of acute balance of payments situation, etc. The National schedule of concessions agreed in GATT 1947 has been revised in successive rounds of trade negotiations by enlarging the list of products and reducing the bound rate of duties.

Pakistan had a national list of concessions on about 150 products agreed in mid-fifties. However, over time the actual rate of duties in respect of many products had exceeded the bound rate. We used to obtain waiver from GATT Council being a less developed country facing acute balance of payments situation. Quantitative and other non-tariff restrictions on imports in the past were also justified on this ground.

Negotiations were held under the Uruguay Round on providing greater market access by eliminating or reducing tariffs and non-tariff measures on trade in goods. The national market access schedules agreed in pursuance of Uruguay round represent commitments not to increase tariffs above the lists (bound) rate. For developed countries the bound rates are generally the rates actually charged. Most developing countries have bound the rates somewhat higher than the actual rates charged, so the bound rates serve as ceilings. In addition to commitment on binding the rates there is also commitment to cut the rates. Developed countries tariff cuts have been phased out for most part in over five years from January 1995. This will result in 40% reduction in tariffs on industrial products from an average of 6.3% to 3.8%. The developed countries also increased the number of products whose tariffs are bound from 78% of product lines to 99%. The developing countries have increased the number from 21% to 73%.

Pakistan has bound about 25 percent of the tariff lines under the Uruguay Round. The bound rates range from 100 to 20 percent as shown below:

Sector	Reduction/binding	Current/Applied Tariff (2003-04)
Agriculture	100%	25%
Textile	20-50%	25%
Pharmaceutical	50%	25%

The bound rates are higher than the prevailing actual rates. The bound rates reflect the ceilings and provide for upward revision of rates if need arise.

The subject of market access for non-agriculture products has been included in the new round of trade negotiations agreed at Doha in 2001. The negotiations aim at reducing or eliminating tariffs, including tariff peaks, high tariffs and tariff escalations as well as non-tariff barriers, in particular on products of export interest to developing countries. The negotiations will take into account the special needs and interests of developing countries, including less than full reciprocity in reduction commitments.

The new round is vital for Pakistan. We will be required to expand the number of bound rate products as well as reduce the rates. As far our exports are concerned, the main areas of interests are the tariff peaks and tariff escalations on products of our export interest (like rice, fruits, textile and clothing, footwear and leather goods) in developed countries. The tariffs on those products are much high than average.

Detailed study should be undertaken, in consultation will all stakeholders on:

i) Pakistan's tariff binding under Uruguay Round
ii) Market access provided to Pakistan in major trading partners.
iii) Barriers to Pakistani exports maintained by major trading partners after Uruguay Round (like tariff peaks, tariff escalation, non tariff measures)

A strategy for negotiations on market access for agricultural and non-agricultural products should be initiated in consultation with stake hands.

3.3: TRADE IN SERVICES SECTORS

3.3.1: INTRODUCTION

Trade in services was excluded from GATT 1947, though it was one of the areas included in the Havana charter of ITO adopted in 1948.

Issues relating trade in services were however included in the Uruguay Round (1986-94). Intensive negotiation in the Round led to the conclusion of the General Agreement on Trade in Services (GATS) in Marakesh in 1994. The Agreement provides a framework for the conduct of trade in services and a basis for future liberalization of such trade.

Services sector occupies a crucial position in the global and national economies. It is an expanding sector with significant contribution in output, employment and trade. The share of service sector in the output of developed countries is estimated at 61 percent and that of developing countries at 47%. It accounts for 60-66% of employment in advanced countries and 20-30% in developing countries. International transactions in services are almost equal to half of the value of merchandise trade and are growing at faster rate than trade in goods. Technology and communication based services are expanding rapidly providing efficient and quality services.

3.3.2: MAIN FEATURES OF GATS

The General Agreement on Trade in Services is based on three pillars, namely, a) Articles of Agreements, b) Sectoral annexes, and (c) schedules of commitments of members.

Sectors Covered Under GATS

The following twelve sectors are covered under GATS

- Business services (professional services, IT related services, research & development)
- Communication services (post, telecommunication, audiovisual, radio, TV, and other)
- Construction and related engineering services
- Distribution services. (commission agent, wholesale, retail trading)
- Education services
- Environment services (sewerage, refuse disposal)
- Financial services (banking, insurance, securities)
- Health and related social services
- Tourism and travel related services (Hotel, travel, tourist guide)
- Recreational and cultural services (Entertainment, news agency, sports services)
- Transport services (shipping passenger, freight)
- Other services (Not elsewhere in included)
  WTO has further divided them into 155 sub-sectors.

3.3.3: OBLIGATIONS AND COMMITMENTS UNDER GATS

- General obligations: The members are obligated to extend most-favoured nation (MFN) treatment to services of other members, under Article II. However under Annex on Article II a member can seek exemption of some services from this obligation. These exemptions are time bound and subject to review.

- Specific commitments: The members are required to make horizontal and sector specific commitments in respect of:
  - Market access (treatment no less favourable than other foreign suppliers)
  - National treatment (treatment no less favourabe than domestic services/providers)
  - Additional commitments (beyond GATS provisions)

3.3.4: MODES OF SUPPLY

The agreement covers the following modes of supply of services.

Cross-border supply: from territory of one member into another (e.g. telecommunications)

Movement of Consumers: in the territory of one member to the service consumer of any other member (e.g. tourism)

Commercial presence: by a service provider of one member through commercial presence in the territory of any other member (e.g. bank branches, agency)

Presence of natural persons: By a service provider of one member, through presence of natural persons of a member in the territory of any other member (e.g. temporary stay of foreign workers)

Progressive liberalization in services: The agreement provides for successive round of negotiations for further liberalization of trade in services. These negotiations have started in 2000 in the special session of the Council on Trade in Services. The Council has laid down the guidelines for negotiations and is receiving proposals from members.

3.4: PAKISTAN AND GATS

3.4.1: SERVICES SECTOR IN PAKISTAN ECONOMY

The position of services sector in the economy is highlighted below:

	(Latest data)
Service share (%) in GDP:	50%
Employment:	34%
Invisible receipts as % of exports	16%
Invisible payments as % of imports	45%
Private unrequited transfer ($ million)	3867
(Workers remittances) ($ Million)	1087

3.4.2: PAKISTAN'S APPROACH:

Initially Pakistan was not in favor of inclusion of services sector under GATT. However it participated in Uruguay Round and signed the Agreement on Trade in Services.

3.4.3: PAKISTAN'S OBLIGATIONS /COMMITMENTS

Pakistan has assumed the general obligation of extending MFN treatment to services of other members. It has however, sought article II exemptions on

- Banking and financial services
- Telecommunication services

Pakistan has also made specific commitments on 6 sectors relating to market access and national treatment:

1. Business services (11 sub-sectors)
2. Communication services (1 sub-sector)
3. Construction and related engineering services (2 sub-sectors)
4. Financial services (2 sub-sectors)
5. Health and related social services
6. Tourism and travel

3.5: WTO AGREEMENT ON TRADE RELATED ASPECTS OF INVESTMENT MEASURES (TRIMS)

3.5.1: INTRODUCTION

It has been observed that some measures relating to investment have distorting effect on international trade. Recognizing the need to address this situation, an Agreement on Trade Related Aspects of Investment Measures was concluded as part of Uruguay Round of Trade Negotiations in 1994.

3.5.2: CONTENTS OF AGREEMENT

The Agreement provides that no member country shall apply any TRIMS inconsistent with Article III (national treatment) and Article XI (prohibition of quantitative restrictions) of the GATT. To this end, an illustrative list of TRIMS agreed to be inconsistent with these articles is appended to the Agreement. The list includes measures which require particular levels of local procurement by an enterprise (local content requirement) or which restrict the volume or value of import such an enterprise can purchase or use to an amount related to the level of products it exports (trade balancing requirement).

The Agreement requires mandatory notification of all non-conforming TRIMS and their elimination within two years for developed countries, within five years for developing countries and within seven years for least developed countries. The Agreement also provides for setting up a TRIMS Committee in WTO.

A Working Group on Trade and Investment has also been set up at the WTO Ministerial Conference in Singapore in 1996.

3.5.3: PAKISTAN AND TRIMS

Pakistan has notified to WTO about its TRIMS, which relate to Policy of Indiginization of industry (liberal concessional import facility for industries using local raw material like automobile, pharmaceutical and electronics) and trade balancing requirements. As a developing country Pakistan is required to eliminate these conditions within five years. It is understood that Pakistan has asked for extension of the period.
[6]

[6] www.wto.org
the economist
Daily DAWN

Research Methodology

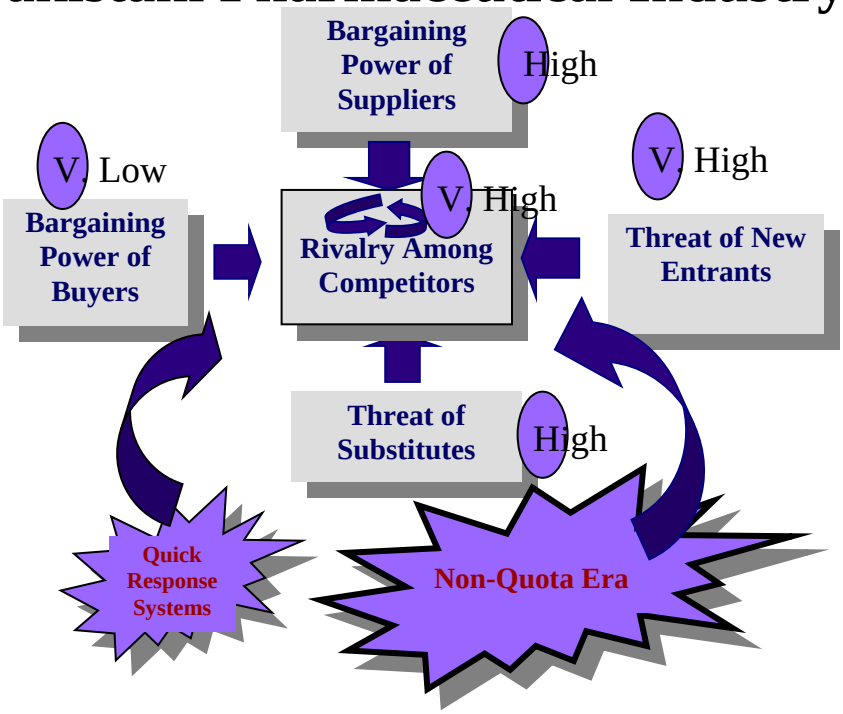
To conduct the research following research methodology has been adopted:

- Internet Search.
- Periodicals like Economist.
- Newspapers.
- Personal meetings with the Management of pharmaceutical companies.
- W T O, websites

CHAPTER # 4

LITERATURE REVIEW

Application of Micheal Porter's Five Forces Model To the Pakistani Pharmaceutical Industry



ANALYSIS OF PHARMACEUTICAL INDUSTRY

RIVALRY AMONG COMPETING FIRMS

Rivalry among firms is usually the most powerful of the five competitive forces. The strategies pursued by one firm can be successful only to the extent that they provide competitive advantage over the strategies pursued by the rival firms. Changes in strategy by one firm may be met with retaliatory countermoves, such as lowering prices, enhancing quality & increasing sales promotion (sales push).
The intensity of rivalry among competing firms tends to increase the number of competitors increases, as competitors become more equal in size and capability, as demand for the industry's product declines and as price cutting becomes common.
Rivalry also increases when consumers switch brands easily. As rivalry among competing firms intensifies, industry profits decline.

EXAMPLES FROM THE INDUSTRY
i) In Pakistan the pharmaceuticals MNCs like Pfizer, GSK etc use the sales push strategy by using different strategies serving doctors to prescribe medicines.

ii) Another example from Pakistani pharmaceutical industry is lowering prices of different medicines for the same disease e.g. Angirex (B) of GSK and Amuex of AMSONS pharma are the same prescribe medicines for Hepatitis B. But their retail prices are different which is lowering price strategy.

POTENTIAL ENTRY OF NEW COMPETITORS

Whenever new firms can easily enter a particular industry easily, the intensity of competitiveness among firms increases. Barriers to entry , however , can include the need to gain economies of scale quickly , the need to gain technology and specialized know how , the lack of experience , strong customer loyalty, strong brand preferences , large capital requirement , lack of adequate distribution channels, government regulatory policies,

tariffs , lack of access to raw materials, possession of patents, undesirable locations , countered attack by entrenched firms , and potential saturation of the market.

Despite numerous barriers to entry, new firms sometimes enter to industry with higher quality products, Lower prices and substantial marketing resources.

EXAMPLES FROM THE INDUSTRY

i) In Pakistani pharmaceutical industry potential entry of new competitors is very high because for an MNC it is easy to enter in such low investment market. They enter with different strategies like Tarivid is an expensive Antibiotic Medicine after the introduction of Cyflox that is cheaper than Tarivid, Cyflox captured the domestic industry.

ii) Another example is Economies of Scale Disprol was expensive than posntan after large scale production locally now the prices of both medicines are equal in the local market.

POTENTIAL DEVELOPMENT OF SUBSTITUTE PRODUCTS

In many industries firms are in close competition with producers of substitute products the presence of substitute products puts a ceiling on the prices that can be charged before the consumers will switch to the substitute product.

Competitive pressures arising from substitute products increase as the relative price of substitute products decline and as consumer switching cost decreases.

EXAMPLES FROM THE INDUSTRY

i) Acetaminophen manufacturers competing with other manufacturers of pain headache remedies in the pharmaceutical industry.
ii) All anti biotic medicines for the same disease different companies produces substitute products at lower prices.

BARGAINING POWER OF SUPPLIERS

The bargaining power of suppliers affects the intensity of competition in the pharmaceutical industry especially when there are a large number of suppliers. When there are only a few good substitute raw materials or the cost of switching raw materials is especially costly. It often in the best interest of both suppliers and producers to assist each other with reasonable prices, improved quality, development of new services, just-in-time deliveries, and reduces inventory costs thus enhancing long term profitability for all concern.

Firms may pursue a backward integration strategy to gain control or ownership of suppliers. This strategy is especially effective when suppliers are unreliable, too costly, or not capable of meetings a firms need. Firms generally can negotiate more favorable terms with suppliers when backward integration is a commonly used strategy among rival Firms.

BARGAINING POWER OF CONSUMERS

When customers are concentrated or large, or buy in volume, there bargaining power represents a major force affecting intensity of competition in the industry. Rival firms may offer low prices to gain customer loyalty whenever the bargaining power of the customer is substantial.

Bargaining power of consumers also higher when products being purchased are standard or undifferentiated. When this the case, consumers often neglect selling price, accessory packages.

EXAMPLES FROM THE INDUSTRY

In Pakistani pharmaceutical market the bargaining power of the consumers is very low there are two main reasons

i) Medicines are necessity of life so there is no or low bargaining from consumers because consumers have to use when it is needed.

ii) The prices of medicines are Government regulated. That it is regulating d by Ministry o Health.

SWOT Analysis

Strengths	Weaknesses
· Quota System · Policies of liberalization & Govt. Support · Strategic location of country · Relatively cheap and abundant labor · Capacity of handling high volume orders · Good Image among buyers	· Low Market share in world pharmaceutical exports (1%) · Lack of sufficient presence in better retail channels · High dependence on imported raw material · Isolated from trade partnerships · Unstable political Situation & Currency
Opportunities	**Threats**
· New Markets · Backward integration in to Production or creating raw material base · Increase value addition · Joint ventures with RM suppliers · Introduce e-business to get competitive edge Adaptation to "Sense and Respond" systems with flexibility and responsiveness	· Emerging Non-Quota era · Mass customization against mass production · Aggressive entry by other competitors · Formation of Economic trade groups · Terrorist attacks effecting adversely · JIT production concepts · Competing countries using hi-tech E-commerce/ IT/ Manufacturing Systems · Emerging Quick response Systems

4.1: The World Trade Organization (WTO)

The World Trade Organization was established in 1994 in Marrakech following the Successful conclusion of the Uruguay Round of Trade Negotiations. The predecessor to the WTO was the General Agreement on Tariffs and Trade (GATT). A key reform of the Uruguay Round was the Agreement on Trade Related Aspects of Intellectual Property Rights, known as TRIPS, codified as an annex to the treaty establishing the WTO. It is important to recognize that the TRIPS Agreement was intended to create a more equitable system of international trade. Wealthy countries agreed to reduce barriers to imports of price competitive imports from abroad while developing countries agreed to open their markets to the high value added exports of the developed nations. These high value added exports disproportionately consist of technology in which much of the value is intangible and must be protected by strong intellectual property regimes to be effectively exploited. Pharmaceutical products constitute one of the most important categories of high technology products.
Among the major requirements of the TRIPS agreement are the following:

• WTO Member States must provide a level of rights equal to those provided in the major global intellectual property treaties administered by WIPO, including the Paris Convention on Industrial Property.

• WTO member states may not discriminate among technologies in providing patent protection, meaning that exceptions to patent protection in many countries for pharmaceutical products must be eliminated.

• WTO member states must provide patent protection for at least 20 years from the date of filing a patent application

• WTO Member States must provide effective judicial enforcement of intellectual property rights.

• A TRIPS Council was created to coordinate WTO policy in the area of intellectual property rights and to manage the resolution of disputes among states on implementation of TRIPS obligations.

4.2: The World Intellectual Property Organization (WIPO)

Headquartered in Geneva, WIPO is the specialized United Nations Agency that serves as the secretariat for administration of most of the global intellectual property treaties. It is the principal forum for negotiation of new patent treaties and the leading provider of technical assistance to developing countries in the field of intellectual property rights. WIPO was created in 1967 as the successor organization to the International Bureau for the Protection of Intellectual Property, which had been in existence since the 19th Century. WIPO Currently has 179 member states.

4.3: International Policies, Trade and Development WTO

The decision to establish the WTO was taken in April 1994 in Marrakech, Morocco, at the completion of the eight-year "Uruguay Round" of renegotiations of the General Agreement on Tariffs and Trade (GATT). The WTO is the successor to GATT, but does far more than simply Continue GATT's role. Unlike GATT, the WTO has an institutional foundation and WTO commitments are full and permanent. According to UNCTAD, the persistence of generalized poverty in developing countries is related less to their lower level of integration into the global Economy or to insufficient trade liberalization than it is to the form of trade integration. International trade is of major importance to the economies of the Least Developed Countries (LDCs). During 1997-1998, exports and imports of goods and services constituted on average 43% of their GDP. But while recent World Bank analyses have promoted the benefits of trade liberalization in poverty reduction, UNCTAD has pointed out that rapid and deep trade liberalization has been associated, at least in the short term, with a rising incidence of poverty.

4.4: What is a Patent?

A patent is a property right granted by a sovereign state to the inventor of a novel, no obvious and useful invention. Because the invention must be novel (meaning that it has not been previously disclosed anywhere in the world) and because it cannot be obvious to one ordinarily skilled in the art, the grant of the property right cannot interfere with the public's access to what already exists. The owner of a patent has the right to exclude others from making,

using, offering for sale, or selling his or her invention for a period of 20 years from the filing of the patent Application.

4.5: Invention

An invention is any new or useful process, machine, article of manufacture, or composition of matter. An improvement on any of these items also can be an invention. Patent rights are territorial in nature and exist only in the national jurisdictions in which the patentee has applied for and received recognition of his property rights. Whether a claimed invention meets the tests of novelty and non-obviousness is determined by comparing it to the body of previously disclosed information in the same field. This information is usually called "prior art." The most commonly used prior art consists of published patents that have already been issued or published by the world's patent offices. While all countries require that the tests of novelty and non-obviousness be met before patent rights can be enforced against infringers, many countries do not determine whether these tests have been met though a substantive examination as in the United States, Japan, the U.K. and Germany. In counties, such as France, claims to patent rights are registered with the state but not actually tested for their validity until or unless they are asserted in a judicial proceeding. At that time the responsible judicial authorities engage in the fact finding process necessary to determine whether the tests of patentability have been met. The benefit of granting an inventor the exclusive property right of a patent for the limited period of 20 years is that he or she is given a powerful incentive to create. The inventor is assured that investors will be given the incentive to commit the financial resources necessary to support the inventor's research and to develop it to the point where it can be manufactured and made available to the market.

4.6: Patents Work Differently in Different Industries

Almost all inventions are patented prior to being made available to the market, regardless of the technology involved. The means, by which patent rights are exercised, however, varies from technology to technology. For example, in the field of consumer electronics Patents are widely shared among competitors through cross licenses. Patents on chemical compounds on the other hand are normally not licensed to others and exclusivity is closely guarded.

4.7: Patenting and Pricing

TRIPs grants a monopoly on a patented product to the holder of the intellectual property rights for 20 years as a reward for investment in research and development in that product and as an incentive for further investment. In practice, this leads to monopoly pricing and higher costs of pharmaceuticals. The actual production costs of pharmaceuticals are usually a fraction of the charged price of the patented pharmaceuticals - the higher prices are meant to act as a reward for research and development efforts. One of the means of dealing with monopoly pricing is compulsory licensing. It is allowed as part of the TRIPS agreement, but the EU and the US have tried to keep the interpretation narrow and have frequently added wordings emphasizing a public health crisis or graveness as prerequisites for its "...any problems in food security or the prices of basic commodities may have the strongest impacts not only on the poorest countries, but also on the poorest Populations within richer countries..."
"Global trade also deals with products of questionable or negative value to health. Trade in tobacco, alcohol and soft drinks is just one example of this."

4.8: Pharmaceutical Licensing

TRIPS Article 39.3 requires governments to provide protection for this marketing approval data. The pharmaceutical industry and some countries have argued for a broad coverage of the Article 39.3 and for a requirement that countries confer exclusive rights on the originators of marketing approval data. In practice, this would benefit mainly the pharmaceutical research-based industry and would hamper the chances of the generic industry to gain faster access to markets and would increase their costs. From a health point of view, openness of the registration process after a decision has been made would clearly benefit the citizens and consumers more than disclosure on a broadly defined basis. This is also important in relation to the openness and accountability of the public administration.

4.9: Trademarks and Health Education

The TRIPS Agreement also provides protection of trademarks. The tobacco industry has used the protection of trademarks under TRIPS to limit public health regulatory activities. From a health policy perspective, it is important that relatively weaker Southern governments are supported in their efforts to curb smoking and alcohol use or to promote breast-feeding as part of their public health policies. It is thus critical to ensure that TRIPS is not used inappropriately to limit legitimate public health policies.
Article 27(b), indigenous knowledge, agriculture and copyright Article 27(b) covers what can and what cannot be patented. The recent analysis from the UK's Intellectual Property Rights Commission has reservations about the possible negative impacts of patents on plants and animals in general. It suggests that, in the absence of any universally-recognized definition of what constitutes a microorganism, developing countries should remain free to adopt a credible definition that limits the range of material covered by a patent. Matters related to indigenous knowledge and biopiracy deal often with health due to the importance of knowledge in healing properties. Important aspects of IPRs deal also with seeds, farmer's rights and food security.

4.10: The Impact of WTO Agreements on Health and Development Policies

Commission on Intellectual Property Rights (CIPR) report, commissioned by the United
Kingdom has highlighted that, in the corporate sector, research and development costs are predominantly geared towards larger markets and the diseases of more affluent populations. These account for about 95% of investments while just 5% is allocated to diseases of major importance to developing countries. Recent emphasis on pharmaceutical research and development as a global public good and the consequent necessity for the developed world to pay higher prices in order to ensure access to pharmaceuticals in the developing world is a problematic approach. Firstly, it gives the incorrect impression that higher pharmaceutical costs in the developed world have to be accepted in order to ensure access to

pharmaceuticals in developing countries. Secondly, it provides little incentive to ensure that health-related priorities are realized in the corporate sector's further R&D efforts. Developed countries will need to pay more to ensure that R&D is carried out into diseases prevalent in the developing world. But the suggested mechanism to address this problem may act more as a smokescreen to obscure the more mundane causes of rising costs of pharmaceuticals in developed countries.

4.11: The TRIPS and Public Health Debate: An Overview

The Trade-related Intellectual Property Rights (TRIPS) agreement of the World Trade Organization establishes minimum standards for intellectual property rights. TRIPS obligate developing countries to introduce property rights legislation similar to the advanced developed countries. Ostensibly, this should not pose a major problem since all developing countries' existing national legislation around property rights are based on former colonial models and or the American model. What is new and or different about the TRIPS is that developing countries must modify existing national legislation to tighten up property rights and extend coverage to all areas including medicines and Pharmaceuticals. In addition, property rights protection now must have at least a twenty year protection. Many developing countries had heretofore not covered medicines and Pharmaceutical products and offered intellectual property rights (IP) protection only on product but not process. Some developing countries also had patent coverage for as short as three years (Thailand) and as long as sixteen years (South Africa). This generally allowed for the production of cheap generic medicines in the local economy where possible. While TRIPS is relatively new (since 1995) and countries are in different stages of the implementation process, the pressure to change IP laws has begun since the early 1990s through the instigation of the US government and multinational corporations MNCs).Furthermore, countries are obligated to offer 'market exclusivity' to new products (equivalent to patent protection) pending implementation of TRIPS compliant domestic legislation (CPT 2001, and TAC 2001). Because the new IPR regime now being implemented world-wide covers both product (a traditional area) as well as process patents and extends the period for market exclusivity arrangements it is increasingly difficult for developing countries to manufacture generic drugs or to produce copies of medicines using different processes. Additionally, the increased time frame for patent protection and other complex IPR rules mean that drug companies can monopolize the drug

market through a variety of measures and tactics. Behind the TRIPS is the powerful trade sanctions enforcement mechanism of the WTO as well as potentially expensive Litigation over patent dispute with giant MNCs.

Given the increasing crisis in HIV/AIDs epidemic in the global economy, which is felt more severely in the South, the availability and affordability of medicines is critical. In the context of IPR rules which are unclear and ambiguous about public safeguard exceptions, the possibility of being held hostage to trade sanctions, and the financial and human resources necessary to devote to legal suits and dispute settlement procedures have an intimidating effect on the governments of poor countries. As a result, many developing countries have been reluctant to take proactive stance in implementing such measures. This has raised serious questions about the impact of TRIPS on public health and hence the life and well-being of millions of men, women and children living in poverty in the South.

Currently, many least developed countries such as Burundi, Central African Republic, Ethiopia, Lesotho, Malawi, Rwanda and Zambia have HIV infection rates higher than 10% (TAC 2001). In Thailand 750,000 people are living with AIDS while 350,000 have died from it. Less than 5% of these people have access to anti-retroviral medicines needed to combat the disease, due to high cost of drug therapy (Oxfam). South Africa has four million people afflicted with HIV/AIDs.

The major form of treatment for HIV/AIDs is anti-retroviral but in many countries these are too costly and are hence not readily available, if at all, in the public sector and are extremely expensive in the private sector. This poses serious problems for persons who live in countries where private health insurance is inadequate or unavailable. In such situations poor patients must rely on their household income and or the public sector. But given low wages and chronic problem of inadequate budgetary resources that plague developing countries, many people suffer and die needlessly. This is because the monopoly pricing and practices of pharmaceutical companies ensure that in many places only brand names are available, at high cost, and places stumbling blocks in the way of countries seeking to obtain cheaper generic drugs.

In addition to HIV/AIDs, there are other diseases for which the prohibitive cost of medicines denies people the right to safe and affordable medicines. These include widespread diseases such as thrush and Cryptococcus and meningitis. According to the World Health Organization (WHO) most patented drugs are sold at 20-100 times marginal costs. Furthermore, NGOs such as Health Action International, Consumer Project on Technology, Oxfam and Médecins Sans Frontiéres and the Kenyan Coalition on Access

to Essential Medicines have demonstrated that there is a wide range in drug prices. For example, Amoxil (produced by SmithKline Beechman's) sells for $8, $14, $29, $34, $36, and $40 in Pakistan, Canada, the Philippines, Malaysia, the US and Indonesia respectively. Glaxo prices for Zantac and Voveran are lower in the UK than in Indonesia (from a study by Balasurbramanian of HAI, cited in CPT 2001.) South Africa represents a high profile case where pharmaceutical MNCs tried to stop the provision of affordable medicine. But other cases occur in Ghana (with Glaxo Smith Kline. Even though it is not clear that thy actually hold the patent on the drug Combiviar in Ghana they have tried to stop the company Cipla from providing generic medicine- TAC 2001). The drug companies withdrew their case against South Africa only after great international outcry and organized effort by NGOs. But other countries such as Malaysia and Thailand are still under threat from lawsuits and US section 301 (US Trade Law) priority watch list.

4.12: TRIPS and Public Health

The public health dimension of TRIPS has taken centre stage in the recent months with most discussions focused on medicines for HIV/AIDS. The debate is likely to be a protracted one as much is at stake. The fact is that patent protection gives the patent holder monopoly rights within a recognized time period over the manufacture, sale and importation of the patent drugs. The WTO, principally the Secretariat, the European Commission (EC) and the US, argue that the current TRIPS framework permits a great deal of flexibility in allowing governments to take measures to protect national public health. They therefore are resistant to any attempt to weaken the TRIPS agreement. Opponents, primarily NGOs such as Medicine sans frontier and Oxfam, Treatment Action Campaign--South Africa argue that the TRIPS agreement straitjackets governments and imposes high cost on drugs and medicines. The UN Human Rights Commission has also weighed-in on the debate with a recent statement calling on countries to be mindful of the human rights impact of changes in national IP legislation which may impact negatively on human rights. The UN Rights Commission's resolution (April 2001) called on "all states to ensure that application of international agreements is supportive of public health policies which promote broad access to safe, effective and affordable preventive, curative or palliative pharmaceutical and mechanical technologies."

Many developing countries are concerned about the presumed flexibility of TRIPS and worry that the provisions are vague and subject to narrow or restrictive interpretation which can leave them vulnerable to dispute settlement proceedings and or legal suits which are not only protracted and costly but often tend to delay the implementation of measures necessary to remedy public health problems. They, therefore, would like to see the WTO take a strong, clear and firm position on the public health safeguard mechanisms available under TRIPS.

Just what are the critical issues in this public health and TRIPS debate and what is really at stake?

The debate boils down to five critical areas of concern:

1) The TRIPS agreement and countries' latitude in creating measures that will reduce or restrict the effective monopoly of patent holders over medicine. In other words, to what extent can governments override TRIPS provision in order to secure cheaper medicines and greater access to medicine in order to limit the suffering of patients?

2) The scope and rights of countries in determining the grounds for safeguards such as compulsory licensing1 and parallel imports.

3) The proper balance in the TRIPS between the protection of property rights and the protection of the public interest, especially with regard to the affordability and availability of life saving and life enhancing drugs.

4) The scope of ‘exclusivity’ (the period for which the patent holder can exclusively market the innovated products and process) provided by a patent?

5) What are its implication for price competition and hence a wide choice of effective treatment for patients in developing countries?

4.13: Compulsory licensing

Governments can authorize the production of a patented product without the permission of the patent holder. This is justifiable where the patented medicine is essential but unavailable due to lack of supply, or because of unreasonably high price. Other grounds for compulsory license include public non-commercial use and to remedy anti-competitive practices such as high prices due domination of the market.

4.14: Parallel imports

(Also know as 'grey market' imports) are cross border trade in a product without the permission of the manufacturer or publisher. Parallel imports take place when there is a significant price difference for the same good in different markets (CPT 2001).

Clarification of the significance and binding constraints of article 7 and 8 in the interpretation of the other provisions of the TRIPS agreement. These ambiguities have lead to a number of spectacular cases such as the MNCs against South Africa, the EC versus Canada over Canada's patent exceptions for research and testing on generic drugs registration, the US versus Argentina, Brazil and India. In the South African case, the South Africa Pharmaceutical Manufactures Association (PMA) challenged the TRIPs compatibility of a 1997 South African Medicine Act which authorized broad scale parallel imports and compulsory licensing. The PMA argued that the act violates TRIPs which only allows parallel imports from third countries (where drugs are cheaper than those of licensed distributors in host countries) and compulsory licensing in cases of public health emergencies.
This already tense situation is further aggravated by the continuing, aggressive push by the US for TRIPS plus agenda in some countries national legislation. The US is pushing many governments to implement more stringent patent regime than implied under the TRIPS agreement, see for example the case of Thailand and the Dominican Republic.
DRUG GATT/TRIPs and Pharmaceuticals in middle-income countries (Joint Research in North Africa)

Many papers have been circulated among e-drug members and elsewhere about the future impact of the World Trade Organization (WTO) agreements on the pharmaceutical industry in developing country and on the access of the population of these countries to essential drugs at a reasonable price. The GATT/TRIPs agreements mark the end of the period of growth known by drugs firms set up in these countries: customs facilities & protection; fixing of quotas for imported finished goods, implicit clause for the non-extension of the public sector; negotiation and price control; dominated local market. The GATT/TRIPs agreements are upsetting the relative comfortable situation local firms have been enjoying until now.

In the pharmaceutical sector, GATT/TRIPs measures concern two aspects: - the lifting, in the medium run, of any obstacle to pharmaceutical goods free

trade, excluding any possibility of protecting the local production in the countries. The application and the reinforcement of patents? System (extension of their duration, patents of products and patents of process, reinforced sanctions in case of violation). The research focus on two main stakes:

1 **An industrial stake**

Which consequences will the GATT/TRIPs measures have on the existence and the future of the local pharmaceutical industry in North African countries? etc.

2. **A health stake**

Which effects on drugs availability, range of products and prices? etc.

CHAPTER # 5

ANALYSIS

GLOBAL OVERVIEW OF PHARMACEUTICAL INDUSTRY

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The Pharmaceutical Industry

Generally speaking, medicinal drugs are made by two kinds of Companies.

• Pharmaceutical companies which primarily undertake R&D and hold patents in their new discoveries (also known as originators or the research-based industry). Most pharmaceuticals are based in the North. Patented products from the pharmaceutical companies are often referred to as "brands"; Retrovir, Viagra and Zantac are examples of branded goods.

• Generics manufacturers which primarily produce medicines based on formulae in the public domain or patented by other companies. They may do some additional research to produce their own versions. Generics are based both in the North and the developing world.

The primary goal of both pharmaceutical and generic companies is to make a profit. For pharmaceuticals, profit mostly comes from the sales of patented drugs, which only they have the right to manufacture and sell. For generics, profit generally comes from selling unpatented no longer patented or patented elsewhere drugs at prices lower than those of their competitors. The pharmaceutical sector is overwhelmingly Northern-based and dominated by a few large multinational companies. Most of its profits are also made in the North. Although developing countries comprise over 80 per cent of the world's population, they only represent 21 per cent of global medicine sales.

Research, Development and Marketing:

New drugs only reach the market after a lengthy process of R&D. This includes identifying, synthesizing, developing, testing (in laboratories and on people) and securing approval for the new product. Many drug candidates fail; according to industry estimates, not more than one in 5,000 compounds synthesized in the early stages of research reaches the market. While the importance of R&D is not denied, there is considerable disagreement as to how costly it is. Recent estimates of $802 million per drug that reaches the market have been challenged by critics, who claim that this figure ignores several factors that significantly reduce costs. These include: the contributions of publicly funded research and tax deductions to R&D; the fact that significant funding may be invested in trials to bolster marketing claims rather than develop new products; the development of new technologies that reduce the length of time and procedures needed to develop new drugs.

Pharmaceutical Statistics

• A third of the world's population have no access to essential drugs, a figure that rises to half the population in the poorest countries of Africa and Asia.

• In 2000, the US spent $3,724 on healthcare per person. Somalia spent $11 per person.

• 74 per cent of health expenditure in sub-Saharan Africa, 25 per cent in Latin America and the Caribbean, and 7.4 per cent in developed countries goes on medicines

• In rich countries, under 40 per cent of medicines are purchased privately, whereas the figure is 67 per cent for sub-Saharan Africa and as high as 81 per cent in Asia and the Pacific
• The cost of the same treatment for tuberculosis represents income from 500 working hours in Tanzania, 100 in Zimbabwe, 20 in Thailand and 1.4 in Switzerland. The comparable costs for gonorrhoea are 120 hours in Tanzania, 20 in Zimbabwe, 6 in Thailand and 0.4 in Switzerland

• Over 300 medicines are on the World Health Organization's Essential Drug List. Fewer than 20 are patented

• The World Health Organization calculates that in developed countries, the manufacturer's price of a medicine typically represents 50 to 60 per cent of the final consumer price, while in some developing countries up to 80 per cent of the consumer price consists of import duties, taxes, distribution costs, and dispensing fees.

• The World Bank estimates that IP protection will lead to increased foreign investment in middle-income countries, but full implementation of TRIPS would mean a loss to developing countries of $20 billion in patent payments (for all sectors, including health).

• WHO suggests that implementing patent protection where it did not already exist would result in the average price of drugs rising, with projected increases varying from 12 to 200 percent.

• In 1999, the price of Glaxo Wellcome's Zidovudine (AZT) around the globe varied from $124.95 to $53.50 per 250mg/40 capsule packs

• 144 countries are members of the World Trade Organization; 31 countries have applied to join TRIPS-Plus legislation and policy ensuring stronger protection for patents than required by TRIPS.

- Public Citizen, a US consumer organization, claims that once tax deductions and other accounting practices are included, the figure is under $150 million per new drug. The Global Alliance for TB Drug Development calculates that a new drug for tuberculosis could be developed for $115–$240 million.

- Costs in general could be reduced by moving R&D to a developing country. B K Raizada, Senior Vice-President of Indian medicine manufacturer Ranbaxy Laboratories estimates that R&D costs in his country are about 30 per cent of those in the US.

- The Global Alliance estimates the trial component for a new TB drug in the South would be around $10 million, compared to $27 million in the industrialized world.

- Public institutions also play a major role in research, often discovering new molecules which are then developed and marketed by the pharmaceutical industry. Seventy per cent of therapeutically important drugs introduced in the US between 1981 and 1991 were produced with government involvement; some, such as AZT, DDI and D4t,

- Which are all used in HIV/AIDS treatment, have made considerable profit for their manufacturers. Both the academic and small biotechnology sectors are proving to be greater pharmaceutical innovators than the large, research based pharmaceutical companies.

- From one perspective, the public contribution to R&D is increasing. Eighty per cent of new drugs were generated entirely within companies in the 1960s, a ratio which fell to about 50 per cent in the 1990s. Observer's estimate that 60 per cent of drugs would not have been discovered or would have had their discoveries delayed without public sector research.

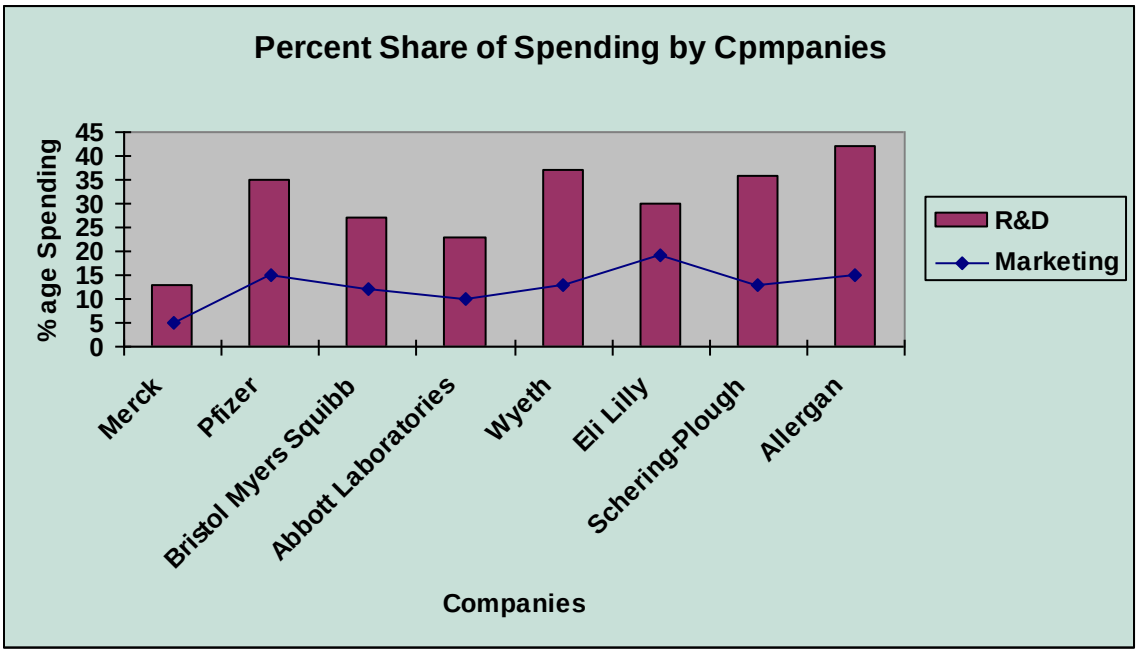
- However, some analysts are concerned that the role of the public sector is shrinking, as private funding of research in universities increases and public research is increasingly viewed as an investment that needs to create economic value. The industry spends more on advertising and marketing new drugs than on R&D and until very recently, pharmaceutical companies were consistently among the world's most profitable commercial enterprises. In most cases, profits exceed spending on R&D.

- The industry has been the most profitable in the US for each of the past 10 years in 2001 it was five and a half times more profitable than the average for Fortune 500 companies.

- The compensation (salary, shares, bonuses etc) paid to the industry's highest officers reflects this in 2001 the five highest-paid drug company executives received over $183 million, considerably more than the entire health budget of many impoverished nations.

- Most advertising and marketing is carried out in the US, where, until recently, the cost of drugs was relatively uncontroversial. Marketing, to both the public and the medical profession, is essential when there is little therapeutic advantage between drugs.

Relative spending by pharmaceutical companies
Per cent of revenues spent on marketing/ spent on R&D
Company advertising/administration (2004)



Source: Families USA (www.familiesusa.org/new2001data.htm)

The price of drugs

The above costs, plus the costs of ingredients and production, are factored into a manufacturer's price of a patented product. (Generic, unpatented drugs have relatively few R&D costs.) However, once these costs are taken into consideration, the actual price charged by manufacturers is primarily determined by what the market will bear how great a demand there is for the product and, where demand is high, whether there is competition. The manufacturer's price represents only part of the price paid by consumers, who may be individuals, governments or other healthcare providers. The consumer price must also cover government taxes, if any, and distributors' and retailers' margins.

The World Health Organization's Essential Drugs List

The World Health Organization (WHO) calculates that in developed countries, the manufacturer's price typically represents 50 to 60 per cent of the final consumer price, while in some developing countries up to 80 per cent of the consumer price consists of import duties, taxes, and distribution costs and dispensing fees comprises medicines that "satisfy the priority healthcare needs of the population selected with due regard to public health relevance, evidence on efficacy and safety and comparative cost effectiveness. They are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford".20 Over 300 medicines are on the list, fewer than 20 of which are patented. Member states are encouraged to develop their own essential medicines list, and by early 2004, over 150 nations had done so.

Competition

Do patents lead to higher prices? The industry responds that the link between patents and high prices is weak or non-existent and price is not the only factor in access to drugs. Apart from HIV/AIDS and drug-resistant infectious diseases, almost all the leading causes of death and illness in developing countries can be treated or prevented by old, inexpensive drugs and vaccines that have long been off patent. Yet few people in the developing world with those diseases are treated fewer than 15 per cent of people with tuberculosis in India and Brazil receives life-saving generic medicines. Harvey Bale, Director-General of the International Federation of Pharmaceutical Manufacturers' Associations, believes the real barriers to access to drugs are: "a combination of poverty, lack of access to sufficient international financial assistance, the absence of trained medical personnel in many regions of all developing countries, lack of diagnostic equipment, lack of effective political leadership to address health as a priority". A 1993 World Bank study estimates that in many African countries, inefficiency may have led to only 12 per cent of tax money allocated to the purchase of drugs being effectively utilized.

The industry argues that patents are not a monopoly. Patented medicines often compete with off-patent products, and with each other. However, while that is true for some illnesses and therapies, such as high blood pressure,

there are many cases in which patented drugs do have a monopoly. There are many patented antiretroviral (ARV) drugs, for example, but the nature of HIV/AIDS treatment is such that the patented drugs are not alternatives that compete with each other but must be used in combination. Without generic versions there would be no competition.

The industry points out that patented drugs form a small percentage of drugs consumed. Only five per cent of the top-selling 200 drugs in the US in 1994 were patented, as are fewer than 20 of the products on the WHO Essential Drug List. However, although patented drugs are a smaller proportion by volume, they form a higher proportion of healthcare by cost. The industry says that patents do not prevent the sale of other drugs, for example, a 2001 study in 53 African countries concluded that patents on ARV drugs for HIV had only been applied for in 172 of 795 possible cases. This had allowed importation of the generic versions in the remaining 623 cases.

Critics of the study point out that South Africa, the region's richest country and with the highest number of people living with HIV, had most patents in force, and that patents on particular drugs in other countries often blocked use of the combination therapy that is key to HIV treatment.

In other words, patents are applied for, and restrict choice, where there is a potential market, as in South Africa. The industry notes that competition from generics does not always bring prices down: in 1999 Argentina had annual dosage costs for two of the main AIDS triple therapy drugs of over $10,000 per person per year, even though the country had several generic manufacturers, while in Brazil, with only one seller, the cost was $5,019.

However, Argentina appears to be the exception rather than the rule. Prices of ARVs have fallen substantially in most countries where generic versions are available from $10,000 a year to as little as $209 a year while remaining high elsewhere. In Uganda in October 2000, "there was an 80 to 90 per cent price cut when (the leading clinic) brought in generics". And a 1995 study found that the prices of new drugs were on average about five times higher than for older drugs in Pakistan, and as much as 25 times higher in Sri Lanka.

Patents and the pharmaceutical industry

Globalization of trade in the last 20 years has been accompanied by the development of international standards for intellectual property rights. These have been codified in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement. IPO's mission is to promote IP protection

globally and to harmonize national legislation. It is not required to consider the benefits or costs of increased protection for intellectual property rights. Patents have often been a source of dispute between nations. Richer countries tend to insist on patents to protect manufacturers, while poorer ones tend to ignore them in order to create wealth. In the nineteenth century, the US built up its industrial base by copying many British inventions. Today it is one of the strongest defenders of the patent system. The first patent statute was passed in Venice, Italy in 1484, but many countries have not had a patenting system until recently. Even in the North, pharmaceutical patents were not fully applied in many countries until the 1970s. During the same decade India and Brazil loosened patents on pharmaceuticals, partly for the benefit of public health and partly to stimulate national economic development. The argument underlying wide recognition of patents is that they provide financial incentives for research and development (R&D). Innovations often require substantial investment of time and money and if an invention is made public without patent protection, the inventor may not be able to recoup or benefit from that investment. Without patents, or if patents are ignored, there would be less incentive to innovate and, in the pharmaceutical industry, fewer new drugs to tackle such diseases as HIV/AIDS, tuberculosis and cancer. Those who favor weak patent protection argue that the monopoly granted to patents allows the patent holder to charge high prices, depriving the poor of an essential product or technology. Without the ability to copy patented products, particularly in countries where the patent holder has little commercial interest, nations will not be able to use and develop new technologies. “Applying stringent patent protection in developing countries will not generate more revenue for companies, but it will significantly limit poor people’s access to vital medicines,” says the British non-governmental organization Oxfam

Extending Patents

Tension persists over whether and how the period of patents can be extended. While the TRIPS agreement mandates 20 years’ protection from the time a patent is first applied for, manufacturers argue that safety regulation procedures can take eight or nine years, thus reducing effective patent life to no more than eleven years.

The pharmaceutical industry is therefore keen to extend patents whenever possible, while generic manufacturers and others seek to limit patent life.

This means that towards the end of a product's patent, two conflicting processes come into play. On the one hand, the Bolar Provision, recognized in many, but not all, countries, allows generic companies to develop drugs (and research if necessary) while they are still under patent so that they can stockpile them for sale immediately the patent expires. On the other hand, to protect a drug's monopoly, manufacturers may claim additional patents on drugs that are about to go off patent (a process known as "ever greening"). The industry is often accused of disguising minimal developments with little or no additional therapeutic value as innovations, claiming patents for them under legal loopholes. Pharmaceutical companies today have found that the return on investment for legal tactics is a lot higher than the return on investment for R&D," says Sharon Levine, associate executive director of a US healthcare provider. A patent can also be extended informally, if a pharmaceutical company pays a generic manufacturer to delay market entry of the generic version.

TRIPS: A GLOBAL INTELLECTUAL PROPERTY REGIME

The World Trade Organization (WTO), to which two thirds of the world's nations belong, regulates international trade. The WTO argues that a stable and transparent global intellectual property regime is an essential prerequisite for expanded international trade and investment. The basis for this regime is the international agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) signed in 1993.

Under TRIPS, patents are granted for products and processes, with protection set at 20 years from the date of application. Under TRIPS, all members of the WTO, including those countries which had no patent protection, or very little, must now introduce a new and standardized level of protection. Developed countries had until 1996 to do so, most developing countries had until 2000, with some allowed to extend until 2005, while there are 30 least developed countries that have until 2016 to pass legislation requiring patent protection for pharmaceuticals and agricultural chemicals. TRIPS has not been universally welcomed, particularly in countries where patent protection has been weak. But in order to achieve WTO membership, patent legislation had to be accepted as part of a package of benefits for developing countries, such as lowered tariffs for the agricultural products they wanted to export. Whether or not the overall package benefits the South is a matter for debate. The arguments in favor of patent law are that it

encourages multinationals to invest, and supports innovation by producers within the country. People who argue against it say that it will raise prices and discourage innovation. Poor countries are generally at a disadvantage in international negotiations, partly because their positions are often compromised by economic dependence on wealthy countries which support TRIPS and partly because their personnel often have little training in the field in which they are negotiating. The US in particular is frequently criticized for using its power to achieve its goals at the expense of others, either during negotiation or as a unilateral action under Provision S301 of the US Trade and Tariff Act.

Dr Supachai Panitchpakdi, the Director-General of the WTO, said "There are many things in the TRIPS requirements that we need to reconsider, so that the requirements would not place an unnecessary burden on the poor countries. It would also enable the poor countries to pursue their developmental goals, for example educational development and healthcare development."

REGIONAL OVERVIEW

Chinese pharmaceutical industry

Some business analysts predict that China will become the world's largest pharmaceutical market by 2020. But the country is still assessing the impact of joining the WTO on its domestic market.

China's pharmaceutical industry has grown by an average of 17.5 per cent per year since 1978, when economic reforms were followed by a series of policy changes, including the introduction of a national Essential Drugs List. In 2000, the production of pharmaceutical raw materials reached 240,000 tons, the second highest in the world after the US. The industry's total output was $28 billion, accounting for 5.7 per cent of world market share. $3.8 billion worth of pharmaceuticals were exported. In addition to other drugs, China produces many Traditional Chinese Medicines (TCM) – 8,000 different types in 1998. These come under the same intellectual property laws as other medicines. Patents for pharmaceutical and chemical products have been applied in China since 1993, with other laws to protect intellectual property in place since 1982. China's most recent drug law came into effect in December 2001, the same month that the country joined the WTO. It stipulates that medicine sales should follow international conventions – and

also meet China's needs. It is too early to measure the impact of WTO membership on the country's pharmaceutical industry. Furthermore, the pressures placed on the industry by membership will be matched by internal change, including the reform of social security and the medical and health systems. There are 16,000 pharmaceutical wholesalers in China, although fewer than 1,000 are large-scale and only 70 have annual sales exceeding $30 million. In recent years, however, severe competition has caused enterprises to reduce profits to a minimum. At the same time, structural problems in the industry have become apparent. Only two innovative drugs produced in China have been approved internationally and more than 97 per cent of drugs produced are generics. In addition, China's production standards are low, with only 87 companies being awarded the internationally accepted Good Manufacturing Practice certification. Faced with severe penalties of $400 million to $1 billion in penalty fees, generic manufacturers will be forced to cease production of illegal copies and reduce export volume. While some companies could gain technologically as a result of association with multinationals, the majority must either invest in research or obtain production licenses (each license could cost at least five million dollars) from the multinationals. In both cases, the costs are likely to be out of reach for the majority of companies.

By 2005, customs duty on imported pharmaceutical products will be reduced from 10 to 4.2 per cent. For non-patented drugs, this will reduce the competitive edge that domestic products have over imported ones. However, it is unclear whether patented drugs will also take advantage of this reduction in tax or whether lack of competition will keep prices high. Traditional Chinese Medicine may be less affected than the conventional pharmaceutical industry by WTO membership. Competition from other countries will place pressure on domestic producers, but this is expected to have a beneficial effect in forcing the restructuring of the TCM industry. This will include establishing a scientific basis for the efficacy of herbal medicines, which is imperative if China is to develop medicines that conform to international standards and to produce more for export.

Publicly listed companies in the pharmaceutical industry will also be affected by WTO membership. The negative impact is expected to be relatively minor on those which mainly manufacture penicillin and Vitamin C, as most of their products are made for export and WTO membership will facilitate their overseas market expansion. However, publicly listed companies mainly oriented towards the domestic market will face competition from imports and reduced opportunities to manufacture generic drugs under the new regime. Under WTO membership, multinational

pharmaceutical companies will be able to acquire a large share of the Chinese pharmaceutical market. They may be able to gain control over distribution networks and not have to rely on the existing complex and costly system. An open market will give them a better chance of having their products included on China's provincial and municipal lists of drugs that are subject to state reimbursement. China has also agreed that current trading rights and distribution restrictions are to be phased out over a three-year period, allowing foreign companies to import most products, including pharmaceuticals, into any part of China. Western imports are expected to top $60 billion by 2010 and some business analysts predict that China will become the world's largest pharmaceutical market by 2020. On the other hand, it is considered unlikely that foreign pharmaceutical enterprises will enter the Chinese market at the basic level of unpatented drugs, where they will face stiff competition from domestic Chinese enterprises.

Indian pharmaceutical industry post-TRIPS

The debate over the patenting of pharmaceuticals rages in a country with a large domestic industry and considerable international clout. Until the early 1970s, Indian patent law was relatively strict. Drug prices were amongst the highest in the world and only 30 per cent of sales were manufactured domestically. In 1972, however, the 1970 Indian Patents Act came into force, loosening patent protection. Pharmaceutical processes but not products could be patented and only for seven years. In the next 20 years the industry flourished. By 2000, 500,000 people were employed in a sector comprising 20,000 private enterprises, and domestically produced drugs accounted for over 70 per cent of the market. India is the world's fourteenth-largest market for pharmaceutical products in value terms and the fourth largest market in unit terms. Exports of finished formulations rose from $9.6 million in 1980–81 to $1.3 billion in 1999–2000. Nearly 65 per cent of the Indian export market is to the developed world. The larger companies both copied drugs patented elsewhere and fostered R&D. However, although the money spent on R&D reached $66 million in 1999–2000, as a percentage of overall sales it remained very low, averaging two per cent of turnover.

During this period, prices fell significantly. By the 1990s, the cost of both patented and non-patented drugs in India was much lower than in the developed world and significantly less than in neighboring Pakistan, where health and income conditions were similar but patent protection had not been abolished. To comply with TRIPS, the 1970 Act was first amended in 1999, though not agreed by Parliament until May 2002. This changed the law in several key areas. Perhaps the most important is that product patents will be recognized. Although applications will not be processed until December

2004 (the "mailbox" system). Exclusive marketing rights will be granted before then if a patent for the product has been granted in another WTO member country – and the application has not previously been rejected in India. Those who support a weak intellectual property regime consider that the new legislation goes too far in some aspects – for example, new dosage forms or new formulations have been included as "inventions" that are eligible for patents but recognize that some important provisions of the 1970 Act have been retained. These include the use of the patented product or process for the "purpose merely of experiment or research including the imparting of instructions to pupils".

Some prominent sections of the industry are very much in favor of the new laws. But they recognize that investment in R&D will have to be stepped up. Most Indian pharmaceutical companies spend less than 0.25 per cent of turnover on R&D. Overall, these needs to be increased to nine per cent to keep abreast of global competition. The Organization of Pharmaceutical Producers in India mostly represents companies with a R&D base. According to spokesperson P S Khanna, the organization does not believe that the amended Act goes far enough in protecting payments and is not TRIPS compliant. Khanna says that strong patent laws are needed as only a healthy industry can bear the costs of R&D and strong patent laws are required for investment.

Amar Lulla, joint managing director of Cipla, a leading Indian pharmaceutical company that exports generic versions of ARV drugs, feels that while companies may stand to gain from product patenting, the consumer will suffer. "Unlike other consumables, medicines are not a matter of choice but necessity. Patents mean a monopoly and the right to charge any price." Nevertheless, Lulla believes, the Indian industry will survive because of the generic market.Gajanan Wakankar, executive director of the Indian Drug Manufacturers' Association, also believes the future is in generics, as each year some 20 to 40 medicines go off patent. Even then, he cautions, developed countries often harass companies exporting off-patent drugs.

Country perspectives

Developing country governments vary in their response to the real or apparent conflict between patents and public health. While some resist significant pressure to implement strong intellectual property (IP) regimes, others, intentionally or by default, draft policies and legislation that

strengthen the hand of patent holders. The UK Commission on Intellectual Property Rights argues that "policies required in countries with relatively advanced technological capability where most poor people happen to live, for instance India or China, may well differ from those in other countries with a weak capability, such as many countries in sub- Saharan Africa. The impact of IP policies on poor people will also vary according to socio-economic circumstances. What works in India, will not necessarily work in Brazil or Botswana."

Although Southern countries have until 2005 or 2016 to implement TRIPS-compliant legislation, in many the process is already complete or near completion. As the articles from Pakistan and Uganda indicate, drafted or enacted legislation frequently prioritizes patent rights over public health. Ken Bluestone of the British charity VSO argues that "many countries will have to redraft their national legislation if they are to take advantage of the new political climate post-Doha. The debate must be rekindled in these countries. It is far more challenging to change existing legislation in some cases than develop something from scratch."

Patent Offices

Effective implementation of patent legislation depends to a large part on the efficiency of the national or regional patent office, which accepts and rules on national patent applications. As a far greater number of patent applications than was the norm before TRIPS floods into patent offices, in many countries the patent office does not have sufficient capacity to deal efficiently with the larger number of applications. While the US Patent and Trademark Office has an annual budget of $1 billion and a staff of more than 3,000 scientists, engineers and legal experts, the equivalent office in Pakistan, with half the population of the US, has an annual budget of $80,000 and seven technical staff. One study suggests that on average it would cost a country $1.5 to $2 million to build a basic infrastructure to implement TRIPS money that is often unavailable. Pakistan is not untypical, and the result in many countries, observers fear, is that patents will be granted that should otherwise be refused, while the overworked system will also deter third parties from protesting unreasonable patents. Yet even in the US the system is not perfect, and 46 per cent of patents when challenged found to be invalid. In countries with overburdened patent offices and few specialized lawyers, it is likely that a considerable number of patents are invalid but not challenged in the courts. During the transition period for

medium developing countries – until 2005 – applications are generally dealt with under the "mailbox" system, where the application is not examined until the end of the transition period but exclusive market rights (EMR), which are tantamount to a temporary patent, are allowed. Least-developed countries, which do not have to amend their legislation until 2016, are allowed to waive EMR.

Drug regulation and supply

Patented drugs are only a minority of drugs consumed, but they represent a considerable percentage of healthcare. In 2000, three per cent of the Brazilian healthcare budget was spent on ARV drugs, although HIV/AIDS affects less than 0.3 per cent of the population.

To ensure adequate supply and distribution, an efficient state body is essential for the regulation of all drugs. Yet according to the WHO, fewer than one in six countries has effective drug regulation with an independent agency ensuring comprehensive and up-to-date laws for all drug products, and developing appropriate standards for the production, dissemination and consumption of all drugs.

The WHO says four factors are critical for securing access to essential drugs:

Rational selection & use adequate financing

Government funding ensures the best access to essential drugs and countries which allocate adequate funding to high-impact public health problems such as tuberculosis, malaria, HIV/AIDS and childhood illness experience greater economic development.

Affordable prices

Which can be partly achieved by reducing or eliminating import duties and taxes?

Mix of Public and private supply systems

Many countries have unregulated private supply networks for profitable urban areas and inefficient public supply systems for the rest of the country, and lack of regulation frequently leads to corruption in particular the diversion of products from their intended market for sale elsewhere.

Pakistan

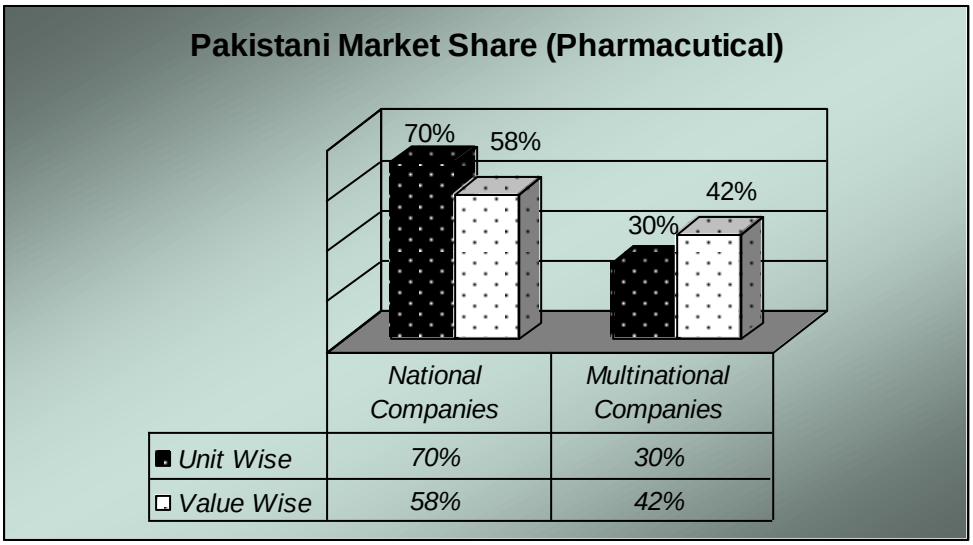
Overview of Home pharmaceutical industry

Today, we can be proud of the hi-tech, essential and high quality national pharmaceutical industry, which has significance for the country in terms of self-reliance to a great extent.

The national industry comprises 350 manufacturing units throughout the country, with a break-up of 319 national or Pakistani owned and licensed manufacturing units and 31 licensed international subsidiaries of well known world-wide based pharmaceutical corporations.

However, we should treat all such units as our national treasure, as all the people who work in this industry are all Pakistanis.

Together, all these 350 companies represent a very strong health care base in Pakistan, in terms of being able to provide a very wide range of quality life-saving, essential and non-essential or support medicines in virtually all therapeutic categories of the medicine, through a very well established manufacturing base and distribution system comprising many hundreds of efficient national, regional and town-wise distributors, stockiest, wholesalers, and of course over 40,000 retail chemist outlets



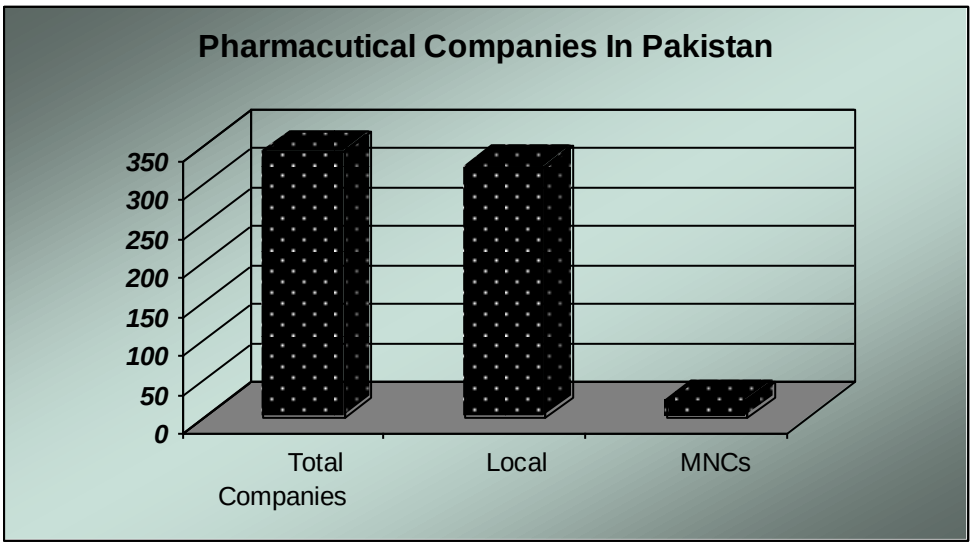
*__Source__: PPMA Lahore (Pakistan Pharmaceutical Manufactures Association)

Over the past 20 years or so, the national industry has improved its basic infrastructure by leaps and bounds, now reaching internationally accepted levels of quality in terms of Good Manufacturing Practices (GMP), quality assurance standards, efficient modern production systems and tremendous upgrading of specialized machinery and other plant equipment.

Recognition must be given to the Federal Health Ministry in this regard, which has worked relentlessly, especially over the past two decades, towards helping the industry attain this position today.

Out of all the manufacturing industries operating in Pakistan today, the pharmaceutical industry is perhaps one of the few which has attained high international standards and recognition, as is widely acknowledged in the existing and potential exports markets, which is evident by the ever-increasing export performance figures of medicines to over 30 different countries in Africa, Middle East, Far East, Europe, CIS States, Russian Federation, etc, both by national and international subsidiaries currently operating here.

The single distinguishing feature that separates the pharmaceutical industry from others is that of consistent quality. This intrinsic value is the hallmark of a good manufacturer, from product to product, from batch to batch, around the clock and throughout the year.



*Source: PPMA Lahore (Pakistan Pharmaceutical Manufactures Association)

This is an industry which requires constant, unwavering attention by the main regulatory authority, i.e. the Federal Health Ministry, which under the Drugs Act of 1976, along with its revisions and updates to keep abreast of developments, governs the storage, sale, distribution and manufacturing of registered medicines, of which there are currently over 28,000.

Our national industry produces over 80% of the national domestic demand, which is indeed a remarkable achievement.

Another interesting fact is that the overall quality of our locally produced medicines, both by high quality national companies and international subsidiaries, are of a visible and real higher standard when compared to those of neighboring and regional countries, both in terms of product and packaging quality.

Main Issues of Pakistani pharmaceutical Industry

Price Controls and Forced Price Reductions

While the Government of Pakistan has committed itself to allowing annual price increases utilizing a formula which considered currency devaluation

and local inflation, the last price increase was allowed in November 1996. Even when price increases were allowed, they were substantially below the indexed figure which represented the true cost increases that the industry had to bear. It is now two years since the last increase. Pharmaceutical Association seeks the support for the U.S. Government to ensure that the Government of Pakistan allows price increases immediately, and at a level which will be sufficient to stem the dramatically declining profitability of the research-based pharmaceutical industry during recent years.

Dramatic Decline in Profitability

A cost increase of 90% over the last five years generated by three factors an inflation of 76%, a devaluation of Pakistani currency by 85% in relation to the U.S. Dollar, and an introduction of duties of 10% beginning June 1996. Insufficient price increases which do not compensate for the cost increases. For "Controlled" drugs, the price increase was only 21% in the last five years For "Decontrolled" drugs; the price increase was only 29% in the last five years.

Compulsory Price Reductions

Government imposed compulsory price reductions on targeted products which were based on an unjustified price comparison with India.

There are three other recent developments that have harmed the industry significantly and have had enormous impact on pricing decisions. These include:

Show Cause Notices

With political pressure for cost containment, many multinational companies received Notices with orders to reduce prices of products by 30%. After negotiation, the industry agreed on reductions ranging from 5-28% on 21 packs of 17 products. (Double those numbers were on the original list). The drive behind this move is political and the reason given is the prices which prevail, for the same products, in India. Utilization of prices applicable to the Indian market is inappropriate when applied to pricing of pharmaceuticals in the Pakistani market. India has a significantly lower cost base for all materials, utilities and employee costs; and the purchasing power of the average Indian is significantly below a Pakistani citizen. In addition, all prices have, in any case, been approved by the Ministry of Health (MoH).

Furthermore, they ignore all those products where there is a much lower price in Pakistan than in India.

119 High Price Products

Apparently the MOH has a list of 119 packs of 56 products, including those already targeted, they consider having high prices (again the rationale is the price of these particular products in India). The likely outcome is that when prices are increased, these 119 presentations will not be allowed any increase.

Alleged Illegal Price Increases

There has been much recent coverage in the Pakistani media alleging that companies have been illegally raising prices. Such claims are untrue because of requirements that all price increases have to be notified to, and authorized by, the Ministry of Health. The MOH has the legal ability and right to take appropriate action to withdraw any increases made illegally. In fact, research-based companies have complied with the Government's controls on prices in good faith during the financial turmoil in Pakistan, only to find that the Government is reneging on its legal obligation to allow for annual price adjustments.

These data clearly demonstrate the serious difficulty facing the pharmaceutical industry. No other industry in Pakistan has been put under such stringent price control; and no other industry has been forced to reduce prices. Given the significant level of foreign investment and international quality of locally produced products, it is only fair that the Government of Pakistan seriously consider the negative impacts of the current economic environment upon the industry when making decisions regarding the price increases which are now due.

In order to return to the profitability level of four years ago (i.e. 1993) the Government-allowed price increase should be of over 50% according to the SRO 1038(I)94 formula. However, the industry understands that such a large increase cannot be approved by the government for political reasons. Furthermore, the industry would not wish to burden the people for humanitarian reasons.

In order to return to an acceptable minimum profitability level, PPMA supports the efforts of the research-based pharmaceutical industry in Pakistan to achieve:

1. Immediate implementation of upward adjustments for prices for "controlled" products recognizing that the adjustment due now is for a two year period from November 1996 to November 1998. A figure in excess of 20% will in no way compensate for the historical shortfall but will allow the industry to maintain supply of quality products.

2. The Government must commit to honoring annual price adjustments for controlled products in the future, according to an acceptable formula that will enable the industry to plan for the future with some confidence.

3. Either remove Customs Duty or allow compensation in price adjustment. Note that the adjustment must be to maintain margin not simply to pay the duty. Hence, since approximately 65% of industry cost base is imported material, the extra increase must be 6.5%.

4. Withdraw all notion of a high priced group of products on which no upward adjustments will be allowed.

5. Introduce the concept of market driven pricing for the "decontrolled" products (i.e. abolish any control over these prices.

Intellectual Property Barriers

Pakistan has a law for the protection of intellectual property. In Pakistan, patents are registered under the Patents & Designs Act of 1911 and trademarks are registered under the Trademarks Act of 1940. Protection for patents is for processes only, and the duration of protection normally is 16 years.

The Patents & Designs Act, 1911 (PDA) confers on the patentee exclusive privilege for making, selling and using his invention throughout Pakistan and of authorizing others so to do. The primary purpose of the PDA is to protect new invention and to encourage the growth of industry in the country.

In case the patentee is inadequately remunerated for his patent during currency of the patent period, he may apply to the Federal Government for patent extension at least six months before the expiry of the patent period. The Pakistan Government may refer the application to the High Court which may, after hearing, grant an extension for a period of five years.

The PDA covers "manners of new manufacture" i.e., process patent as registered in Pakistan. In the event the same item is manufactured from

another process, it would not be construed as patent infringement. As a consequence there is only little litigation of patent infringements cases registered in Pakistan. Moreover, there is always the chance that someone with a slightly different process can reproduce the same product/formula and market it at on an equal footing.

There are several specific problems with the Pakistan law in addition to its lack of product patent protection for pharmaceuticals. These include the following:

- The right of the patentee is not adequately protected in the law, with the result that the infringer continues to freely manufacture counterfeit products.
- Numerous pending cases in High Courts result in delay of justice. Due to the delay in the court proceedings, the patentee cannot immediately obtain injunction orders against infringer.
- The patent-owner only can file a suit against the infringer. The law does not allow a licensee of a pharmaceutical product to institute a legal proceeding against the infringer.
- There is always a threat of revocation of the patent through compulsory licensing. An application in the High Court can be filed claiming that the patented article in Pakistan is not being met to an adequate extent and on reasonable terms and can thus force a compulsory license to be issued.

In sum, the two basic issues are that: (a) more active legal enforcement should take place, and (b) product patents should be allowed as well. The existing law needs to be amended and clarified in terms of providing clear protection to genuine original patent holders, whose process patents are infringed upon by others who have a slightly different process. The law should provide protection in "letter and spirit" and there should be no lacunae in the law.

In addition, the penalties for infringement should be more severe, and there should be a dedicated Government Office, as well as a separate panel of well-trained judges who fully understand the laws and are competent exclusively to try intellectual property infringement cases. This could result in the formation of an effective deterrent to potential infringers.

PPMA does applaud the fact that, in 1996, Pakistan's Government moved expeditiously to provide a form of interim protection for certain qualifying pharmaceutical products through a "Mailbox" provision in its law, as per its obligations under TRIPS.

Other Barriers

Product Registration

The regulations to obtain a sales permit for a given pharmaceutical product require that the dossier of supporting data be accompanied by Certificates of Free Sale, confirming the approval for sale of the product in developed countries of the world, such as the U.S., Europe and Japan. The research-based industry has understood and accustomed itself to this requirement.

Now, however, it seems that the Pakistan Ministry of Health is unilaterally adopting a discriminatory policy against multinational pharmaceutical companies by insisting that they can only register products which are on sale in the country of incorporation of the respective company. Local companies, however, can register products from any source. This policy discriminates, therefore, against the research-based companies operating in Pakistan, many of which have registered in Pakistan as Pakistani companies.

Moreover, the general experience of many multinational pharmaceutical companies in Pakistan is that the time required for the registration process often is two years and sometimes longer. For the benefit of patients in Pakistan, and in view of increasing costs of pharmaceutical research and development and limited patent life of drugs, it is vital to keep the procedure of registration as brief as possible. PPMA believes it necessary that the Government of Pakistan enhance the capacity of its equipment and manpower sufficiently to complete a registration process within a maximum period of twelve months.

There is a related issue in this area which also concerns the research-based pharmaceutical industry in Pakistan, and that is the proposed amendments in the form of a revised application for the Renewal of Product Registration Form. There are several proposed amendments that are cumbersome, not really necessary, and, in some cases, irrational. The Technical/Regulatory Affairs Subcommittee of the Pharma Bureau in Pakistan (i.e., the local equivalent of PPMA) is examining these amendments with a view to filing formal objections to those clauses which they believe are not required, or discriminatory. However, it is still too early to paint a clear picture of where this issue stands and how far it has progressed.

Drug Labeling Rules

By a Pakistan Government notification dated August 24, 1994, the generic name of the substance has to be printed "with at least equal prominence as

that of the brand name." This has now been carried forward as policy by the Pakistan Government.
The addition of the generic name in equal prominence to the trademark constitutes an infringement of the proprietary rights of the originator. This is intended to dilute existing differences in quality, efficacy and safety, and incorrectly implies total interchangeability and equality of two different products. PPMA asks the U.S. Government to note that these laws also appear to place Pakistan in violation of WTO TRIPS rules protecting trademarks, and therefore should be amended to comply with TRIPS.

Potential Exports/Foreign Sales

Pakistan remains an "Outsider" in the global community of nations providing some form of intellectual property protection for pharmaceutical products. At present, there is no product patent protection in Pakistan, but only protection for processes. It is incumbent upon the patent holder in Pakistan to prove that the "pirate" is using the same process as the inventor, which is practically impossible in the current Pakistan legal environment. One of the most important current issues for our industry in Pakistan is that this piracy continues to inflict losses on the research-based pharmaceutical industry, now estimated at $15 million to $20 million per year. While these "losses" are not as significant as those that we incur in India, they still represent a threat to the industry's ability to utilize its resources for the discovery of new medicines to address problems of morbidity and mortality, and uncured diseases worldwide.

Specific Barriers of Pharmaceuticals Sector

Pakistan typically grants special tariff and tax exemptions for pharmaceuticals not available domestically. However, the special exemptions end once firms commence domestic manufacturing of competing pharmaceutical products. Pakistan periodically has increased the import surcharges known as "regulatory duties" on those imports which remain competitive despite the end of the special tariff exemptions. In addition, Pakistan has raised the sales taxes repeatedly on many imported pharmaceutical packaging and raw materials while prohibiting firms from passing the sales tax increases on to end-product customers. With effective tariff rates reaching 95 percent on some pharmaceutical raw materials and

with strict price controls in place, many foreign pharmaceutical firms reportedly are considering withdrawing altogether from the Pakistani market.

Labeling, Marking Requirements

Pakistan has no uniform or universal system of imposing labeling and marking requirements on products. However, individual industries or sectors are subject to the regulations of specific bodies. For example, the Ministry of Health sets requirements for the pharmaceutical industry.

High Tariffs & Import Taxes

Pakistan has traditionally maintained a complex system of indirect taxes in the trade sector. High basic tariffs, additional surcharges, a variety of excise taxes and sales tax with different applicability on domestic and foreign goods combine to distort prices in domestic markets. The tariffs, which were established for both protectionist and revenue raising motives, have become generally counter-productive. Many tariff rates are too high and stimulate smuggling and corruption. Revenue collections are also undermined by many exemptions and concessions. The government has since liberalized its trade regime, reduced tariff levels, and streamlined procedures for imports and exports.

Pakistan uses the Harmonized System to classify and describe goods. Customs duties are levied on an ad valorem basis. Maximum tariff rates were reduced from 92 percent to 70 percent in 1994 and to 65 percent in 1995. The government, encouraged by the World Bank and the IMF, decided to lower the maximum tariff rate in a phased manner, but delayed implementation of this decision until Prime Minister Nawaz Sharif announced drastic cuts in the tariff structure as part of his 1997 economic revival package. The maximum tariff rate has since been reduced to 45 percent.

Other than customs duty, the government charges sales tax (10-12.5 percent) on the duty paid value of a variety of goods produced in or imported into the country. Customs duty and other charges are payable in rupees.

The Pakistani tariff regime also is characterized by complexity, broad bureaucratic discretionary powers, and very limited transparency.

Administrative decisions frequently grant exemptions and concessions from general rules under the system of special regulatory orders (SRO) that amount to temporary duty suspension decrees. As a result, different rates are frequently applied to the same product and average applied rates are sometimes lower than statutory duties.

Complex Customs Procedures

Investors sometimes complain of a gulf between incentives advertised at the policy level and on-the-ground implementation, and these complaints often relate to customs problems. For example, preferential tariff rates are usually subject to the proviso that the goods in question are not domestically manufactured. Disputes sometimes arise over this provision, with investors arguing that local output, while available, does not meet their specifications. Investors also cite arbitrary and inconsistent customs valuations and frequent changes in rates. Delays are also reported in administration of the "duty drawback" scheme, which refunds partial tariff charges on imported inputs once the final output they were used for is exported. Charges that customs officers demand bribes are also common.

Customs Valuation

The government has canceled its controversial pre-shipment inspection (PSI) valuation system has reverted to Import Trade Price (ITP) based valuation system. The Import Trade Price manual is updated periodically to facilitate the valuation process.

Import Licenses

In 1993 Pakistan ceased requiring import licenses for all "freely importable" goods, (i.e., all items not on the negative list of items banned for religious, health, or security reasons, or justified according to provisions of international agreements). As Pakistan has liberalized its trade regime both on its own and as part of various trade agreements, Pakistan has reduced its negative list of banned import items from 215 categories of products in 1990 to 68 by 1996.

All importing firms in the private sector must register as importers with the Export Promotion Bureau and must have valid registration at the time of

importing. The government permits imports from all countries except Israel or goods originating in Israel. However, in the case of loans, credits or U.S. PL-480 (bilateral agricultural credits), imports shall be made subject to availability from the specified source only.

Importers must also:

- Obtain special authorization of the Ministry of Commerce for importing items from the negative/restricted list

- Ensure that correct Harmonized Schedule code number of every imported item is mentioned in the import documents.

Imports from India are a special case. Only items on a list issued by the Ministry of Commerce may be imported; that list includes 581 individual items, classified by Harmonized System numbers.

Government Procurement

The government, along with its numerous state-run corporations, is Pakistan's largest importer. Work performed for government agencies, including purchase of imported equipment and services, is usually awarded through tenders that are publicly announced and/or issued to registered suppliers. The government subscribes to principles of international competitive bidding, but political influence on procurement decisions is common, and these decisions are not always made on the basis of price and technical quality alone. Charges of official corruption and long delays in bureaucratic decision-making are common.

Pakistan is not a member of the World Trade Organization (WTO) Government Procurement Code.

Pakistani government agencies and public sector companies allow only exclusive agents to submit bids for tenders as an assurance that they receive only one quotation from each supplier. Many firms (especially Japanese) add a clause on direct negotiation which allows them to deal directly with the end-user, should the firm believe that the agent may have difficulty in concluding a sale. On such sales, the commission payable to the agent, if

any, is determined by the principals and is based on the proportion of services rendered by the agent.

Pakistani law does not prohibit payment of commissions on commercial procurement of large amounts of military equipment. However, the Directorate General Defense Purchase (DGDP) requires that the foreign principal provide the following:

- Ex-factory value of items supplied
- Free on board (FOB) value of these items; and
- Percentage or amount of commission/or any other fee for services provided by the local agent.

Legislation and bureaucracy

The Patent Office in Pakistan is understaffed and under equipped leading to a potential backlog of applications in 2005. Prices of drugs in Pakistan are higher than in other countries of the region. During the last decade 156 drugs have registered an increase in price of between 200 and 700 per cent. Any further rise in the price of drugs to consumers would have serious implications in a country where the average annual per capita income is $460 and 38 per cent of the 140 million populations earn less than a dollar a day. Government-provided healthcare reaches only 20 per cent of the population, with most of the remaining 80 per cent uninsured. It is estimated that almost half the population has no access to primary healthcare. The price of drugs has been a sensitive issue for many years. In 1993, prices were deregulated as part of the free market agenda adopted under pressure from international finance institutions. However, following significant price rises they were frozen again in 1994. Then in March 2002, as part of an agreement with the International Monetary Fund, the government raised general sales tax on non-life-saving drugs from 0 to 15 per cent. That decision was rescinded five months later after widespread protest. That, in turn, led to severe shortages on the market as the government had not announced a mechanism for refunding tax on existing stocks.

As a member of the WTO, Pakistan is moving to introduce Trips compliant domestic patent laws. Until 2000, patents were governed by the Patent and Design Act 1911, a law introduced in colonial times. The Patent Ordinance 2000 is criticized for being made in haste and without public consultation. “There wasn’t enough debate. The process wasn’t given enough time,” says Aziz Ur Rehman, a specialist in intellectual property rights who teaches at the Islamabad-based Islamic University. Zafar Mirza of The Network for

Consumer Protection, a leading non-governmental organization, claims that the new law does not fully exploit all the public health provisions in TRIPs. "The government genuinely thinks it has framed a good law. It doesn't want to accept that the law is flawed. It could have been a robust piece of legislation," he says. He adds: "The debate is how to have a provision which could be invoked when drugs are available in the market but are out of the reach of the people." Implementation of the law depends largely on the capacity of the Patent Office and the judiciary. The Patent Office was established in 1948. Headed by controller Yasmeen Abbasi, a law graduate with training in patent-related issues, the Patent Office falls under the jurisdiction of the Ministry of Commerce and Industry. Sitting in a poorly furnished hall are two assistant controllers, and four patent examiners, who comprise the only technical staff to handle all patent applications, including pharmaceutical. Last year the Patent Office received 1,200 applications for patent and design registration an average of 300 per examiner or more than one every working day. All paperwork, filing and documentation is done manually. Computers have been provided by the World Intellectual Property Organization, but the appropriate software had not been developed by mid-2002. Because patents are under transition and product patents will not be granted before 2005, applications are being received under the
"Mailbox" system. Currently, 90 per cent of pharmaceutical applications are from multinational corporations, and 95 per cent of those are related to chemicals, both product and process. Exclusive marketing rights are granted to all patent applicants, preventing generic versions being old before resolution of the patent in 2005.Abbasi points out that since TRIPs the workload on her office has increased many times. However, the real challenge will come when the mailbox is "opened" and thousands of applications will have to be processed within the stipulated period of 20 months. That will be impossible under the current set-up. Abbasi has requested a better working environment, computerization, online research facilities, staff incentives and specific examiners for specific fields. She has proposed that a proportion of application fees be allocated to the Patent Office rather than going to the national exchequer.

CHAPTER #6

CONCLUSION

Conclusion

This analysis of the implications of the TRIPS agreement for the pharmaceutical industry in Pakistan is merely the starting point for a continuing process. Ongoing changes in the structure of the economy, regulations, patent laws and a myriad of other factors mean that further study and action will be needed. The TRIPS provisions relating to patentability, the effects of protection or term of patents, transitional period arrangements, compulsory licensing, exclusive marketing rights, and the burden of proof will require further review.

The Pakistani government, the private sector and the population in general should prepare themselves for the consequences of the country's Patent Drug Act. In both the short and the long term, some economic disadvantages are expected for the Pakistani pharmaceutical industry.

Each country has specific, sometimes unique, characteristics and needs. Domestic laws and regulations therefore have to be changed in order to match national conditions and help to orientate the pharmaceutical industry in a desirable way, while allowing compatibility with international agreements. The present Research does not reveal any price change due to the patent protection act and does not provide strong evidence of FDI and technology transfer. In anticipation of price movement or low-grade technology transfer, the research proposes that some aspects of the existing Patent Act be changed in particular, that attention be given to the following:

The term or duration of patent protection; non-patentable subject matter; the rights and privileges of patentees; import monopoly; non-voluntary licenses unrelated to non-working patents; the definition of working and non-working patent; actions against non-working patents (e.g. provision for revocation or for feature of patent); stipulation on conditions promoting

technology transfer; the repeal of any disadvantageous interim measures; and regulatory mechanisms. Bolar provision (early working) is another exception specifically applicable to pharmaceutical patents. It relates to using an invention without the patentee's authorization for the purpose of obtaining approval of a generic product before the patent expiration date.

An appropriate time frame for effective action and the extent to which patent laws are implemented and practiced would undoubtedly help to alleviate the economic burden of buying more expensive drugs. In the long run, Pakistan should endeavor to learn more from other countries before fully committing itself to new aspects of more progressive intellectual property protection, e.g. patent term extension. Above all, the involvement of the government is extremely important if progressive development is to be ensured. The pharmaceutical industry has not received enough consideration and national authorities should have a clear vision for this industry and should understand the implications for health if they do nothing. Lessons learnt from other countries and continuing study can be expected to lead to solutions appropriate to conditions in Pakistan. The provision and revision of pharmaceutical policies should not only conform to present standards in the industry and to international commitments but should also ensure an improved quality of life for the Pakistani people as a whole.

Recommendations

In the long run, only the strongest companies are likely to survive in the Pakistani pharmaceutical market. However, it is doubtful whether many of them will be Pakistani-owned. In anticipation of future market conditions, therefore, Pakistani companies should focus on those areas where they are most skilful. Many chemicals are still not covered by patent law, and the development of drugs from these chemicals is therefore potentially profitable for local pharmaceutical industries. Full drug development is expensive and currently unrealistic, not only for Pakistani companies but also for those in many other countries that are not research-based. Pakistan would gain by investing in areas where it is relatively competent and where benefits are likely to be obtained for society as a whole. At the same time, key players in the Pharmaceutical sector have to prepare themselves for a new era of competition.

As a Member of WTO, Pakistan has to comply with the mandates set forth in the TRIPS Agreement. With a view to alleviating the potentially negative impact of such compliance we propose a strategy with the following components.

WTO is a reality, which has come to stay. We have to face the emerging challenges and grasp the opportunities. We need to develop strategy to get maximum benefit from globalization.

The foremost areas of concern are:

- An innovative purchaser strategy to establish rational cost-effective drug selection procedures for public and private health care facilities and to create a government financing system for drugs and other aspects of health care.

- A prescriber and dispenser strategy to promote the rational use of drugs in health facilities and encourage the prescribing of generic drugs. Both national and multinational firms should be urged to

develop an agreed set of business practices to ensure maximum benefit for the public and punish the unethical promotion of medicine

WAYS AND MEANS TO FACE THE CHALLENGES OF W.T.O. COMING INTO FORCE IN 2005

TRIPS, GATS, Trade Remedy Laws, Agriculture, TBT, SPS and TRIMs are of great importance.

Steps to be taken on TRIPS Issues

(i) Pakistan is on the watch list of special 301 report issued by USTR and this indicates that if we will not improve the IP enforcement regime there are chances that our status may be raised to priority watch list which would reflect us as an investment unfriendly country.

(ii) A pharmaceutical policy and agro-chemical policy should be devised keeping in view the deadline of 31st December, 2004.

(iii) Documentation and listing of Geographical Indications.

(iv) Document and list all sources of Traditional Knowledge, folklore, and arts / crafts

(v) Negotiate common Geographical Indications with India, Bangladesh, Iran, Turkey, Central Asian Republics and other SAARC members, for their protection.

(vi) Regarding TRIPS negotiations on public health, Pakistan should not agree to any specific list of diseases so that we have the policy space to cope with any epidemics that may sprout in future.

Technical Barriers to Trade

Technical Barriers to Trade (TBT) is a major impediment to international trade as it imposes an unnecessary restriction especially on the exports of developing countries. So, Pakistan should following steps at international;

(i) It should be ensured that countries should regulate TBT measures only to the extent necessary to protect public health and safety or other legitimate objectives.

(ii) Technical regulations should be simple and based on basic requirements.

(iii) To mitigate the conflicts about standards, International standards should be followed than the national or regional standards. And for formulation of such international standards each contracting party should be involved.

General Suggestions

- Pakistan should supports removal of tariff peaks and tariff escalation.

- General reduction of tariff levels on all goods of export of developing country especially, with reference to Pakistan, in pharmaceutical and textile.

The proposals for negotiations:

- Do not commit any thing on applied tariffs and the bound tariff lines should be negotiated to keep them as high as possible.

- To safeguard local industry, additional time should be borrowed under the Special and Deferential (S & D) treatment avenues. The auto mobile sector, for instance, cannot withstand tariff free market for a certain period of time.

- While textile quotas will come to an end by December 2004, it should be made sure that North should give us enough market access through considerably reducing tariffs on value added (from semi-manufactured to finished products) textile items and phasing out export subsidies.
- Practically, after abolishing of quotas the West is going to provide access to textile products which are of little interest to developing countries. Free trade areas further pose difficulties to countries like Pakistan in this sector.

- WTO failed to enhanced employment opportunities, technology transfer and sustainable development in developing countries. So, Pakistan should engage itself in the WTO very vigilantly and must take strong and proactive position to review the WTO process so far before making any further progress or expansion in the system.

Government's Role

- To face the WTO challenges ahead, government, private sector and civil society (NGOs) should work together and in future negotiations.

- Experts from civil society organization should also be included in the official delegation to WTO.

- There is an important need for cost-benefit analysis along the way. This is more important with reference to the fallout on poor people, employment, incomes, small and medium scale businesses, informal sector, environment and rational development goals.

- For current negotiations, we need to chalk out, initially, our overall and sector specific objectives.

- During the negotiations, whatever then suits our objectives we should go for that and we resist moves that are detrimental to our economy, sovereignty, people, local industry, etc.

- Pakistan needs both defensive position (to safeguard our current agriculture system) and offensive position (to earn maximum market access) simultaneously to won the negotiations in country's favor.

Other Recommendations

1. The country urgently needs to build a strong network of Anti-dumping and countervailing duties to protect the local industry against the onslaught of unfair foreign competition. It is heartening to note that Trade Policy 2003-04 envisages enhancement of capabilities of NTC and it is further recommended that NTC should be restructured and converted into an autonomous body employing private sector professionals. This is

necessitated, apart from other reasons, by the fact that many a cases involving dumping pertain to firms belonging to friendly countries like China against whom government is reluctant to initiate proceedings.

2. The developing countries including Pakistan face problems in hiring law firms to advice on WTO related issues, which is a constraining factor in seeking relief from Dispute Settlement Body. This underscores the need to train local lawyers with WTO expertise.

3. Our survival lies in enhancing credibility through adoption of international quality standards, but Pakistan has a long way to go in obtaining certifications of ISO9000, IS014000 and other standards. We need to set up PNAC accreditation testing laboratories for conformity assessment.

4. GoP must collect data in respect of standards of pharmaceutical manufacturing companies.

5. GoP may amend the policies for manufacturing of pharmaceutical products so that it' offsets the effect on their performance due to termination of grace period of TRIMS by end 2004.

6. We should take up our concern at WTO for a regarding replacement of tariff barriers by some countries with SPS and TBT - which is evident from increased emphasis being placed on inspection of imported food and agricultural products.

7. As a member of WTO, Pakistan is committed to fulfilling TRIPS obligations, for which five law amendments have been promulgated. There is urgency for enforcement of laws regarding infringement of IPRS, a sine qua non for attracting foreign investment, for which necessary rules should be framed and notified on a priority basis. The Government had announced, in Trade Policy 2002-03, establishment of umbrella organization PIPRO for improving the administration and enforcement scenario, but necessary legislation for PIPF,C.) to start functioning is still pending.

8. Pakistan has done well by undertaking liberalization measures relating to communication and financial sectors well over and beyond its commitments under GATS. But the measures have not been translated

into internationally binding commitments. We should undertake partial or full commitments, where feasible, which will provide an assured and relatively stable environment for investment for foreigners and overseas Pakistanis. Attempts may be made to obtain commercial quid pro quo from other countries. Pakistan in collaboration with other LDCs needs to stress for further progress on the issue of movement of natural persons, which is an unfinished agenda of GATS.

9. According to a recent study, the major flaw in Pakistan's approach towards GATS has been that while it paid a great deal of attention to inward flow of foreign investment and technology it did not view GATS as a means of export of its services. This needs to be rectified.

10. As the time-bound concessions given to developing and least developed countries with regard to implementation of commitments under WTO, have either expired or are about to expire. But the developing countries are still in a low level of economic equilibrium, which was the raison d'etre of grant of grace period. There was, however, one exception relating to applicability of WTO norms on "prohibited subsidies", contingent upon export performance admissible to 20 countries including Pakistan until they attain per capita GNP of US $ 1000. We suggest that other concessions of grace period should likewise be linked with attainment of specific level of economic progress and institutional capabilities.

11. Besides, most of the provisions of WTO Agreements regarding S& D. treatment are declaratory. In the absence of implementation modalities, these provisions have not been of any particular use to developing countries. Pakistan should evolve joint strategy with other developing states and press hard at Cancun Ministerial for finalization of necessary modalities, as envisaged in Doha Development Agenda.

12. In this era of globalization, regionalism has assumed great importance. It is high time that we make SAARC and ECO more proactive to spur up intra- regional trade to ward off the risk of being marginalized.

13. The core WTO related issues are discussed and debated in the technical committees, where our participation is not effective, as it is not backed by background research for submission of technical papers. This underscores the need for meaningful coordination of efforts at

Government level and industry level under the aegis of SAARC to ensure effective participation in the meetings.

14. We still do not possess the institutional and technical capabilities to develop, advocate and formulate the standards and legislations to meet the WTO requirements, while WTO, in principle, offers technical assistance to developing countries to develop the capabilities to implement obligations and to benefit from its membership rights, Pakistan has not tapped into these opportunities well. It is time that we take full advantage of technical assistance and capacity building programs of WTO and other multilateral agencies.

15. There is urgent need for capacity building of private sector institutions for dissemination of information on WTO and provide research feedback to Government for policy formulation and for their on going negotiations with WTO under Doha Round.

16. GoP should take up studies to ascertain the impact on trade of Pakistan
    - Due to accession of China to WTO.
    - Due to the enlargement of European Union from 15 to 20 countries.
    - Due to bilateral agreements in which countries of our interest are also involved.

17. Alternative methods of worldwide sharing of R&D costs should be developed.

18. Unilateral pressure on countries to adopt trade, patent or health legislation that is not in the public interest and is not legally required should be ended.

19. Reliable cost data on the development of new drugs should be made public.

20. Commitment of funding by the international community, and many different partnerships between governments, multilaterals, non-governmental organizations, research institutions and private companies.

21. Public involvement to ensure development of new drugs for certain priority health problems.

22. WIPO should integrate development objectives into its approach to intellectual property protection.

23. Ministries of health must work closely with other ministries (trade, justice etc) to formulate and/or revise national patent legislation to ensure that public health needs are fully taken into account.

24. National legislation should narrow to an absolute minimum the type and scope of pharmaceutical patents.

25. Developing countries should ensure that their legislation allows for compulsory licensing.

26. Proposed national legislation should be subject to extensive scrutiny by policy-makers, the media, non-governmental organizations and others representing patients' needs and rights.

27. Least-developed countries should delay granting of pharmaceutical patents as long as possible.

28. Development objectives should be integrated into the promotion of intellectual property rights in developing countries.

29. There should be policies and commitment by governments to establish funding priorities and national healthcare capacity.

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Annexure

Glossary

Bioequivalence (of drugs) having the same effect on the body as another drug

Bolar Provision a rule in patent law which allows generic manufacturers to develop drugs while they are still under patent so that they can be stockpiled and then marketed immediately the patent expires.

Compulsory Licensing a license issued by a court or government to produce a generic version of a patented product, while the patent holder is compensated through royalties from sales ever greening extending a monopoly by taking out a new patent on a minor aspect of a product once the main patent is due to expire generic a version of a patented drug that meets bioequivalence tests and has the same pharmaceutical presentation and dosage as the original drug.

Intellectual Property (IP) a creation of the mind, such as inventions, artistic works and trademarks invention a product or process which is new, useful and capable of manufacture parallel trade the import of branded patented goods without the approval of the patent holder the intellectual property right for an invention.

TRIPS international agreement on Trade- Related Aspects of Intellectual Property Rights

Intellectual property refers to creations of the mind such as Inventions and artistic works

Invention it is defined as a product or a process which is new, useful and capable of manufacture.

Patent It is the intellectual property right for an invention –the monopoly right to benefit financially from the invention for a limited period. Patents were originally designed for industrial technical inventions A patent is applied for and functions in each country separately. Most countries have laws to protect intellectual property and a national patent office to assess and approve patent applications. Different countries may have different views about whether something fulfils the requirements for a patent – that it is really something new, for example. Some countries have formed regional patent offices, such as the European Patent Office and the African Regional Industrial Property Organization, to examine patent applications. The World Intellectual Property Organization (WIPO) accepts a single international application that is valid in many countries, but patents are still granted on a national basis.

The World Intellectual Property Organization (WIPO) is the principal international institution responsible for organizing the negotiation and administration of intellectual property (IP) treaties.

VOLUNTARY LICENSING : The granting of license by the patent holder to a third party of the right to manufacture a product for a specific market.

ABBREVIATIONS

WTO	World Trade Organization
EMR	Exclusive market rights
PPMA	Pakistan Pharmaceutical Manufacturing Association
S & D	Special and Deferential
CIPR	Commission on Intellectual Property Rights
TRIPS	Trade-related Intellectual Property Rights
TBT	Technical Barriers to Trade
USTR	United States Trade Representative
ILO	International Labor Organization
MFN	Most favored-nation
GSP	Generalized System of Preferences