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## **Prospects for Drug Accessibility and Economic Growth as Indian Pharmaceuticals Enter the Product Patent Era**



by  
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**6.901: Inventions and Patents  
Massachusetts Institute of Technology  
December 9, 2004**

## **I. Introduction**

Signed in 1994, the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) established the World Trade Organization (WTO), the first and only international institution for the regulation of trade between nations. Under the Agreement on Trade Related Intellectual Property Rights (TRIPs), developing nations have a grace period of ten years, ending January 1, 2005, to update its laws to grant product patents on previously unprotected technologies.

India led the opposition to the GATT provision on product patents, citing the prospective burden on the country's poor with the institution of product patents in the pharmaceutical industry. Legalizing the reverse engineering of drugs under the Indian Patent Act of 1970, India defined the goal of its pharmaceutical industry to be the ability to produce generic drugs at a low cost to its citizens. As a result, generics in India currently sell for ten to forty times cheaper than their brand-name equivalents in the United States. With the reinstatement of product patents, India argues, prices will be driven beyond the reach of the average patient.

The Indian Patent Act eliminated all product patents in the pharmaceutical sector and reduced the term for patents on pharmaceutical processes from 14 years from the date of filing to 7 years from the date of filing or 5 years from the date of the award, if shorter. The legalization of reverse engineering stimulated the Indian Pharmaceutical Industry (IPI), specifically companies specializing in generics, to increase its market share from 10% of the Indian pharmaceutical market in 1970 to 60% in 1990. Conversely, however;

the threat of these generic companies reverse engineering and under-cutting brand names reduced the incentives for trans-national corporations (TNC's) to develop new drugs for the Indian market so much so that their market share fell from 80% to 39% over the same time period.<sup>1</sup>

Developed nations argue that the Agreement on TRIPs will stimulate foreign and domestic investment in the Research and Development (R&D) branch of the Indian pharmaceutical market. They point to the immediate potential for research into the under funded field of tropical diseases. The Global Forum for Health Research, cited by the World Health Organization (WHO), estimates that 90% of global R&D expenditure targets diseases that account for only 10% of the global disease burden. This result is referred to as the "10/90 Gap".<sup>2</sup> Developed nations do not invest in the development of new drugs for tropical diseases, because the lack of purchasing power of the victims of these diseases limits the profitability of such ventures. If developing nations were to begin investment in the development of drugs for tropical diseases, however; they could find domestic niche markets for their products in which they do not face the challenge of competition from TNC's with superior R&D capabilities.

Although India's lack of infrastructure in the pharmaceutical industry puts competition with developed nations in markets for heavily researched diseases in the near future beyond the realm of imagination, India brings great advantages in potential to the

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<sup>1</sup> Redwood, H. "New Horizons in India, The Consequences of Pharmaceutical Patent Protection." Oldwick Press, 1994

<sup>2</sup> "Genomics and the Global Health Divide." World Health Organization. 2004  
<<http://www.who.int/genomics/healthdivide/en/>>

playing field such as education and cheap labor that may one day be realized as we see India capture a significant share of the global pharmaceutical market.

This paper will examine the potential effects of the imminent product patent regime on the IPI. It will study the immediate effect on drug prices, and the prospect of stimulated R&D of drugs targeting tropical diseases for the domestic market in the medium-term after the new system takes effect, examining the subtleties and inconsistencies in the arguments of both sides of the debate. Then it will begin to study the long-term structural changes the IPI must undergo to survive under the new regime, and India's prospects of competing for a share of the global market with developed nations.

## **II. R&D in Drugs for Tropical Diseases under Product Patents**

During the Uruguay Round of the GATT, developed nations focused their argument for the Agreement on TRIPs to include a provision for product patents in developing countries by 2005 on the long-term benefits to those countries. One dimension of this argument cited the incentive for R&D in the sector of the IPI for drugs targeting tropical diseases. The 10/90 Gap illustrates both the need and opportunity for investment in this sector for the benefit of society.

Why then, have TNC's failed to target the major portion of the global market for drugs? The answer is not only that they fear the lack of patent protection will allow generics to undercut their product, but also that consumers in developing countries

simply do not have the purchasing power to make targeting them an attractive option for TNC's. A small minority of disease patients in the world have the majority of the purchasing power. Low-income AIDS and malaria patients from India may outnumber cancer patients in the US by far, but those cancer patients proportionally more wealth to make them far more profitable market. India spends \$3 per capita per year on pharmaceutical products compared to the United States' \$191 per capita annual expenditure on drugs.<sup>3</sup>

Under the new patent regime, TNC's may be no more likely to invest in R&D for drugs specific to the disease burden in India than they were in the past. By the same token, Indian firms may similarly lack incentive to invest in R&D operations for drugs targeting the domestic disease burden. Under the current structure the IPI profits from the manufacture of generic drugs, and since the new patent regime is not retroactive, Indian firms can continue manufacturing generics of the same old drugs for profit. However, the new regime will cause high prices on new drugs, limiting patient access to these products.

Because the Indian firms lack the infrastructure to break into innovative markets, patent protection alone will be slow to stimulate structural changes in the industry. In the history of developed nations, the extent of patent protection has followed the advancement of technology. A developing country operating in a global market with uniform patent regulations will certainly suffer from its technology gap in that it will not

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<sup>3</sup> Joshi, Hemant N. "Analysis of the Indian Pharmaceutical Industry." Pharmaceutical Technology. January 2003: 90.

grow by producing its own new inventions, but rather it will bear the cost of importing new products from more technologically advanced, innovative nations.

The solution to achieving economic growth and improving access to new drugs under a product patent regime comes first by realizing that granting increased protection to the developers of new drugs is not a panacea, but a trade-off between access to current drugs for the population and the incentive for firms to develop new ones.<sup>4</sup> Indian firms will be forced to undergo structural changes to survive in the pharmaceutical market in the long-run, and must identify the basic needs underlying those changes to address.

To evolve from generic-manufacturing machines into innovative entities, Indian firms must consider four fundamental challenges: funds, infrastructure, R&D management, and human resources.<sup>5</sup> So the question whether the IPI can successfully enter the new economic era under the GATT boils down to its ability to advance in these four areas.

The most promising source of funding for the IPI will be from Foreign Direct Investment (FDI), which describes any activities controlled by TNC's based outside of India. It is important to distinguish between TNC's operating in India while still targeting developed nations' markets, and TNC's operating in India targeting Indian markets. An increasing number of TNC's are implementing the latter strategy by means of

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<sup>4</sup> Lanjouw, Jean O. "Intellectual Property and the Availability of Pharmaceuticals in Poor Countries." Innovation Policy and the Economy. Vol. 3. 2002: 4.

<sup>5</sup> Joshi, Hemant N. "Analysis of the Indian Pharmaceutical Industry." Pharmaceutical Technology. January 2003: 82.

cooperation with Indian firms. The result is a dynamic where TNC's bring superior funds, infrastructure, and R&D management to the table, while Indian firms bring local manpower, and knowledge of the local market. For example, the German firm Hoechst-Marion-Roussel has entered recently into an agreement with India's Nicholas Piramal.

A more difficult question is whether Indian companies have the potential to succeed in domestic innovation without collaborating with TNC's. Some of the major players in the IPI have the funds to conduct research on a reasonable scale, but it is difficult to predict whether they will be able to meet future demands in the other three categories for development.

To address its human resources needs, a pharmaceutical industry must recruit employees from the fields of pharmacology, chemical engineering, organic chemistry, biochemistry, etc. Anyone familiar with the Brain Drain of talent from India to the United States in the past two decades knows that India produces a large number of science and engineering graduates each year. And the recent software boom in Bangalore has proven that highly-skilled Indian graduates are willing to stay at home to work if the opportunity presents itself. Therefore the vast potential in human resources for an emerging innovating domestic pharmaceutical industry in India is undeniable.

R&D management will follow, with some effort, from an influx of talent into the industry. Creating infrastructure, on the other hand; requires technical know-how as well

as funding. Companies will have to take big risks in infrastructure spending, and only time will tell if their investments pay off.

One Indian firm that has begun this process is Dr. Reddy's Laboratories. They have set up a \$2.3 million research facility in anticipation of the new patent regime, and they are already breaking into domestic and even global markets for the development of new drugs. Their new facility focuses on cancer, diabetes, and bacterial infections research.<sup>6</sup> Diabetes is more prevalent in India than anywhere else in the world, whereas cancer gets more attention in the developed world.

The final provision necessary for the success of Indian firms in the long run under the new patent regime is the support of public institutions. India has implemented tax breaks for R&D over the coming years, but one major problem that still exists is the lack of regulatory infrastructure similar to the United States' FDA. Because the IPI has not been innovative for decades, an underlying regulatory system has not been necessary. However, if one cannot be developed at the same pace as drug development under the new patent regime, Indian firms will suffer major setbacks. India must therefore find the funds, infrastructure, and human resources to advance its own FDA.

In conclusion, Indian pharmaceuticals have the potential to evolve into an innovative industry on the domestic market in the long-run as long as they take the right steps to meet the challenges of funding and infrastructure. The government must also take

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<sup>6</sup> "TRIPs and Pharmaceuticals: Implications for India". August 1997 < <http://www.cuts-international.org/1997-8.htm> >



parallel steps to create a pro-business environment to foster the success of these firms. Indian citizens might not necessarily suffer from less access to generics in the short run, but they will suffer in the long run if the IPI doesn't proceed with the proper foresight.

### **III. Structural Changes as IPI Enters Global Market in the Long-Run**

#### **CURRENT TRENDS**

With a 1.5% share of the world market, India's pharmaceutical market currently stands ninth in the world. Although current demands of the Indian pharmaceutical remains high at \$5 billion, its average per capita expenditure on pharmaceuticals remains low at only \$3, compared to \$412 in Japan, \$222 in Germany and \$191 in the US. This is not only due to the prevalence of alternative healing methods in India, such as ayurvedic medicine and homeopathy, but also due to the *prices for drugs which have been kept artificially low by the government*. In fact, India's pharmaceutical industry is one of the most highly regulated industries in the country. Price controls have a strong effect on the industry's profitability. In addition, India's *weak patent protection poses a long-term threat to investment in its drug market*. This in effect has deterred foreign firms from operating in India due to arbitrary local FDA decisions, arbitrary Bureau of Industrial Cost and Pricing (BICP) pricing changes, complex import procedures, and high import duties (about 42%).

However, while India's pharmaceutical sector will most likely remain regulated in the short run, plans for long-term reform have already be taking place. Pressure from the World Trade Organization is currently driving the national government to improve patent protection. In addition, the pharmaceutical industry's sheer size and growth is making it increasingly difficult for the government to regulate prices for every single firm. As a result, foreign pharmaceutical firms can expect improved market opportunities in India's enormous drug market over next several years.

## **PRICE CONTROL**

Since 1961, heavy price regulation has dominated pharmaceuticals in India. Domestic drug prices in India are among the lowest in the world, severely affecting the profitability of the industry, especially since the prices of basic raw materials and the costs of packing have shot up over the past years. Pharmaceutical manufacturers have also suffered from high transaction costs, including obstacles associated with

administrative processes, dishonesty of public agents, delays in obtaining finance, and transportation bottlenecks.

Price controls are implemented under a Drug Price Control Orders (DPCO). Aside from lowering profitability and constraining the market, there are many administrative problems with DPCOs that have been worsening as the Indian drug industry expands. The government often fails to update the financial data on which it bases its criteria for inclusion, aggravated by the long time lag between the collection of data and announcement of new pricing policy. Furthermore, the way the government calculates the fixed prices for many drugs is problematic.

Due to the large number of bulk drug manufacturers, the DPCO has also been gradually losing importance . Thus, to improve its efforts at drug price control, the government set up the National Pharmaceutical Pricing Authority (NPPA) in 1997 to

update the list of bulk drugs covered under DPCO. The NPPA was also authorized to fix and revise prices of controlled bulk drugs and monitor the prices of decontrolled drugs and formulations and oversee the implementation of DPCO.

The government's stance on price control has been mixed. Although it has set up organizations like NPPA, the number of drugs under price control has gradually been reduced over time (see Figure 1 below).

**Figure 1.**

<b>PC Trends in India</b>	<b># Drugs Under PC</b>	<b>% Market Under PC</b>
<b>1979</b>	347	90%
<b>1987</b>	142	70%
<b>1992</b>	76	50%

Source: "Drug prices review committee extended." Financial Express, September 14, 1998.

Therefore, until decisive reforms are made, foreign drug companies will continue to be at a disadvantage due to intense price competition from local manufacturers in addition to the heavy import tariffs imposed by the government.

## **PATENT PROTECTION**

Under pressure from the WTO in late 1998 has forced India to finally amend its 1970 Patents Act, which to date was the country's only legislation providing patent protection for pharmaceuticals. The 1970 Indian Patents Act was grossly inadequate in that it only provided *process* protection for pharmaceuticals, which as opposed to full

*product* protection did not give a patent to the original inventor of the product, but rather only for a specific production process. Products could therefore be copied easily by developing a new process for producing the same drug. Furthermore, the Indian Patents Act provided only 7 years of process protection for pharmaceuticals, as opposed to the average 15 years required to develop and test a new drug.

Given the high number of pharmaceutical firms in the informal sector, foreign drug companies in India have therefore been deterred from entering the industry as they run a large risk that their patented drugs will be pirated. Lack of adequate patent protection has been one of the main reasons that investment in the industry has slowed over the past several years--research based pharmaceutical companies in India lose up to \$500 million each year through patent piracy, and pharmaceutical R&D remains low as a percentage of total sales compared to developed countries.

Price Comparison of Certain Drugs in U.S. & India

Brand Name	Generic Name	Dosage	U.S. Price Per Tablet (\$)	Indian Price Per Tablet (\$) <sup>a</sup>
Pilosec / Astra-Meck	Omeprazole	20 mg	\$3.76	\$0.09
Prozac / Eli Lilly	Fluoxetine	10 mg	\$2.28	\$0.63
Zocor / Merck	Simvastatin	10 mg	\$2.07	\$0.21
Zantac / Glaxo-Wellcome	Ranitidine	150 mg	\$1.72	\$0.02

However, pressure from the WTO to adhere to its Trade-Related Intellectual Property Rights (TRIPs) agreement had finally forced the Indian government to shift its patent coverage from process to product protection. The government has developed an outline

of reforms to occur. This included, enacting a provision setting up a formal "mailbox" for companies to filing for product patents by April 19, 1999; granting Exclusive Marketing Rights (EMRs) to products patented in a WTO signatory country by January 1, 2000; and awarding product patents by January 1, 2005. EMRs will give a five-year, patent-like monopoly for products covered by the product patent applications made under the mailbox system. Under this WTO TRIPs agreement, India has a maximum of ten years to bring its patent laws into compliance, which will involve recognizing product patents and extending protection period to 20 years.

However, there will be some difficulties. Granting an EMR will probably take about two years, and the government can still exercise control over drug prices through DPCOs and its Monopolies & Restrictive Trade Practices Commission. Also, for foreign manufacturers, EMRs cease to exist once a product patent is granted. Products which were selling under an EMR may or may not be granted patent, whereas any product can be granted a product patent regardless of whether it was once under EMR.

India also established a controversial patents amendment ordinance that included compulsory licensing provisions. Under these provisions, the government can withdraw an EMR from a company if it feels that the product is unsafe. The provisions also allowed the government to fix floor prices for essential drugs, and places the burden on the company to prove that an application filed for patent is its invention (earlier, the burden was on the drug controller). It remains to be seen whether the WTO will approve these provisions in upcoming meetings.

In anticipation of the new patent regime, Indian pharmaceutical companies have already started to form new joint ventures with multinationals to strengthen R&D in the industry and profit from what should be a more favorable intellectual property environment. Many are forging special partnerships where an Indian company provides base ingredients while a foreign firm converts the base drug to an effective pharmaceutical. Multinationals have also accelerated their patent applications in India -- patent applications tripled from 1996 to 1997 -- and many international companies are also eyeing the strong Indian network of public sector laboratories and research capabilities at private Indian companies for development work in India. The government has helped foster this trend as well, by relaxing its 40% equity cap to 51% for multinational firms in 1995, and by planning to relax conditions relating to tax incentives for domestic R&D in its upcoming 1999 budget.

The WTO intellectual property agreement has signaled a significant change in India's pharmaceutical industry. By agreeing to recognize pharmaceutical patents, firms were encouraged to switch their efforts from producing generics, and actively engage in R&D of their own. This is evident in the alliance between the German company Bayer and one of India's major players, Ranbaxy. Ranbaxy is developing a new and patentable dosage form of Bayer's antibiotic Ciprobay (ciprofloxacin) before patent expiry. Similarly, another leading Indian firm, Cipla, has developed a new dosage form of AstraZeneca's anti-ulcerant Losec.

A major development has been the work carried out by Indian companies on developing entirely new molecules--one such company is Dr Reddy's Laboratories, which has several original molecules in its pipeline. Dr Reddy's has collaborated with Danish company

Novo Nordisk on two products, both for diabetes and related illnesses. Novo Nordisk is testing these products in clinical trials, with the first product potentially on sale by 2005. Likewise, Ranbaxy is conducting patient trials on a new molecule to treat enlarged prostate glands in ageing men.

To support developments of this kind the Indian government is providing a range of tax concessions designed to encourage R&D, including a ten-year tax holiday on income arising from R&D. The aim is to at least double the domestic pharmaceutical industry's level of R&D expenditure, which is low by international standards, by 2005. There is also the expectation that the new tax regime will attract inward investment by multinationals.

A pioneer of new product R&D has been Dr Reddy's which, in 1993, started a major R&D effort by expanding activities in India and setting up a US base. Though the company has increased its R&D budget this year by 20% to around US\$3.5 million, the expenditure is still small in comparison to Western counterparts. Indian companies have been known to put the cost of developing a novel drug delivery system at less than £1 million due to India's cost advantages in research and development. Under the 1994 WTO TRIPs agreement, India has a maximum of ten years to bring its patent laws into



compliance, which involved recognizing product patents and extending the patent protection period to 20 years.

## **CONCLUSION**

If proposed reforms such as relaxing price control and improving patent protection go through, India's pharmaceutical market will offer many opportunities for foreign pharmaceutical companies in the future. The growing number of joint ventures formed between foreign and Indian pharmaceutical manufacturers already reflect high hopes that these reforms (or at least effective patent legislation) will be carried out in the next few years. Foreign drug manufacturers can also benefit from the industry's efficient process development and modern manufacturing equipment; labor, equipment, and capital cost advantages to manufacturing in India, and a highly skilled labor force with excellent chemical synthesis capabilities.

However, there are still major structural obstacles to success in India's pharmaceutical market--transportation and distribution bottlenecks, corrupt inspectors, and an entrenched bureaucracy. Foreign pharmaceutical companies should therefore make sure that they perform thorough market research for their product, understand the industry's regulations completely, and establish reliable connections in the country to ensure that they remain in the industry for the long run. Only if they are willing to put up with the industry's inefficiencies and maintain a long-term vision can foreign drug companies expect success from the enormous Indian pharmaceutical market.

#### **IV. Drug Accessibility: Case Studies in Generics**

Indian drug companies are not only manufacturing generic brands of expensive drugs today such as *Lipitor*, *Vioxx* and *Zoloft* and selling them as low as one-fortieth of the brand name price, but they are also exporting billions of dollars each year to the Americas while the poor rural parts of India do not have access to these drugs.

When India joined the World Trade Organization in the 90's, they agreed to a Trade Related Intellectual Property Rights (TRIPS) pact which requires, as of January 2005, India to adopt a product patent system that will prohibit firms from manufacturing the basic patented drug in any form and through any route. This has caused public concern over the pricing of "poor country diseases" such as malaria and HIV/AIDS. Currently, the Indian pharmaceutical company Cipla has numerous products and antibiotics designed to combat many infectious diseases; most importantly, it is producing drugs to combat AIDS (Padma 2001). Many fear that once India implements a patent system, the cost of these drugs would be too expensive.

#### **VIAGRA CASE STUDY:**

An interesting point to note is that Indian drug manufacturers have not only created generic brands of drugs relating to heart disease, asthma, and allergies but have also profited from generic brands of "fun" drugs like Viagra. Viagra's case study is interesting because Pfizer, the manufacturer of Viagra, lost the right to patent the chemical Sildenafil Citrate in much of Europe. The loss of patent rights in one region has opened the door for generic copy-cats. India is one of the countries that produce the

Viagra generic pill, under the names of Caverta, Kamagra and Veega. (Viagra 1). Viagra generic pills also have the benefit of being made available through the internet and through e-drugstores. This opens the market place globally for generic products. Therefore, the drug companies that manufacture the generic Viagra pills do not need to spend time advertising their product because Pfizer did the advertising for them. These generic pills contain Sildenafil Citrate, the main active ingredient in Viagra (Viagra 2). Therefore, the customer enjoys savings on Viagra generic sales of Sildenafil Citrate.

In an article in Health & Body, a trial is run with 100 mg of Viagra and 100 mg of Kamagra (the Viagra generic pill made in India). The cost of the Viagra pill was more than ten euros whereas the Kamagra pill was five euros. The study consists of ten volunteers taking one pill on a Friday and the next pill on the following Friday, giving the body time to recover completely. The panel had to make a score between 1 and 10 for each pill, 10 being the highest score. Kamagra scored the highest with 7 and 8 while Viagra scored a 6. More than half the panel suffered from a headache, a stuffed nose, or a swollen head while using Viagra. Kamagra caused less or none of these side effects (Vancapell, 2003).

### **CASE STUDY CONCLUSION:**

This study's conclusion was that the generic drug was more effective than the brand named drug. It raises an interesting point: what if the generic drug is more effective than the name brand drug? Even though the main ingredient Sildenafil Citrate is active in both pills, Pfizer still holds the patent to the manufacturing process of Viagra. Hence,

Ajanta Pharma Ltd, the pharmaceutical company that produces Kamagra creates the copy cat in a different process.

Pfizer justifies the higher price of Viagra by claiming that the generic pills may pose health risks. However, these drugs conform to the WTO guidelines on safety and are even approved by the FDA's own approval (Viagra 1). Because Kamagra and other generic pills are sold globally, via the internet, including the United States, they must meet certain safety regulations.

Therefore, it seems that Kamagra is not only approved by the same health and safety guidelines as Viagra, but it also as effective while posing fewer side effects at half the cost. This conclusion leads to the question as to whether patent laws hinder the development of "better" drugs. If other manufactures were allowed to use the main active ingredient in drugs, but forced to process them in a different method, it could allow for the drug to evolve in an improved and superior form. Viagra is not a necessary drug for survival. However, if what was learned about this drug is applied to those that are aimed at heart disease, cancer, HIV/AIDS, etc... a cure may be found.

#### **POLICY PROPOSAL:**

Jean O. Lanjouw, a visiting fellow in Economics Studies at the Brookings Institute, has written a patent policy proposal for global disease which requires no change in international treaties and would cost very little to implement. Lanjouw's proposal affects only those inventors whose patents relate to a global disease. The patentees would

be “required to choose to make use of their patent protection either in rich countries or in poor countries, but not both” (Lanjouw 2). This proposal is effective because it allows for the drug companies to make patents as it makes the drugs affordable to poorer countries. This is possible because the majority of the patentees would choose to patent their product in a rich country where the potential for profit is much greater. Thus, this means that the patentee would surrender their patent rights in the poor countries which would allow these countries access to these drugs at a lower cost (Lanjouw 2). Lanjouw’s proposal is solely for global diseases. However, it may be beneficial to implement this policy to all pharmaceutical patents.

Lanjouw provides an example to better understand his proposal, assume there are three hypothetical drug companies, a research-based multinational PharmaUS, an India-based firm CiplaIndia, and a generic producer USGeneric:

“PharmaUS has a cancer drug protected by a single patent in the United States and a corresponding patent in India, and the company sells the product in both countries. Then CiplaIndia enters the Indian market with its own version of the same product” (Lanjouw 3).

When this happens, PharmaUS can compete, withdraw from the Indian market or sue for patent infringement. However, if PharmaUS decides to protect its patent in India, it is forfeiting its U.S. patent unenforceable. Because the U.S. market is bigger for cancer, the chances are slim that this pharmaceutical company will sue for infringement. This allows CiplaIndia to enter the market, driving prices lower. (Lanjouw 3).

This policy's main advantage is that it does not contravene existing treaties nor does it require expensive reinforcement. The reinforcement will come from the fact that patentees have a "duty to deal with the patent office in good faith, and failure in this regard is clear grounds for rendering a patent unenforceable" (Lanjouw 3). This also does not require changes to developing countries' new patent system nor does it make it susceptible to domestic political pressure. An added benefit not mentioned by Lanjouw is that this eliminates drug monopolies and allows for the evolution of a drug, as described in the Viagra case study.

Lanjouw suggests that the proposed mechanism to determine which patents protect a product is a lawsuit.

"One important reason for this feature is that when an infringement suit is filed to prevent the sale of a product it is on the basis of a set of patents. In order to be successful in prosecuting its suit, the patent owning firm has an incentive to correctly announce which patents it believes best protect the product in question. Thus, the link between products and patents is made automatically, which resolves the otherwise intractable problem of how to identify the use of particular patents" (Lanjouw 4).

However, the best solution may not be to have lawsuits determine which patents protect a product. This is an expensive process and time may be a factor. The most effective way to determine which patents protect a product is to register it when as the product is being registered in the patent office. This would clear the confusion as well free it from a costly process.

Pharmaceutical companies, although they may object to this proposal initially, will have a means to create a “low cost source of supply” which will cause them to favor this policy. It is obvious that the rich world can not supply the developing world with drugs at U.S. prices. A necessary means in order to protect U.S. pharmaceutical companies is to establish a separation of markets (Lanjouw 4). A separation of markets can be enabled through a legislative confirmation that maintains that holders of U.S. patents have the right to prevent products from coming into the United States from elsewhere.

#### **CONCLUSION:**

In 2005 when the TRIPS agreement takes effect, India’s pharmaceutical company will need to undergo a structural change. Although patents before a certain date remain unprotected, these firms can not survive unless a drastic structural change occurs. Cipla and other major firms in the industry have slowly prepared for the inevitable, yet, India’s pharmaceutical economy remains ill-equipped for January 1, 2005.

The Viagra case study implies that because a drug is generic, it does not mean that the quality is inferior to the brand named drug. It even goes as far as to suggest that the generic brand may even be superior with fewer side effects than the original. This finding opens up the possibility of evolving brand name drugs. In order for this to be possible, the strict U.S. patent laws must be replaced with international patent laws that are less stringent.

## **V. Additional Case Studies**

Despite efforts from the TRIPS component of the GATT treaty, India still remains one of the biggest threats to pharmaceutical industries in developed countries. In the past few years, Indian pharmaceutical companies have “piggybacked” on the efforts of several major drug companies, using reverse engineering to obtain chemical compositions of drugs that have been proven effective through clinical trials and testing, and have been approved by the FDA. This was possible under a domestic policy that allowed Indian pharmaceutical companies to create “copies” patent-protected drugs and sell them domestically or in unregulated countries as long as they used a different manufacturing process. Pfizer, which is currently being challenged on its patent for Lipitor (the number one selling drug for lowering cholesterol), has made headlines in the past for a similar case on the drug, Norvasc.

This portion of the paper will cover Pfizer’s involvement with the Indian pharmaceutical companies, more specifically, with the drugs Norvasc and Lipitor, and their role in Indian pharmaceuticals. This portion of the paper will also predict the outcome of the recent suit Ranbaxy brought against Pfizer regarding Lipitor, based on the court decision of the Norvasc case (Pfizer, Inc. v. Dr. Reddy’s Laboratories, Ltd. No. 02 Civ. 02829 (D.N.J. December 17, 2002))<sup>1</sup>, and will discuss the patent and intellectual property rights violations for each of the drugs mentioned.

### **Norvasc Case Study**



Dr. Reddy's Laboratories, one of India's leading drug producers challenged one of Pfizer's bestsellers, Norvasc, a drug which treats hypertension (high blood pressure), and won. However, Pfizer, not wanting to give Dr. Reddy's Laboratories a chance to create a generic version of Norvasc, its second highest grossing drug, sued Dr. Reddy's Laboratories for copyright infringement to the Court of Appeals for the Federal Circuit (CAFC). Just last year the CAFC heard arguments from both sides, and considered, for the first time, patent protection during a patent's term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act).

The Hatch-Waxman Act defines the terms of drug patents, and specifies the terms that need to be followed in order to renew a drug's patent. The major questions regarding the Hatch-Waxman Act are whether a patent owner is entitled to the full scope of a patent during the time of the patent's extension, or whether the patent is limited to only the specific product approved by the FDA.<sup>2</sup> Patent extensions under the Hatch-Waxman Act are usually granted based on the amount of time the drug underwent clinical trials for FDA approval, and are usually limited to five years.

Pfizer was given FDA approval on Norvasc's active ingredient: amlodipine besylate, although the patent application for Norvasc covered the derivative salt amlodipine maleate as well (Patent No. 4,572,909).<sup>1</sup> Since FDA approval was granted for amlodipine besylate only, the patent extension was granted to only amlodipine besylate for over three years- February 25, 2003 to July 21, 2006.<sup>1</sup> In March, 2002, Dr. Reddy's Laboratories filed an NDA under 505(b)(2) of the Federal Food, Drug, and

Cosmetic Act for market approval for amlodipine maleate, which was granted FDA approval.<sup>1</sup> Dr. Reddy's Laboratories planned on marketing the copycat drug of Norvasc, with the changed active ingredient by August 2003, but was sued by Pfizer in June 2002 for patent infringement before production was possible.

Several factors went into deciding the outcome of this case. In favor of Dr. Reddy's Laboratories, the court found that FDA cannot review every single different form of a compound within a reasonable amount of time. However, the role of the patent is to provide the rights to produce, and exclude others from producing a product. One of the main arguments questioned the validity of Dr. Reddy's Laboratories FDA approval on amlodipine maleate which relied heavily on Pfizer's clinical studies and test results from amlodipine besylate.<sup>1</sup> The argument concluded that this dependence on test data for Norvasc showed that the two compounds cannot be considered separate or distinct.

Earlier this year, the CAFC ruled in favor of Pfizer, overturning the court's previous decision, thus disabling Dr. Reddy's Laboratories production of the Norvasc-generic drug. The court's decision created a predecessor for future cases that defined how closely generic manufacturers are able to compete with larger corporations during the time of a patent term extension.

### **Lipitor Case Study**

Ranbaxy Laboratories Ltd., another one of India's largest pharmaceutical industries, has presented a similar case to Dr. Reddy's. In the past month, Ranbaxy has

challenged Pfizer's patents on Lipitor, the number one selling drug in the United States. Ranbaxy aims to sell a copycat generic Lipitor and argues that its drug does not infringe on Pfizer's original patent. Because of the second patent granted to Pfizer on Lipitor until 2011, Ranbaxy is arguing that the extension was wrongly awarded with the claims that Pfizer withheld crucial scientific data from the patent-review board, which may have affected the decision to grant the extension, and is therefore challenging Pfizer's original patent on Lipitor which would end in 2006.<sup>3</sup>

Pfizer argues that the original patent discussed a general class of compounds, while the second focuses on atorvastatin calcium- the effective chemical in Lipitor.<sup>3</sup> Pfizer's representatives argue the validity of the second patent since the particular compound atorvastatin calcium was unique in its effectiveness in treating high cholesterol.

Ranbaxy argues that Pfizer's original patent only discussed a mixture of compounds, and not the individual components the compounds.<sup>3</sup> Because of this detail, Pfizer should not have been granted a second patent since there were no claims to atorvastatin calcium.

The trial, which is expected to last until December 10<sup>th</sup>, 2004, is likely to be the last of the copycat drug cases brought by leading pharmaceutical companies since product patent rights are effective in India starting next year, 2005.

**Conclusions:**

With the implementation of product patent rights, effective in 2005, Indian drug companies will no longer be able to produce these copycat drugs and will lose status as one of the main competitors in the generic drugs market. Statistically speaking, the North American market comprised 32% of Dr. Reddy's total revenues in 2003, which amounts to approximately \$123 million.<sup>3</sup> For Ranbaxy, revenues in the United States alone totaled \$304 million, which accounts for roughly 42% of Ranbaxy's total revenues.<sup>3</sup> Since India can produce drugs at a fraction of the costs to make them in developed countries, such as the United States, the generic drugs industry has created huge revenues in exports for India. According to the Organization of Pharmaceutical Producers of India, total drug exports increased from \$1.8 billion in 2001 to \$2.5 billion in the 2003 fiscal year.<sup>3</sup>

While leading pharmaceutical industries may feel relieved with the patent protection rights that will be enforced this coming year, the concern on raised drug prices in India and less developed countries still needs to be addressed. Similarly to the initial fears of India to the GATT treaty signing, Individuals believe that the loss of the generic drug market could prevent drug use by the less fortunate individuals who need them. Unfortunately, there is no easy solution for this matter. The GATT treaty aimed to erase the problem between lesser developed countries (LDC) and drug use, but ultimately resulted in additional problems with drug re-importation and escalated drug prices. A proposed solution would be to create a partnership between pharmaceutical companies such as Dr. Reddy's Laboratories, or Ranbaxy Laboratories, to create certain generic

versions of drugs needed in both LDC and developed countries. Since drug re-importation may still pose as a problem to the major pharmaceutical industries, a partnership between the generic producers could ensure major companies such as Pfizer a fair portion of revenues. Although this proposal is not guaranteed to appease either sides of the drug industry, by bridging companies in LDC and developed countries together, the GATT treaty can still effectively aid LDC obtain the necessary drugs they require, and reasonably compensate larger pharmaceutical companies with partial revenues.

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