Chapter-3

WTO-TRIPs and Public Health
Chapter 3: WTO-TRIPs and Public Health

3.1 INTRODUCTION
The developing countries today face the complex challenge of implementing various international agreements that were negotiated during the Uruguay Round. In the process, they are becoming aware of the many far-reaching implications for their development, economies and societies inherent in some of these agreements.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) is a case in point. Its implementation is emerging as a major concern for all developing countries. The present document was prepared with the intention of assisting the developing countries in their efforts to adapt their laws to the standards set by TRIPs in relation to pharmaceutical products and processes, in the context of a general concern that such legislative reform can have a major impact on people’s access to drugs and on public health policies in the South. In particular, the document aims to show that various options exist for developing countries in formulating their national legislation in conformity with the relevant provisions of TRIPs.

The importance of policy-oriented and technical analyses of this kind for developing countries is evident. They provide essential, practical tools to assist developing countries in promoting their national and global development objectives.

Post World War II, the Western Allies had set up international organizations and regulations that would form the basis for an international economic order based on economic liberalism and trade cooperation. Thus, the 1944 Bretton Woods agreements created the International
Monetary Fund and the World Bank. Thereafter, the General Agreement on Tariffs and Trade (GATT) was signed in 1947 and was recently succeeded by the World Trade Organization (WTO) in 1995. The liberalization of trade flows was undertaken rapidly after the war and world trade increased faster than world GDP. Indeed, trade in merchandise rose to 6.2 trillion dollars in 2000 from 58 billion dollars in 1948, which corresponds to a multiplication of nearly 22 times in the volume of trade (an average annual increase of 6%). Over the same period, world GDP in real terms was multiplied by 7, or an average annual increase of 4%. The nature of trade also changed profoundly.

Progress in dismantling barriers to trade was achieved through negotiations between the contracting parties of the GATT. GATT had evolved into an increasingly lengthy process over the years due to both the increasing number of member countries and issues discussed. Until the Kennedy Round, negotiations had essentially focused on lowering tariff barriers on manufactured goods. Beginning with the Tokyo Round, the scope of negotiations was widened to non-tariff barriers on manufactured products, and agricultural issues began to be raised.

However, it was during the long negotiations of the Uruguay Round, 1986 to 1993, closing with the 1994 Marrakech Agreement, as the decisive steps were taken. Indeed, until this round, the industrialized countries the US and Europe - had been the main actors in the liberalization process, which concerned almost exclusively the lowering of tariff and non-tariff barriers on manufactured goods. Over the course of the Uruguay Round, agriculture once again became a major issue, when prior to the Uruguay Round, agriculture had for the most part been the subject of exemptions. The same held true for textiles.
However, the Uruguay Round participants decided to bring textiles back within the scope of WTO rules by gradually dismantling the Multifibre Agreement of 1974. This agreement had limited imports into countries whose national production sectors could be weakened by a flood of foreign products. The Uruguay Round allowed for a decrease in tariff duties of 36%, which, including all countries fell from 9.9% to 6.5%\textsuperscript{41, 42}. In addition, the number of products subject to high import duties was reduced.

Moreover, the goal of regulatory integration was added to the effort on tariff integration. The new and extremely ambitious issues of services, investments and intellectual property were also brought forward during this round. Taking into account the legal and regulatory impact on the national level for each of the member countries, these new themes are especially sensitive for developing countries. Despite their sometimes-diverging interests, in these negotiations they began coalescing into a genuine force capable of making proposals.

The Trade Related Intellectual Property Rights (TRIPS) Agreement came into existence the same day the WTO did, as it was a result of the Uruguay Round of negotiations for GATT. Intellectual Property Rights (IPRs) are the limited rights legally granted to someone who creates a new product to be the sole producer of the product for a definite period of time. IPR are very important for researchers who invest significant time and money into developing a new product, be it a new way of making the pulp for paper, a faster computer chip, a new genetically engineered type of banana, or a new pharmaceutical drug. While research costs are high, once the new idea or method comes about, it is usually very easy to reproduce. Thus without IPR protection, there would be little incentive for anyone to invest in innovation.

At the Doha World Trade Organization (WTO) Ministerial Conference (9-14 November 2001), the WTO Members decided to adopt a special declaration on issues related to the
Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) and Public Health. Discussion on this declaration was one of the outstanding issues at the Conference, which launched a new round of trade negotiations on a broad range of issues. This was the first outcome of a process that started in early 2001 when, upon the request of the African Group, the Council for TRIPS agreed to deal specifically with the relationship between the TRIPS Agreement and Public Health.

In summary, this chapter provides details of international framework of WTO, TRIPS agreements and important milestones such as Doha declaration and its implication on public health issues.

3.2 BRIEF HISTORY OF WTO-TRIPS AGREEMENT

The WTO's creation on 1 January 1995 marked the biggest reform of international trade since after the Second World War. It also brought to reality — in an updated form — the failed attempt in 1948 to create an International Trade Organization. Much of the history of those 47 years was written in Geneva. But it also traces a journey that spanned the continents, from that hesitant start in 1948 in Havana (Cuba), via Annecy (France), Torquay (UK), Tokyo (Japan), Punta del Este (Uruguay), Montreal (Canada), Brussels (Belgium) and finally to Marrakesh (Morocco) in 1994. During that period, the trading system came under GATT, salvaged from the aborted attempt to create the ITO. GATT helped establish a strong and prosperous multilateral trading system that became more and more liberal through rounds of trade negotiations. But by the 1980s the system needed a thorough overhaul. This led to the Uruguay Round, and ultimately to the WTO.
From 1948 to 1994, the General Agreement on Tariffs and Trade (GATT) provided the rules for much of world trade and presided over periods that saw some of the highest growth rates in international commerce. It seemed well-established, but throughout those 47 years, it was a provisional agreement and organization. The original intention was to create a third institution to handle the trade side of international economic co-operation, joining the two Bretton Woods institutions, the World Bank and the International Monetary Fund. Over 50 countries participated in negotiations to create an International Trade Organization (ITO) as a specialized agency of the United Nations.

The draft ITO Charter was ambitious. It extended beyond world trade disciplines, to include rules on employment, commodity agreements, restrictive business practices, international investment, and services. Even before the talks concluded, 23 of the 50 participants decided in 1946 to negotiate to reduce and bind customs tariffs. With the Second World War only recently ended, they wanted to give an early boost to trade liberalization, and to begin to correct the legacy of protectionist measures which remained in place from the early 1930s.

This first round of negotiations resulted in 45,000 tariff concessions affecting $10 billion of trade, about one fifth of the world’s total. They also agreed that they should accept some of the trade rules of the draft ITO Charter. This, they believed, should be done swiftly and provisionally in order to protect the value of the tariff concessions they had negotiated. The combined package of trade rules and tariff concessions became known as the General Agreement on Tariffs and Trade. It entered into force in January 1948, while the ITO Charter was still being negotiated. They became founding GATT members (officially, contracting parties).
Although the ITO Charter was finally agreed at a UN Conference on Trade and Employment in Havana in March 1948, ratification in some national legislatures proved impossible. The most serious opposition was in the US Congress, even though the US government had been one of the driving forces. In 1950, the United States government announced that it would not seek Congressional ratification of the Havana Charter, and the ITO was effectively dead. Even though it was provisional, the GATT remained the only multilateral instrument governing international trade from 1948 until the WTO was established in 1995.

For almost half a century, the GATT's basic legal principles remained much as they were in 1948. There were additions in the form of a section on development added in the 1960s and plurilateral agreements (i.e. with voluntary membership) in the 1970s, and efforts to reduce tariffs further continued. Much of this was achieved through a series of multilateral negotiations known as trade rounds the biggest leaps forward in international trade liberalization have come through these rounds which were held under GATT's auspices. In the early years, the GATT trade rounds concentrated on further reducing tariffs. Then, the Kennedy Round in the mid-sixties brought about a GATT Anti-Dumping Agreement and a section on development.

The Tokyo Round during the seventies was the first major attempt to tackle trade barriers that do not take the form of tariffs, and to improve the system. The eighth, the Uruguay Round of 1986–94, was the last and most extensive of all. It led to the WTO and a new set of agreements.
Following is the Tabular summary of the GATT trade rounds:

Table-3.1 - The GATT Trade rounds

<table>
<thead>
<tr>
<th>Year</th>
<th>Place/Name</th>
<th>Subjects Covered</th>
<th>Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>1947</td>
<td>Geneva</td>
<td>Tariffs</td>
<td>23</td>
</tr>
<tr>
<td>1949</td>
<td>Antwerp</td>
<td>Tariffs</td>
<td>13</td>
</tr>
<tr>
<td>1951</td>
<td>Torquay</td>
<td>Tariffs</td>
<td>38</td>
</tr>
<tr>
<td>1956</td>
<td>Geneva</td>
<td>Tariffs</td>
<td>26</td>
</tr>
<tr>
<td>1960-1961</td>
<td>Geneva (Dillon Round)</td>
<td>Tariffs and anti-dumping measures</td>
<td>13</td>
</tr>
<tr>
<td>1964-1967</td>
<td>Geneva (Kennedy Round)</td>
<td>Tariffs</td>
<td>26</td>
</tr>
<tr>
<td>1973-1979</td>
<td>Geneva (Tokyo Round)</td>
<td>Tariffs, non-tariff measures, &quot;framework&quot; agreements</td>
<td>102</td>
</tr>
<tr>
<td>1986-1994</td>
<td>Geneva (Uruguay Round)</td>
<td>Tariffs, non-tariff measures, rules, services, intellectual property, dispute settlement, textiles, agriculture, creation of WTO, etc.</td>
<td>123</td>
</tr>
</tbody>
</table>

Source: website, www.wto.org

Out of the above rounds of negotiations, last two rounds were the most intense rounds which have led to the formation of WTO. Following is the brief summary of these rounds.

3.3 THE TOKYO ROUND

The Tokyo Round lasted from 1973 to 1979, with 102 countries participating. It continued GATT's efforts to progressively reduce tariffs. The results included an average one-third cut in customs duties in the world's nine major industrial markets, bringing the average tariff on industrial products down to 4.7%. The tariff reductions, phased in over a period of eight years, involved an element of harmonization: the higher the tariff, the larger the cut, proportionally. In other issues, the Tokyo Round had mixed results.

It failed to come to grips with the fundamental problems affecting farm trade and also stopped short of providing a modified agreement on safeguards (emergency import measures). Nevertheless, a series of agreements on non-tariff barriers did emerge from the negotiations, in some cases interpreting existing GATT rules, in others breaking entirely new ground. In most cases, only a relatively small number of (mainly industrialized) GATT members subscribed to these agreements and arrangements.
3.4 THE URUGUAY ROUND

It took seven and a half years, almost twice the original schedule. By the end, 123 countries were taking part. It covered almost all trade, from toothbrushes to pleasure boats, from banking to telecommunications, from the genes of wild rice to AIDS treatments.

It was quite simply the largest trade negotiation ever, and most probably the largest negotiation of any kind in history. At times it seemed doomed to fail. But in the end, the Uruguay Round brought about the biggest reform of the world's trading system since GATT was created at the end of the Second World War. And yet, despite its troubled progress, the Uruguay Round did see some early results.

Within only two years, participants had agreed on a package of cuts in import duties on tropical products which are mainly exported by developing countries. They had also revised the rules for settling disputes, with some measures implemented on the spot. And they called for regular reports on GATT members' trade policies, a move considered important for making trade regimes transparent around the world.

The seeds of the Uruguay Round were sown in November 1982 at a ministerial meeting of GATT members in Geneva. Although the ministers intended to launch a major new negotiation, the conference stalled on agriculture and was widely regarded as a failure. In fact, the work programme that the ministers agreed formed the basis for what was to become the Uruguay Round negotiating agenda. Nevertheless, it took four more years of exploring, clarifying issues and painstaking consensus-building, before ministers agreed to launch the new round.
They did so in September 1986, in Punta del Este, Uruguay. They eventually accepted a negotiating agenda that covered virtually every outstanding trade policy issue. The talks were going to extend the trading system into several new areas, notably trade in services and intellectual property, and to reform trade in the sensitive sectors of agriculture and textiles. All the original GATT articles were up for review.

It was the biggest negotiating mandate on trade ever agreed, and the ministers gave themselves four years to complete it. Two years later, in December 1988, ministers met again in Montreal, Canada, for what was supposed to be an assessment of progress at the rounds half-way point.

The purpose was to clarify the agenda for the remaining two years, but the talks ended in a deadlock that was not resolved until officials met more quietly in Geneva the following April. Despite the difficulty, during the Montreal meeting, ministers did agree a package of early results. These included some concessions on market access for tropical products — aimed at assisting developing countries as well as a streamlined dispute settlement system, and the Trade Policy Review Mechanism which provided for the first comprehensive, systematic and regular reviews of national trade policies and practices of GATT members.

The round was supposed to end when ministers met once more in Brussels, in December 1990. But they disagreed on how to reform agricultural trade and decided to extend the talks.

Despite the poor political outlook, a considerable amount of technical work continued, leading to the first draft of a final legal agreement. This draft “Final Act” was compiled by the then GATT director-general, Arthur Dunkel, who chaired the negotiations at officials level. It was put on the table in Geneva in December 1991.
The text fulfilled every part of the Punta del Este mandate, with one exception it did not contain the participating countries' lists of commitments for cutting import duties and opening their services markets. The draft became the basis for the final agreement. Over the following two years, the negotiations lurched between impending failure, to predictions of imminent success. Several deadlines came and went.

New points of major conflict emerged to join agriculture: services, market access, anti-dumping rules, and the proposed creation of a new institution. Differences between the United States and European Union became central to hopes for a final, successful conclusion.

In November 1992, the US and EU settled most of their differences on agriculture in a deal known informally as the Blair House accord. By July 1993 the “Quad” (US, EU, Japan and Canada) announced significant progress in negotiations on tariffs and related subjects (“market access”).

It took until 15 December 1993 for every issue to be finally resolved and for negotiations on market access for goods and services to be concluded (although some final touches were completed in talks on market access a few weeks later). On 15 April 1994, the deal was signed by ministers from most of the 123 participating governments at a meeting in Marrakesh, Morocco. The delay had some merits. It allowed some negotiations to progress further than would have been possible in 1990: for example some aspects of services and intellectual property, and the creation of the WTO itself. But the task had been immense, and negotiation-fatigue was felt in trade bureaucracies around the world.
The difficulty of reaching agreement on a complete package containing almost the entire range of current trade issues led some to conclude that a negotiation on this scale would never again be possible. Yet, the Uruguay Round agreements contain timetables for new negotiations on a number of topics. And by 1996, some countries were openly calling for a new round early in the next century.

The response was mixed; but the Marrakesh agreement did already include commitments to reopen negotiations on agriculture and services at the turn of the century. These began in early 2000 and were incorporated into the Doha Development Agenda in late 2001.

The WTO replaced GATT as an international organization, but the General Agreement still exists as the WTOs umbrella treaty for trade in goods, updated as a result of the Uruguay Round negotiations. Trade lawyers distinguish between GATT 1994, the updated parts of GATT, and GATT 1947, the original agreement which is still the heart of GATT 1994.

3.5 WTO AND ITS PRINCIPLES OF TRADE

The WTO began life on 1 January 1995, but its trading system is half a century older. Since 1948, the General Agreement on Tariffs and Trade (GATT) had provided the rules for the system. (The second WTO ministerial meeting, held in Geneva in May 1998, included a celebration of the 50th anniversary of the system.) It did not take long for the General Agreement to give birth to an unofficial, de facto international organization, also known informally as GATT.

Over the years GATT evolved through several rounds of negotiations. The last and largest GATT round, was the Uruguay Round which lasted from 1986 to 1994 and led to the WTOs creation. Whereas GATT had mainly dealt with trade in goods, the WTO and its agreements
now cover trade in services, and in traded inventions, creations and designs (intellectual property). As of Today, World Trade Organization (WTO) deals with the rules of trade between nations at a global or near-global level.

The WTO agreements are lengthy and complex because they are legal texts covering a wide range of activities. They deal with: agriculture, textiles and clothing, banking, telecommunications, government purchases, industrial standards and product safety, food sanitation regulations, intellectual property, and much more. But a number of simple, fundamental principles run throughout all of these documents. These principles are the foundation of the multilateral trading system.

A brief summary of these principles is discussed as follows:

3.5.1 MOST-FAVORED-NATION (MFN): TREATING OTHER PEOPLE EQUALLY

Under the WTO agreements, countries cannot normally discriminate between their trading partners. Grant someone a special favour (such as a lower customs duty rate for one of their products) and you have to do the same for all other WTO members. This principle is known as most-favoured-nation (MFN) treatment.

It is so important that it is the first article of the General Agreement on Tariffs and Trade (GATT), which governs trade in goods. MFN is also a priority in the General Agreement on Trade in Services (GATS) (Article 2) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (Article 4), although in each agreement the principle is handled slightly differently. Together, those three agreements cover all three main areas of trade handled by the WTO.
For the purpose of this study we would be focusing only on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

3.5.2. National treatment: Treating foreigners and locals equally

Imported and locally produced goods should be treated equally — at least after the foreign goods have entered the market. The same should apply to foreign and domestic services, and to foreign and local trademarks, copyrights and patents.

This principle of "national treatment" (giving others the same treatment as one's own nationals) is also found in all the three main WTO agreements (Article 3 of GATT, Article 17 of GATS and Article 3 of TRIPS), although once again the principle is handled slightly differently in each of these.

National treatment only applies once a product, service or item of intellectual property has entered the market. Therefore, charging customs duty on an import is not a violation of national treatment even if locally-produced products are not charged an equivalent tax.

3.6 THE AGREEMENTS

The WTO Agreements cover goods, services and intellectual property. They spell out the principles of liberalization, and the permitted exceptions. They include individual countries commitments to lower customs tariffs and other trade barriers, and to open and keep open services markets. They set procedures for settling disputes.

They prescribe special treatment for developing countries. They require governments to make their trade policies transparent by notifying the WTO about laws in force and measures adopted, and through regular reports by the secretariat on countries trade policies.
These agreements are often called the WTOs trade rules, and the WTO is often described as rules-based, a system based on rules. But its important to remember that the rules are actually agreements that governments negotiated.

This chapter also focuses on the Uruguay Round agreements, which are the basis of the present WTO system particularly. Additional work is also now underway in the WTO. This is the result of decisions taken at Ministerial Conferences, in particular the meeting in Doha, November 2001, when new negotiations and other work were launched.

The Uruguay Round of Multilateral Trade Negotiations: The Legal Texts is a list of about 60 agreements, annexes, decisions and understandings. In fact, the agreements fall into a simple structure with six main parts: an umbrella agreement (the Agreement Establishing the WTO); agreements for each of the three broad areas of trade that the WTO covers (goods, services and intellectual property); dispute settlement; and reviews of governments trade policies.

The agreements for the two largest areas goods and services share a common three-part outline, even though the detail is sometimes quite different.

They start with broad principles: the General Agreement on Tariffs and Trade (GATT) (for goods), and the General Agreement on Trade in Services (GATS). (The third area, Trade-Related Aspects of Intellectual Property Rights (TRIPS), also falls into this category although at present it has no additional parts.)
Then come extra agreements and annexes dealing with the special requirements of specific sectors or issues.

Finally, there are the detailed and lengthy schedules (or lists) of commitments made by individual countries allowing specific foreign products or service-providers access to their markets. For the additional details these agreements and annexes deal with the following specific sectors or issues. GATT, these take the form of binding commitments on tariffs for goods in general, and combinations of tariffs and quotas for some agricultural goods.

For GATS, the commitments state how much access foreign service providers are allowed for specific sectors, and they include lists of types of services where individual countries say they are not applying the mostfavoured-nation" principle of non-discrimination. Underpinning these are dispute settlement, which is based on the agreements and commitments, and trade policy reviews, an exercise in transparency.

Much of the Uruguay Round dealt with the first two parts: general principles and principles for specific sectors. At the same time, market access negotiations were possible for industrial goods. Once the principles had been worked out, negotiations could proceed on the commitments for sectors such as agriculture and services.

The basic structure of the WTO agreements: how the six main areas fit together the umbrella WTO Agreement, goods, services, intellectual property, disputes and trade policy reviews. Following is the tabular explanation of the major agreements of WTO:
3.7 TRADE RELATED INTELLECTUAL PROPERTY RIGHTS (TRIPs)

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) requires all WTO Member countries to adapt their laws to the minimum standards set out in the Agreement, within established transitional periods. Conforming with the Agreement by recognizing or strengthening the protection of pharmaceutical products and processes by intellectual property rights (IPRs) has posed a special challenge for developing countries.

The way in which the required legislative reform is made may have a significant impact on public health policies, and particularly on the population’s access to drugs.

The basic premises of this work are that, within the limits imposed by international obligations, notably the TRIPs Agreement of the World Trade Organization, developing country patent laws should be: a) designed to serve the interests of all groups in the society, and b) responsive to health policy objectives and, in particular, to the needs of the poor.
coming from the rise of India's new affluent consumers, who lead more Western-style lives and are demanding innovative drugs to treat the chronic illnesses that these changing lifestyles may produce.

India's leading drug manufacturers are becoming global players, utilizing both organic growth, through the gradual development of their business, and mergers and acquisitions (M&A) as they seek to boost their presence in existing markets and open up new ones.

4.2 MARKET OVERVIEW

With an estimated market value of US$ 8.2 billion (at consumer prices) in 2004, India accounts for approximately two per cent of the world market for pharmaceuticals and ranks as the fourth largest globally in terms of volume and the 13th largest by value\textsuperscript{18}.

Table-4.1- Summary of the Indian Pharmaceutical Market\textsuperscript{18}

<table>
<thead>
<tr>
<th>Summary of the Indian Pharmaceutical Market in 2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>Market Size (US$ millions)</td>
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<tr>
<td>as % of total health expenditure</td>
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<tr>
<td>as% of GDP</td>
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<tr>
<td>as% of world market</td>
</tr>
<tr>
<td>Growth rate %</td>
</tr>
<tr>
<td>Per capita expenditure (US$)</td>
</tr>
</tbody>
</table>

Source: KPMG report
The Indian pharmaceutical market has been forecast to grow to as much as US$ 25 billion by 2010 as per Organisation of Pharmaceutical Producers of India (OPPI) estimates. However, Espicom’s market projections forecast more modest but stable annual market growth of around 7.2 per cent, putting the market at US$ 11.6 billion by 2009\textsuperscript{18}.

Experts say it is currently registering a nine per cent growth compared to global sales growth of seven per cent besides consistently increasing its exports to key overseas markets such as North America, Europe and Japan – which account for about 87 per cent of the total global pharma sales.

The Indian pharma industry currently ranks fourth in volume-and 13th in value term. Estimates suggest that about eight per cent of the world’s drugs are manufactured in India. The Indian pharmaceutical industry is already all set to overtake Italy as the world’s second largest manufacturer of active pharmaceutical ingredients (API).

The Indian API (Active Pharmaceutical Ingredients) manufacturing industry is currently the third largest in the world and is expected to grow at an average yearly rate of 19.3 per cent, according to a study conducted by Italy’s Chemical Pharmaceutical Generic Association. India has also become the second largest market for pharmaceutical products and ingredient exports from China, next to the US – registering a big leap of 172.44 per cent growth during the year 2005, in comparison to the previous year\textsuperscript{123}.
The country has over 300 large and medium scale pharma companies and about 10,000 small companies. Nearly 80 per cent of the production is met by top 100 large companies. The country's pharma industry manufactures about 400 bulk drugs.

India currently represents just U.S. $6 billion of the $550 billion global pharmaceutical industry but its share is increasing at 10 percent a year, compared to 7 percent annual growth for the world market overall. Also, while the Indian sector represents just 8 percent of the global industry total by volume, putting it in fourth place worldwide, it accounts for 13 percent by value, and its drug exports have been growing 30 percent annually.

The "organized" sector of India's pharmaceutical industry consists of 250 to 300 companies, which account for 70 percent of products on the market, with the top 10 firms representing 30 percent. However, the total sector is estimated at nearly 20,000 businesses, some of which are extremely small. Approximately 75 percent of India's demand for medicines is met by local manufacturing.

According to the German Chemicals Association, in 2005, India's top 10 pharmaceutical companies were Ranbaxy, Cipla, Dr. Reddy's Laboratories, Lupin, Nicolas Piramal, Aurobindo Pharma, Cadila Pharmaceuticals, Sun Pharma, Wockhardt Ltd. and Aventis Pharma. Indian-owned firms currently account for 70 percent of the domestic market, up from less than 20 percent in 1970. In 2005, nine of the top 10 companies in India were domestically owned, compared with just four in 1994.
Developing an innovative new drug, from discovery to worldwide marketing, now involves investments of around $1 billion, and the global industry's profitability is under constant attack as costs continue to rise and prices come under pressure. Pharmaceutical production costs are almost 50 percent lower in India than in Western nations, while overall R&D costs are about one-eighth and clinical trial expenses around one-tenth of Western levels. India's long-established manufacturing base also offers a large, well-educated, English-speaking workforce, with 700,000 scientists and engineers graduating every year, including 122,000 chemists and chemical engineers, with 1,500 PhDs. The industry provides the highest intellectual capital per dollar worldwide, according to OPPI.

Following is the list of Top 10 branded drugs rated for the year 2004 by OPPI.

**Table-4.2 - Top ten branded drugs**

<table>
<thead>
<tr>
<th>India's top 10 branded drugs 2004</th>
<th>Asthalin (salbutamol)</th>
<th>Sponidex (cephalexin)</th>
<th>Digene (aluminium hydroxide)</th>
<th>Magnesium hydroxide</th>
<th>Betnesol (betsarnethasone)</th>
<th>Althrocin (erythromycin)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corex (chlorpheniramine maleate)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>codeine phosphate</td>
<td></td>
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<tr>
<td>Human Mistard (maulin)</td>
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<tr>
<td>Voveran (diclofenac sodium)</td>
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<tr>
<td>Beesules (vitamin B complex, vitamin C)</td>
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<tr>
<td>Taxim (celotaxima)</td>
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</table>

India's largest-selling drug products are antibiotics, but the fastest growing are diabetes, cardiovascular, and central nervous system treatments.

The industry's exports were worth more than $3.75 billion in 2004-05 and they have been growing at a compound annual rate of 22.7 percent over the last few years, according to the government's draft National Pharmaceuticals Policy for 2006, published in January 2006.170

The Policy estimates that, by the year 2010, the industry has the potential to achieve $22.40 billion in formulations, with bulk drug production going up from $1.79 billion to $5.60 billion: “India's rich human capital is believed to be the strongest asset for this knowledge-led industry. Various studies show that the scientific talent pool of 4 million Indians is the second-largest English-speaking group worldwide, after the USA.”170

Table 4.3 - The Indian Pharmaceutical Industry in 2004170

<table>
<thead>
<tr>
<th>The Indian Pharmaceutical Industry in 2004</th>
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</thead>
<tbody>
<tr>
<td>Turnover: 6.02 billion, up 6.4 percent year over year</td>
</tr>
<tr>
<td>Exports: 8.26 billion</td>
</tr>
<tr>
<td>Imports: 8.8 billion</td>
</tr>
<tr>
<td>Bulk drug production: 2.16 billion, with over 400 bulk drugs produced. Over 62,000 formulations produced, in 60 therapeutic categories</td>
</tr>
<tr>
<td>Capital investment: up 14.8 percent to $116 billion</td>
</tr>
<tr>
<td>Employment: 6 million direct, 24 million indirect</td>
</tr>
</tbody>
</table>


4.3 IMPLEMENTATION OF VAT

In April 2005, the government introduced value-added tax for the first time and abolished all other taxes derived from sales of goods. So far, 22 states have implemented VAT, which is set at 4 percent for medicines. This led to pharmaceutical wholesalers and retailers cutting their stocks dramatically, which severely affected drug manufacturers' sales for several months.
4.4 OPPORTUNITIES FOR INDIAN PHARMACEUTICAL INDUSTRY

The main opportunities for the Indian pharmaceutical industry are in the areas of:

- Generics (including biotechnology generics)
- Biotechnology
- Outsourcing (contract manufacturing and R&D outsourcing)
- Basic Research (Innovating new molecular entities)

Prescription drugs worth $40 billion in the U.S. and $25 billion in Europe are due to lose patent protection by 2007-08. Indian firms will likely take around 30 percent of the increasing global generics market. Currently, the Indian industry is estimated to account for 2 percent of the generics world market\textsuperscript{18}. Low production costs give India an edge over other generics-producing nations, especially China and Israel.

Indian drug manufacturers currently export their products to more than 65 countries worldwide\textsuperscript{18}. Their largest customer is the U.S., the world's biggest pharmaceutical market. The use of generic drugs is growing quickly in the U.S. due to cost pressure by payers and the introduction on January 1 this year of the Medicare Part D prescription benefit, giving seniors and people with disabilities prescription drug coverage for the first time. With 74 facilities, India has the largest number of U.S. Food and Drug Administration (FDA)-approved drug manufacturing facilities outside the U.S. Indian firms now account for 35 percent of Drug Master File applications and one in four of all U.S. Abbreviated New Drug Application (ANDA) filings submitted to the FDA\textsuperscript{18}. 

85
Analysts at Credit Lyonnais Securities Asia say they expect the number of generic drug launches by Indian companies in the U.S. to increase from 93 in 2003 to over 250 by 2008\(^{18}\).

<table>
<thead>
<tr>
<th>Company</th>
<th>FY04</th>
<th>FY05</th>
<th>FY06</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glenmark</td>
<td></td>
<td>7</td>
<td>14</td>
</tr>
<tr>
<td>Zyvia Cadila</td>
<td>12</td>
<td>13</td>
<td>81</td>
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<tr>
<td>Orchid</td>
<td></td>
<td>18</td>
<td>wi</td>
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<tr>
<td>Wockhardt</td>
<td>12</td>
<td>14</td>
<td></td>
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<tr>
<td>Aurobindo</td>
<td>2</td>
<td>22</td>
<td>3</td>
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In January 2006, the Indian exporters' representative body, the Pharma Export Promotion Council (Pharmexcil) said it planned to raise a number of concerns with the U.S. government over what it sees as barriers to trade with them. One is a U.S. regulation that disqualifies Indian firms from bidding for government contracts, and another is the requirement Indian drug manufacturers submit separate applications for each U.S. state (there is no U.S.-wide regulatory requirement), even when the firms have FDA-approved products and facilities\(^{18}\).

As far as Biogenerics are concerned firms based in India and China could be among the first to bring biogenerics (generic versions of biological products) to the regulated markets and faster than expected. The first biogeneric product was approved by the
European Medicines Agency (EMEA) which refers to these products as “biosimilars,” in April 2006.

IMS estimates that biotechnology products accounted for 10 percent of global pharmaceutical sales in 2004, or about $55 billion in worldwide sales for the year. By 2003, the U.S. accounted for 62 percent of the global biotech drugs market, while in that year Japan's share of the total had fallen to 7 percent from 28 percent in 1994. Patents on the first generation of blockbuster biopharmaceuticals are beginning to expire, and the high cost of these products means the generic versions will find large markets among hard-pressed governments and other payers. Sales of biogenerics are flourishing in the unregulated markets. The only regulated-market approvals so far are in Australia, granted in October 2004 for the recombinant DNA growth hormone Omnitrope, manufactured by Sandoz, as well as in the EU, granted in April 2006.

Biotechnology is one of the most prominent fields with high returns in the pharma industry. In 2003-04, biopharmaceuticals accounted for 60 percent of India's total biotechnology market, which was worth an estimated $709 million—up 39 percent over the previous period.

Investment in the sector was up 26 percent to $137 million—and exports accounted for 56 percent of industry revenues. The domestic biopharmaceuticals sector grew 38.5 percent.
and had the largest local market share, at 76 percent, followed by bioagriculture at 8.4 percent, bioservices at 7.7 percent, and industrial products at 5.5 percent and bioinformatics at 2.5 percent. With 200 biotech companies and total revenues of $500 million annually, India's biotechnology sector is still in the relatively early stages of development. However, it is growing fast, with an initial emphasis on vaccines and bioservices. The industry is situated mainly in Karnataka, although there are operations in Andra Pradesh, Hyderabad, Kerala, Maharashtra and West Bengal. The top 10 players in terms of revenues in 2004 were Biocon, Serum Institute of India, Panacea Biotec, Nicholas Piramal, Novo Nordisk, Venkateshwara Hatcheries, Wockhardt, GSK, Bharat Serums & Vaccines, and Eli Lilly & Co, reports Burrill & Co, the U.S.-based life sciences merchant bank. As is generally the case worldwide, most biotech companies in India have developed along the contract or collaborative research models.

As far as contract manufacturing is concerned the global pharmaceutical market is estimated to represent a $48 billion opportunity for India by 2007, in terms of:

- manufacturing outsourcing-supply of active pharmaceutical ingredients (APIs) and intermediates
- development outsourcing-conducting preclinical and clinical trials
- customized chemistry services-contract research services for compounds pre-launch.
Worldwide revenues for pharmaceutical industry contract manufacturing and research services (CRAMS) totaled $100 billion in 2004 and will grow at an average annual rate of 10.8 percent to reach $168 billion by 2009, say analysts at Frost & Sullivan. Within this total, the global market for contract manufacturing of prescription drugs is estimated to increase from a value of $26.2 billion to $43.9 billion, although the over-the-counter medicines and nutritional products sector will show the fastest growth.

The Asian region has recently been challenging North America and Europe's traditional domination of the global pharmaceutical contract manufacturing market: India and China could potentially account for 35 percent to 40 percent of the outsourced market share for active pharmaceutical ingredients, finished dosage formulations and intermediates.

<table>
<thead>
<tr>
<th>Indian Company</th>
<th>International Partner</th>
<th>Outsourced Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cadila Healthcare</td>
<td>Albona</td>
<td>Two intermediates for Albona's undisclosed molecule Protonix ( pantoprazole)</td>
</tr>
<tr>
<td>Hikal Limited</td>
<td>Degussa</td>
<td>Hikal has signed an agreement with Degussa for supplying pharmaceutical intermediates and active pharmaceutical ingredients</td>
</tr>
<tr>
<td>Nicholas Piramal</td>
<td>AMO</td>
<td>Neutralizing tablets and sterile FFS packs (product names not disclosed)</td>
</tr>
<tr>
<td>Nicholas Piramal</td>
<td>Allergan</td>
<td>APIs for Lovenox® (Bazeo) and Biltridine® (Alphagan and Alphagan - D)</td>
</tr>
<tr>
<td>Nicholas Piramal</td>
<td>Pfizer</td>
<td>7 year agreement relating to R&amp;D services under which Nicholas Piramal will provide process development and scale up services to Pfizer's animal health division from the latter's facilities in India</td>
</tr>
<tr>
<td>Dishman Pharma</td>
<td>Solvay</td>
<td>6 projects, the main one being for starting material and advanced intermediates for Tevatan (terconazone maleate)</td>
</tr>
<tr>
<td>Dishman Pharma</td>
<td>AstraZeneca</td>
<td>Intermediate for Noroxin (esomeprazole)</td>
</tr>
<tr>
<td>Dishman Pharma</td>
<td>Merck</td>
<td>Intermediate for Losartan (to be supplied to its contract manufacturer in Japan)</td>
</tr>
<tr>
<td>Shasun Chemicals</td>
<td>GlaxoSmithKline</td>
<td>バンヒドリン API</td>
</tr>
<tr>
<td>Shasun Chemicals</td>
<td>ElLyn</td>
<td>Nitazoxin, mecoprop and cyclosporine APIs</td>
</tr>
</tbody>
</table>

Indian successes in this area have already created some significant international developments. For example, last year, Jubilant Organosys, which has the largest CRAMS business in India, acquired Target Research Associates plus 64 percent of Trinity Laboratories and its wholly owned subsidiary Trigen Labs, all U.S.-based firms. Another large Indian firm, Bilcare Ltd, acquired its first manufacturing facility in the U.S. last year, with the purchase of Philadelphia-based proClinical Inc\textsuperscript{18}, \textsuperscript{160}.

4.5 ADVANTAGE INDIA

India offers tremendous cost advantage in terms of cost acquiring the resource, allocating and utilization of the acquired resource. Costs of clinical trials in India are around one-tenth of their levels in the U.S., and it is estimated that they could be worth $300 million to India by 2010. Major drug producers that are already conducting trials in India include Pfizer, estimated to have some 20 ongoing clinical trials there; GSK, with seven trials; Eli Lilly, with 17 trials; plus AstraZeneca and Novartis. As well as Chiltern, leading contract research organizations (CROs) such as Quintiles, SFBC International and ICON Clinical Research have extensive operations in India.

India's other Advantages for off shoring are briefly described as follows:

- Low-cost skill base
- Current Good Manufacturing Practice (cGMP) and U.S. FDA compliance levels
- High visibility in generics
- High-quality, compliant manufacturing
- Strong financial position with ability to scale up
- Manufacturing capacity
- Access to new technologies

90
4.6 FUTURE PROSPECTS OF INDIAN PHARMACEUTICAL INDUSTRY

As per WTO, from the year 2005, India will grant product patent recognition to all new chemical entities (NCEs) i.e., bulk drugs developed then onwards. The Indian Government's decision to allow 100 percent foreign direct investment into the drugs and pharmaceutical industry is expected to aid the growth of contract research in the country. Technology transfer to 100 percent Indian subsidiaries of MNCs is expected only in 2005\textsuperscript{160,161}.

Indian pharmaceutical interests in making a mark on the global scene got a boost when Dr. Reddy's licensed two of its anti-diabetic molecules to Novo Nordisk and when Ranbaxy licensed its Novel Drug Delivery System (NDDS) of ciprofloxacin to Bayer. MNCs in India faced the problem of having a very high DPCO coverage, weakening their bottom lines as well as hindering their growth through the launch of new products. DPCO coverage is expected to be diluted further in the near future benefiting the MNCs. New legislation is also expected in the OTC segment increasing the number of brands in the Over the Counter (OTC) segment.
The Indian pharmaceutical industry is also getting increasingly U.S. FDA compliant to harness the growth opportunities in areas of contract manufacturing and research. Indian companies such as Ranbaxy, Sun Pharma, and Dr. Reddy's are increasingly focusing on tapping the U.S. generic market, projected to be around $40 billion by 2007-08.

4.7 RESEARCH & DEVELOPMENT

Research & Development is the key to the future of Indian pharmaceutical industry. The pharmaceutical advances for considerable improvement in life expectancy and health all over the world are the result of a steadily increasing investment in research. There is considerable scope for collaborative R & D in India. India can offer several strengths to the international R & D community. These strengths relate to availability of excellent scientific talents who can develop combinatorial chemistry, new synthetic molecules and plant derived candidate drugs.

R & D in the pharmaceutical industry in India is critical to find answers for some of the diseases peculiar to a tropical country like India and also for finding solutions for unmet medical needs. Industrial R & D groups can carry out limited primary screening to identify lead molecules or even candidate drugs for further in vivo screening, pre-clinical pharmacology, toxicology, animal and human pharmacokinetics and metabolic studies before taking them up for human trials. In such collaborations, harmonized standards of screening can be assured following established good laboratory practices.
The R & D expenditure by the Indian pharmaceutical industry is around 1.9% of the industry's turnover. This obviously, is very low when compared to the investment on R & D by foreign research-based pharma companies. They spend 10 - 16% of the turnover on R & D. However, now that India is entering into the Patent protection area, many companies are spending relatively more on R & D.

When it comes to clinical evaluation at the time of multi-center trials, India would provide a strong base considering the real availability of clinical materials in diverse therapeutic areas. Such active collaboration will be mutually beneficial to both partners. According to a survey by the Pharmaceutical Outsourcing Management Association and Bio/Pharmaceutical Outsourcing Report, pharmaceutical companies are utilizing substantially the services of Contract Research Organizations (CROs).

Indian Pharmaceutical Industry, with its rich scientific talents, provides cost-effective clinical trial research. It has an excellent record of development of improved, cost-beneficial chemical syntheses for various drug molecules. Some MNCs are already sourcing these services from their Indian affiliates.

The Pharmaceutical and Biotechnology Industry is eligible for weight deduction for R&D expense upto 150%. These R&D companies will also enjoy tax holiday for 10 years. A promotional research and development fund of Rs.150 crores is set up by the Government to promote research and development in the pharmaceuticals sector.
The Indian pharmaceutical industry is a knowledge-based industry and has gained global recognition as a producer of low cost high quality bulk drugs and formulations.

Globally, the Indian industry ranks 4th in terms of volume and 13th in terms of value. The Indian pharma industry was valued at approximately $8.0 billion in 2005. The exports constitute almost 40% of the total production of pharmaceuticals in India. India's pharmaceutical exports are to the tune of US$3.5bn currently, of which formulations contribute nearly 55% and the rest 45% comes from bulk drugs.

The current year 2006 is projected to be very good for the sector with performance recorded at double digits. A Pharmabiz study of financial results of 50 large companies during the last three quarters of the current year indicate that their net sales had gone up by over 23 per cent and profits by 38 per cent over the same period of the previous year.

Companies such as Venus remedies, Polar Pharma recorded a growth of 163 per cent and 129 per cent in the nine months of the current year. A few other medium scale companies which recorded a 50 per cent growth in sales during the period are Panacea Biotec, Surya Pharma, Suven Life Sciences and Vivimed Labs.
Against this, industry leaders like Cipla and Dr Reddy's reported only 25 per cent growth in sales while Sun Pharma registered almost 37 per cent sales growth.

- The sector has been witnessing domestic pharma companies on a major acquisition spree in Europe. The current fiscal year 2005-06 is predicted to end on a more healthier note in comparison to the previous year with companies adopting strategic changes and consolidating their positions through mergers and acquisitions, product launches, higher investment in R&D, aggressive entry into regulated and semi-regulated markets, marketing & R&D tie-ups and focus on contract manufacturing etc.

- Dr Reddy's Laboratories, earned the distinction of having acquired the fourth-largest German generic drug maker Betapharm Arzneimittel GmbH for euro 480 million (approximately Rs 2,550 crore). This has been one of the biggest overseas acquisition by an Indian pharmaceutical company.

- Ranbaxy is among the top ten generic pharmaceutical players in the global arena, with manufacturing operations in 7 countries, including China. It has the distinction of being India's largest pharmaceutical company. Its recent accolades include the acquisition of a generics company, Ethimed NV, in Belgium and Romanian Pharma company Terapia for US$ 324 million, the third acquisition as of March.

- The Pharmaceuticals Export Promotion Council (Pharmexcil) has projected a 35 per cent per annum growth in exports during the next five years to take the total export figure to US$ 13.73 billion from US$ 3.77 billion as of 2005.
• The chemical industry is becoming competitive and has very high growth potential for production for local markets as well as exports. Bayer AG, the German chemical and pharmaceutical company, has identified India as the outsourcing hub for both basic and specialty chemicals.

• The Indian Biotechnology sector is emerging as one of the promising sectors. India has a strong potential to become a Biotech hub. The Department of Biotechnology (DBT), Government of India has estimated that the Indian Biotech sector will achieve US$5 billion in revenues by 2010 (CAGR of 35.91 percent) providing an employment of one million jobs. The major growth drivers being biopharmaceuticals, bio services and bio informatics. The Biotech industry is witnessing a rapid growth in investment, with an increase in the Government allocation of funds estimated to be US$ 101.64 million for the year 2005-06.

4.9 SUMMARY OF BIG INDIAN COMPANIES

Consolidation in the global generics industry, where the top 10 players account for 27 percent of the world market, is widely expected, and, following Teva's purchase of IVAX and the takeover of Hexal by Novartis's unit Sandoz, a vast gap has been created between these firms and the rest of the industry. Ranbaxy is widely believed to be seeking to attain the third position through an alliance with a major company. Wockhardt and Dr Reddy's are also particularly active in terms of acquisitions in the generics sector.

An enabling factor for Indian firms' activity overseas is their increased liquidity in the market, with increasing numbers of Foreign Currency Convertible Bond listings and private equity findings.
In the period from January 2004—when Ranbaxy formalized its purchase of RPG (Aventis) for $80 million, making it the fifth-largest generics supplier in France—until October 2005, Indian firms made 18 international acquisitions. Glenmark, Jubilant Organosys, Nicholas Piramal and Ranbaxy each acquired two overseas businesses during this time, but the biggest Indian buy was Matrix Labs' acquisition of Belgium's Docpharma for $263 million in June 2005.

Eleven of the 18 acquisitions are comparatively small, worth $5 to $30 million, but the value of Indian industry purchases is rising fast, having grown from just $8 million in 1997 to $116 million in 2004, and this fast pace is expected to continue.

Although the U.S. is the world's largest generics market, most of the purchases were in the EU. Observers believe that Indian firms consider European valuations to be more reasonable, and there is a wider price range of companies available. Use of generics is growing quickly in Europe, due to government price controls and other pro-generic measures, while the EU regulatory climate is proving a disincentive for some European firms to continue, creating buying opportunities for Indian firms.55 The three main European generics markets are Germany, France and the UK, together worth around $3 billion a year.

Notable developments during 2005 were Dr Reddy's acquisition of Roche's API business for $59.6 million; Nicholas Piramal's buying Avecia Custom Drug Synthesis of the UK for $16.7 million; Ranbaxy's acquisition of a 40 percent stake in Japan's Nihon
Pharmaceutical Industry; and Sun Pharma's completion of its buy of ICN Hungary for an undisclosed sum.

Then in February 2006, the largest-ever acquisition by an Indian pharmaceutical company was announced, when Dr Reddy's bought Germany's fourth-largest generics company, Betapharm Arzneimittel, from UK-based 3i for $573.6 million. Betapharm Chief Executive Wolfgang Niedermaier commented, "Dr Reddy's impressive pipeline of generic and innovative products and its high-quality standards, combined with competitive manufacturing costs, will help further develop our position in the German market and offer an entry platform for the European market."

4.10 CURRENT BUSINESS MODEL OF MAJOR COMPANIES OF INDIAN PHARMACEUTICAL INDUSTRY

From the secondary data and annual reports available in the public domain we have tried to understand the current strategic business model as practiced by major pharma companies of Indian Pharma industry which is as follow:

4.10.1 Dr Reddy's Laboratories

Dr Reddy's Laboratories is an emerging global pharmaceutical and biotechnology company, which was founded by chairman Anji Reddy in 1984. It operates in over 60 countries, although India and the USA each accounts for around a third of the firm's total sales. The company is already strongly present in most of the world's biggest less-regulated markets, such as Russia, China, Brazil and South Africa.
For the nine-month period to December 31, 2005, the firm reported revenues up 14 percent to $387.4 million, driven by sales of APIs (up 48 percent in the third quarter and 19 percent in the first nine months) and branded formulations (up 34 percent in the third quarter, led by growth of 34 percent in India and 35 percent in Russia). Dr Reddy's is also an innovator in the use of venture capital to maintain cash-flow for R&D, having received $57 million from ICICI Venture Funds to support ANDA filings for 18 months beyond FY2005 for royalties from sales in the USA.

Dr Reddy's made history in February when it entered the German branded generics market, the world's second-largest after the USA, not through building a business organically there but with the purchase of Betapharm, Germany's fourth-largest generics manufacturer, for $570 million. This is the largest overseas acquisition by an Indian pharmaceutical company so far.

Despite its size, the German generics market is not experiencing the pricing pressure which is currently being felt in the USA and shrinking business there. Satish Reddy from Dr Reddy's is still optimistic about prospects in the USA, pointing to the huge opportunities which will be presented there by patent expiries on major products going forward to 2010.

Before the Betapharm purchase, Dr Reddy's did not have a presence generally in the European branded generics market, although it is active in the UK pure generics market.
It is now looking towards expansion in Spain, France and the rest of Europe, and also to rolling out its existing product range in major regulated markets including Australia and New Zealand.

4.10.2 Lupin Ltd.\textsuperscript{172}

Lupin is one of the world's largest manufacturers of APIs and finished formulations for TB, bacterial infections and cardiovascular disease. Its products are sold in more than 50 countries. For third-quarter 2006 (ended December 31, 2005), the firm reported gross sales up 51 percent to $98.9 million, with exports up 56 percent (boosted by U.S. launches) at $46.3 million and domestic sales rising 47 percent to $51.9 million. For the nine months to end-December, sales rose 34 percent to $274.7 million, with net profit up 112 percent to $29.5 million.

4.10.3 Nicholas Piramal\textsuperscript{173}

Nicholas Piramal is the flagship company of Piramal Enterprises (PEL), one of India's largest diversified business houses. It was formed in 1988 when PEL acquired Nicholas Laboratories (NPIL) a small formulations company, from Sara Lee. For third-quarter FY 2006 (ended December 31, 2005) the firm reported net sales of $78.3 million, up 9.2 percent on the second quarter, and consolidated sales were up 17.3 percent at $89.5 million. However, net profit plummeted 69.9 percent to $5.2 million, due to lower sales of the firm's leading brand, the controversial promethazine/codeine phosphate/ephedrine cough suppressant Phensedyl, which has been widely abused, and the withdrawal of two valdecoxib brands - Vah and Valto - plus a foreign exchange loss of £468,000.
NPIL's strategy of opting out of early-stage generic exports, which differentiates it from most leading Indian firms, enables it to steer clear of IP challenges and focus on partnering with global firms. Generally, contract manufacturing organizations operate only in certain segments (e.g., intermediates, APIs or formulations), but NPIL is seeking to join the rank of the few players offering the entire spectrum of services, notes SKKI.

4.10.4 Ranbaxy Laboratories

India's largest pharmaceutical company is ranked among the top 10 generics manufacturers worldwide and aiming to be in the top five with sales of $5 billion by 2012. However, with the firm's recent moves to increase its size through the inorganic route, it is seen as aiming to establish itself as the world's number three generics producer much sooner. It has manufacturing operations in seven countries, a ground presence in 46 nations and sells its products in over 100 countries. Ranbaxy has three state-of-the-art research facilities at Gurgaon, near New Delhi - R&D Centers I and II focus on the development of generics and novel drug delivery systems research, while the new R&D Centre III is dedicated to new drug discovery research.

The firm also has the largest R&D budget of any Indian drug manufacturer, standing at 7 percent of sales in 2004, and it plans to progressively increase this to 9 percent-10 percent by 2007.
Ranbaxy has set up a global alliance with GlaxoSmithKline in the area of drug discovery and development. Two research programs, one in the area of anti-infectives and another, in the asthma segment, are now in progress.

For the year ended December 31, Ranbaxy reported sales of $1.17 billion, similar to the previous year, but profits after tax and minority interest slumped 62 percent, largely impacted by continuing price erosion in the key U.S. market, where sales fell 22 percent to $332 million. In Europe, sales rose 5 percent to $202 million, while in the BRIC countries (Brazil, Russia, India and China) they rose 11 percent to $340 million. In January, Ranbaxy's new chief executive Malvinder Singh said the firm is looking for M&A to help it reach its $2 billion sales target by 2007; the goal for 2006 is an increase of 18 percent.

Ranbaxy follows a strategy of aggressively challenging patents of innovator firms to drive its generics business, say analysts at SKKI India, adding: "the robustness of Ranbaxy's global generic model is reflected in its presence in 23 of the top 25 markets in the world including Japan and Canada. Only Teva and Sandoz can match Ranbaxy's global generics footprint. Also, while Teva and Sandoz have built a global footprint, primarily through inorganic initiatives, Ranbaxy's growth has so far been largely organic."

4.10.5 Sun Pharma

Sun Pharma, established in 1983, makes specialty pharmaceuticals and APIs for use in chronic therapy areas such as cardiology, psychiatry, neurology, gastroenterology,
diabetes and respiratory conditions, sold in 26 markets worldwide. Its income for the quarter ended December 31, 2005 was $103.2 million compared with $73 million in the like, year-earlier period, and total nine-month income was $295.8 million. In February 2006, the firm announced the demerger of its innovative R&D programs to a new company which it has set up for this purpose. Around 25 percent-40 percent of R&D spend, which represents 10 percent-11 percent of its sales, is accounted for by innovative R&D, it said.

4.10.6 Wockhardt

The overseas ambitions of this Mumbai-based pharmaceutical and biotechnology-based company have already been covered elsewhere in this report, but in mid-March 2006 Wockhardt announced that it had received approval from its shareholders to raise up to $800 million, in one or more tranches, to fund further foreign purchases. Noting his company's "well-known" ability to create value through acquisitions, chairman Habil Khorakiwala said the move would "empower us to seize global opportunities quickly." He stockholders also authorized an increase in the company's Foreign Institutional Investment cap to 49 percent.

Wockhardt's U.S. business grew more than 50 percent in the year to December 31, 2005, with six products launched there in the period, while European sales of formulations (the firm's biggest market) rose 15 percent. Indian business was up 10 percent and the firm's biotechnology sales surpassed $10 million. Overall, net profits were up 20 percent for the year $57.6 million, with consolidated sales rising 13 percent to $316.5 million. In
February 2006, SSKI India analysts forecast a 16 percent CAGR in Wockhardt's consolidated annual revenues to 2007, mainly led by an export-driven improvement in gross margins. “Increased proportion of sales from U.S. generics and biogenerics, where we believe realizations could be superior, will also contribute to the expansion in overall gross margins,” they added.

4.10.7 Zydus Cadila

Zydus Cadila is India's fifth largest pharmaceutical company. Cadila was founded in 1952 and, following restructuring, the Zydus Cadila Group was established in 1995. For the quarter ended December 2005, the firm reported net profits up 36.1 percent at $8.8 million, with total income ahead 17 percent at $85.5 million. The group has reported year-on-year growth of 138 percent for its exports of formulations. During the quarter, the group received approvals for ribavirin capsules, promethazine tablets and tentative approval for gatifloxacin Tablets from the U.S. FDA. Then on February 24, 2006, the FDA granted tentative approval for sertraline (generic version of Pfizer's Zoloft). The company had already received approval from the French regulatory agency to market sertraline capsules in the French market.

Chairman and managing director Pankaj Patel is aiming for Zydus Cadila to be a top 10 global generic company by 2010, deriving half its revenues from international business, with growth led by Europe, the USA and then its other markets. Alliances and joint
ventures with MNCs will be a central driver of growth for the group, both internationally where it already has arrangements with Mayne pharma, Mallinckrodt and GSK and in India, where it has tie-up with Altana, Schering AG and Boehringer Ingelheim.

Zydus Cadila has received 10 generic approvals so far and has filed a total of 30 ANDAs and 35 DMFs.

4.10.8 Aurobindo Pharma

Aurobindo Pharma manufactures generics and APIs in the antibiotic, antiretroviral, cardiovascular, central nervous system, gastroenterological and anti-allergy fields, and markets them in over 100 countries. In the quarter ended December 31, 2005, it reported sales up 28 percent to $93.1 million over the same quarter of 2004, with sales of formulations rising 125 percent. The firm filed 10 ANDAs and 13 DMFs in the USA in the quarter, with 70 filings in other markets, bringing its total number of formulation filings to 364. In January 2006, Aurobindo reported that the U.S. FDA had granted tentative approval for its antiretroviral Nevirapine Oral Suspension 50 mg/5 ml, qualifying the product under President George W Bush's Emergency Plan for AIDS Relief (PEPFAR) program. Also in January, the World Health Organization announced the inclusion of Aurobindo's Nevirapine oral suspension 50mg/5ml and Stavudine for oral solution 1mg/ml in its Pre-qualification list - both are used as a part of first-time line treatment in pediatric AIDS.
India's second-largest drug manufacturer was originally established in 1935 as The Chemical, Industrial and Pharmaceutical Laboratories. Until 2000 its business was primarily domestic, but exports, to more than 150 countries, accounted for 45 percent of its fiscal year 2005 sales, giving it what is probably the Indian industry's most geographically-diversified export base, say analysts at SKKI, who add that Cipla "has established itself as the partner of choice for generic companies globally." At the end of December 2005, Cipla signed the largest product development and manufacturing agreement in the country, when it agreed a global deal with German manufacturer Boehringer Ingelheim for the development and supply of the firm's hypertension drug Micardis (telmisartan). The firm also announced at year-end that it planned to launch the first generic version of Roche's Tamiflu (oseltamivir), which is recommended for use against the H5N1 strain of avian flu. In 2004, Cipla took over from GlaxoSmithKline as India's leading drug manufacturer in terms of retail sales (although, including vaccines and institutional sales, GSK still has the leading share, at just under 6.5 percent).

The next chapter, presents a review of amendments in Indian patent act in complying with TRIPs provisions. This chapter provides the details of series of amendments introduced by Indian government in Indian Patent Act, 1970. It is imperative to study the changes which are subjected to new IPR regime before analyzing its strategic impact on pharmaceutical business. Therefore, the next chapter provides a critically review of all the critical provision which are subject to modification and widely debated.