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The Indian Pharmaceutical Industry

Business, Legal & Tax Issues

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Dr. Milind Antani
Gowree Gokhale

93-B MITTAL COURT, NARIMAN POINT
MUMBAI 400 021 INDIA.
TEL: +91 –22 – 5669 5000
FAX: +91- 22 – 5669 5001

220 CALIFORNIA AVENUE., SUITE 201
PALO ALTO, CA 94306 USA.
TEL: +1 –650 – 325 7100
FAX: +1 –650 – 325 7300

PRESTIGE LOKA, G01
7/1 BRUNTON ROAD
BANGALORE 560025. INDIA.
TEL: +91 – 80 – 5693 5001
FAX: +91 - 80 – 5693 5001

LEVEL 30,
SIX BATTERY ROAD
SINGAPORE - 049909.
TEL: +65 - 6550 9855
FAX: +65 - 6550 9856

Nishith Desai Associates ("**NDA**"), an international legal, tax and business counselling firm was founded by international tax lawyer Nishith Desai in 1984. The firm has offices in Mumbai and Bangalore in India and Silicon Valley in the US. NDA's associates are multi-skilled legal and tax professionals, several of whom have additional qualifications in a wide range of specialized disciplines for contextual understanding of the varied businesses of clients.

NDA is research-driven, focusing on selected practice areas which include the pharma industry, biotechnology and nanotechnology. Other main practice areas are, among others, international finance and tax; corporate and securities as well as the telecom, media and entertainment industries. NDA specializes in cross-border transactions and has worked on several first-time transactions. These included the first cross-border stock swap merger out of India – BFL's acquisition of MphasiS -- and the ADR stock swap deal in Silverline's acquisition of Seranova Inc. The firm has advised several major multinational clients on setting up their India-based operations while guiding Indian clients on globalising their businesses.

NDA also has an extensive Funds practice, having structured and acted for a number of private equity funds for India. The firm has acted as the Underwriter's counsel in the American Depository Receipts ("ADR") offerings of Infosys Technologies and Satyam Infoway in the US, in addition to representing Wipro, Rediff.com and Silverline Technologies in their respective ADR listings.

NDA also upholds the principles of social responsibility and has a dedicated social sector team, which advises not-for-profit organizations such as the American India Foundation, the Global Heritage Fund, Sesame Workshop and Grassroots Trading Network for macro-impact social upliftment projects.

NDA was presented the **Indian Law Firm of the Year 2000** and **Asian Law Firm of the Year (Pro Bono) 2001** awards by the *International Financial Law Review*, a Euromoney publication.

The firm's founder, Nishith Desai, has also been ranked at No. 28 in a global listing of the top 50 tax professionals in the world who have influenced tax policy, by *Tax Business*, a UK publication, in 2004.

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Executive summary

The Indian pharmaceutical industry is estimated to be a USD 13.6 billion business today and is growing at the rate of 20% annually[1]. There are several global pharmaceutical companies like GlaxoSmithklineBeecham and Pfizer, which have set up operations in India and are looking at rapidly expanding their existing operations by setting up clinical trial centers and focusing on bio-equivalence studies in India. Outsourcing contract research and development and conducting clinical trials in India is also becoming quite common for most global players. Domestic Indian companies like Ranbaxy,Dr. Reddy's Laboratories, Wockhardt, Zydus Cadilla, and Torrent Pharma are also competing on par with global players in the Indian and international market.

With the advent of the product patent regime, most global pharmaceutical companies are gearing up to hit the Indian market with not only life-saving drugs but also life-style medication.

For a global pharmaceutical company seeking to enter India today, the opportunities seem exciting and the potential is tremendous. On the surface, Indian law appears to be a quagmire of regulations, notifications and approval requirements. However, with steps that India has already taken to honor its WTO commitments combined with the liberalization and the relaxation of the export-import policy, foreign companies seeking to enter this space will see that most of the restrictions that existed on issues like pricing and licensing have now been relaxed to the extent that there is a level-playing field for global and Indian companies. Intellectual property laws have also been made TRIPS compliant including the patent laws, which is the cornerstone of the pharmaceutical industry. We have discussed in detail the legal and regulatory regime as applicable to the pharmaceutical industry.

For a trans-national entity seeking to have a presence in India, structuring of the investment from a tax and regulatory perspective would be critical. This paper highlights some of the relevant issues in this regard.

[1] http://www.yaleglobal.yale.edu/article visited on 1st February 2005

1. The Indian pharmaceutical industry – an overview

The past…

As compared to most other industries with a global reach, the pharmaceutical industry is largely controlled by privately owned companies which focus on stockholders profits. Since the pharmaceutical industry is directly in the business of public health, it is heavily regulated by governments world-over. In India also the pharmaceutical industry is heavily regulated, imposing various restrictions on local manufacturers as well as importers. Till recently, due to an under-developed Indian pharmaceutical industry many global pharmaceutical companies were marketing their products in India. In fact in the early 1970's before the move to enforce process patents, multinational pharmaceutical companies had a 70% plus market share in India2.

In 1991 with the liberalization of the Indian economy, foreign investment started pouring into various sectors of the Indian economy ranging from the manufacture of breakfast cereals to the IT industry. However, the Indian pharmaceutical industry did not attract much foreign investment in the initial years of liberalization for a variety of reasons mainly including apprehension about an adequate patent protection regime, the compulsory licensing system and the issuance of license of rights. Several other factors also affected the development of the Indian pharmaceutical industry including the low drug prices as a result of the control exercised by the Central Government by virtue of the Drug Price Control Order which was introduced in 1985 and which initially regulated the prices of about 143 drugs which has now been reduced to 74 drugs3. A comparative analysis of drug prices in India shows that drugs like Prozac are sold in India at less than half the price at which they are being sold in the U.S.4 Further, the Indian drug market is highly fragmented and multinationals have typically been much more active in formulation of branded products as opposed to Indian firms which concentrated on bulk drugs and generic pharmaceuticals.

Post 1995 when India became a signatory to Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS") global pharmaceutical companies began viewing India with more interest. Subsequently, in India acceded to the Paris Convention for Protection of Industrial Property ("Paris Convention"). India also acceded to the Patent Co-operation Treaty ("PCT") which afforded Indian companies the benefit of seeking multiple country protection for their patents.

The future…

With organizations like the Pharmaceuticals Research Manufacturers Association ("PhRMA") actively pursuing product patent protection in India and the advent of this regime with effect from 2005, most multinationals are now gearing up for a post-2005 regime. The third Patent Amendment Act, 2005

[2] Singh, Gina, "*Prescribed : A Big Dose of India*", Businessworld, 21 April 2003, Page 24.
[3] Infra Chapter 4, "Legal and regulatory regime for pharmaceutical companies in India".
[4] Tancer, Robert and Joysula Srinivas, *"Investing in the Indian Pharmaceutical Industry*", Thunderbird, 1999. P. 5.

has aligned Indian patent protection laws with the recommendations in the TRIPS.

There are several factors that appear attractive to global pharmaceutical companies looking towards India, some of which are set forth below:

- Healthcare spending is and will be on the rise with the middle-class investing more and more on branded medicines
- India is seen as a huge market not only for life saving drugs but also for lifestyle drugs
- Global pharma companies also see the tremendous potential for conducting research and development activities from India as India is known to have a vast talent pool of qualified PHDs. Outsourcing contract research to India is becoming quite common amongst global players
- India is also fast replacing Europe as the leader for sourcing active pharmaceutical ingredients (API) for the generic market where cost and speed to the market are important
- India is also seen to have a huge potential for conducting clinical trials and bioequivalence studies as costs are low for the same. Conducting a clinical trial for a standard drug in the United States can cost about $150 million. A similar drug could be tested in India at a 60 per cent reduction of that whopping cost.[5] Global corporations like Glaxo and Pfizer are beginning to look at the possibilities of setting up their own clinical trial centers in India. Global consultancy McKinsey & Co estimates that by 2010, global pharma majors would spend around $1-1.5 billion just for drug trials in the country.

There are some issues that still concern global pharmaceutical companies doing business in India or exploring the possibility of doing business in India including the compulsory licensing regime and the accessibility to an effective and organized distribution network. With the huge investment that global pharmaceutical companies have put into India and with global organizations like the Gates Foundation set to pump in large sums of money to develop anti-HIV drugs in India, it is an indication that the pharmaceutical industry is all set for the big wave.

This paper attempts to provide an overview of the issues that a global pharmaceutical company would face when it proposes to enter the Indian market.

[5] **George Iype |** December 22, 2004, www.rediff.com

2. India entry strategy

I. *Investment climate in India*

By and large foreign direct investments are now permitted in almost all the sectors in India without obtaining prior regulatory approvals (*i.e.* under the "automatic route") barring some exceptional cases like defense, housing and real estate, print media, *etc.* (commonly referred to as the "**negative list**"). Under the automatic route, the details of the investments are required to be filed with the Reserve Bank of India ("**RBI**") within the prescribed time. However, if the investment is not in accordance with the prescribed guidelines or if the activity falls under the negative list, prior approval has to be obtained from the Foreign Investment Promotion Board ("**FIPB**"). In the case of pharmaceutical companies, foreign direct investment is permitted to the extent of 100% under the automatic route provided that the activity does not attract compulsory licensing or involves the use of recombinant DNA technology and specific cell/tissue targeted formations. Any proposal for the manufacture of licensable drugs, pharmaceuticals and bulk drugs produced by recombinant DNA technology and specific cell/tissue targeted formulations will require the prior approval of the FIPB.

Further, while transfer of shares of an Indian company between two non-residents does not generally require any prior regulatory approvals, the transfer of existing shares from a resident to a non-resident and *vice versa* has been brought under automatic route. The Indian Government has, with a view to further liberalize foreign direct investment, notified vide Press Note No.1 dated January 12, 2005 that any new proposal for foreign investment or technical collaboration by a foreign investor, who has or had any previous joint venture or technology transfer / trademark agreement in the same or allied field in India, will be allowed under the automatic route. This route is however subject to the sectoral policies.

The said Press Note No. 1 has narrowed down the scope of the earlier Press Note No.18 (of 1998), which was applicable to the 'same' and 'allied' field. The Press Note No. 1 now requires prior Government approval only in cases where the foreign investor has an existing joint venture or technology transfer or trademark agreement in the 'same' field. The onus to provide requisite justification as also proof that the new proposal would or would not jeopardise the existing joint venture or other stakeholders would lie equally on the foreign investor or technology supplier and the Indian partner.

Even if the foreign investment is falling in the 'same' field, the Government has carved out following exceptions, for which no prior Government approval is required:

- Investments are made by Venture Capital Funds registered with the Securities Exchange Board of India.
- The existing joint-venture investment by either parties is less than 3%.
- The existing joint-venture or collaboration is defunct or sick.

Hopefully, the changes envisaged through the implementation of Press Note 1 would create the balance in achieving a liberalized environment in India and at the same time protecting to the joint-venture partners to safeguard their interests.

II. *Form of the Indian entity*

A foreign company can establish its presence in India either as a liaison office ("**LO**"), branch office, or a limited liability company. Some of the important regulatory and tax requirements under each of these options are discussed hereunder:

Liaison Office

A foreign company can establish a LO in India only with the prior approval of the RBI. Such approvals are granted on a case-by-case basis provided the activities of the LO are restricted to acting as a communication channel between the foreign company and entities in India. Further, the LO is not permitted to generate any income on its own account and the cost incurred by the LO for its operations are required to be reimbursed by its parent. The liaison offices are currently under attack from tax departments. They are often being treated as 'Permanent Establishment' and being taxed on their deemed profits.

Branch Office

A foreign company can set up a branch in India only with the prior approval of RBI. Such approvals are granted on a case-by-case basis and provided the activities of the branch are restricted to the permitted activities which *interalia* include export/Import of goods; rendering professional or consultancy services; rendering services in Information Technology and development of software in India; *etc*.

In the event that a foreign company is looking at manufacturing pharmaceuticals in India or having an operation of a reasonable size, a branch or an LO may not suit its purpose. In such a case it would be advisable for the foreign company to set up a limited liability company in India which could be in the form of a joint venture with an Indian partner or a wholly owned subsidiary of the foreign parent.

Subsidiary

A subsidiary of a foreign company is treated at par, in almost all respects, with a company having resident Indian shareholders. Establishing a WOS in India is generally preferable vis-à-vis setting up of a branch in India as generally there is more flexibility in relation to the activities that can be carried on in India by the WOS and a branch of a foreign company may not be eligible for certain tax incentives currently available in India.

The WOS could be incorporated under the Indian Companies Act, 1956 ("**Companies Act**") either as a private limited company (which has to have a minimum of two shareholders but not more than fifty shareholders) or a public limited company (which has to have a minimum of seven shareholders). However, in the case of a private company there are restrictions on transfer of

its shares and number of members and a total prohibition on invitation to the public for subscription to its shares and acceptance of deposits from outsiders.

Furthermore the Indian company would have to get registered with other regulatory authorities e.g. under the Shops and Establishments Act which governs the terms of employment, the Income Tax Act, the Provident Funds Act, the Director General of Foreign Trade, the Factories Act etc.

Corporate governance issues in India

Most global pharmaceutical companies would adhere to their corporate governance policies, which are usually formulated on a worldwide basis. Some global corporations have faced difficulties in India[6] due to the vast difference in business practices in India and the country in which these companies have a principal place of business. For instance, unlike the United States, which makes bribery of foreign government officials a criminal offence, India does not have the equivalent of the Foreign Corrupt Practices Act ("**FCPA**"). However, it is an offence to give bribe to government official. There are no exceptions for "small-time" expenses under Indian law as there are under the FCPA.

This scenario is changing slowly with India completing a decade of liberalization entailing the removal of the license *raj,* reduction of tax rates and relaxation of exchange controls, all of which have significantly reduced the potential for bribery and corruption and have brought about greater transparency in the governmental and regulatory systems.

3. Overview of the Indian Tax Laws

The scope of taxability of any entity in India depends on its residential status. A resident taxpayer is taxable in India in respect of its global income. A company incorporated in India or wholly controlled and managed from India is regarded as a resident of India and thus would be chargeable to tax in India on its global income. A foreign company is taxed in respect of its Indian source income. Thus income of a branch and foreign company will be taxed in India. Recently, Liaison offices and foreign companies (though generally not taxable) have been targeted by the Indian tax department.

I. Corporate tax rate

Domestic companies are currently taxed at the rate of 30%. The rates mentioned in this paper are exclusive of currently applicable surcharge at the rate of 10% on tax for domestic companies and education cess of 2 % on tax and surcharge. Foreign companies and a branch of a foreign company [which would be regarded as a Permanent Establishment (**"PE"**) of its parent in India] would be chargeable to tax at the rate of 40% (excluding the currently applicable surcharge of 2.5% on tax and education cess of 2% on tax and surcharge)

II. Deduction for expenditure on research and development

In-house research and development

Companies engaged in the business of biotechnology or in the business of manufacture or production of any drugs, pharmaceuticals, chemicals, etc. and who have incurred any expenditure on scientific research (not being expenditure in the nature of cost of any land or building) on in-house research and development facility as approved by the Department of Scientific and Industrial Research, are allowed a deduction of 1 ½ times of such expenditure. This deduction was restricted for expenses incurred on or before March 31, 2005. The Finance Act 2005 has extended the sunset clause to March 31, 2007. Expenditure on scientific research includes expenditure incurred on clinical drug trial, obtaining approval from any regulatory authority under any Central, State or Provincial Act and filing an application for a patent under the Patents Act, 1970.

Contributions made to other institutions

The Indian Income Tax Act ("**ITA**") confers a deduction of 1¼ times of sums paid to any scientific research association (having as its object the undertaking of scientific research) or to any university, college or other institution to be used for scientific research.

Capital expenditure

The whole of any expenditure on scientific research (other than expenditure on acquisition of any land) being capital in nature, incurred after March 31, 1997 is allowed as a deduction. Further, capital expenditure on scientific research incurred three years immediately prior to the commencement of business is allowed as a deduction in the year in which the business is commenced.

III. Dividends

Dividends are currently exempt from income tax in the hands of all shareholders, irrespective of their residential status. However, the company distributing the dividends is required to pay a dividend distribution tax of 12.5% .

IV. Interest

Under the domestic tax laws of India, interest received by a non-resident on foreign currency loans is generally taxable at the rate of 20%, which can be reduced to 10/15% under some of the tax treaties signed by India with other countries. As in the case of dividends, tax is required to be withheld at source by the resident payer. Further, interest is a tax-deductible expense for the Indian resident (i.e. wholly-owned subsidiary), only if the applicable tax has been withheld before making the payments to the non-resident.

V. Royalties / Fees for technical services

Payment towards royalty and Fees for Technical Services ("**FTS**") currently attract a withholding tax on a gross basis. The Finance Act 2005 has reduced the withholding tax from 20% to 10%. This reduction in withholding tax rates will eliminate the need for foreign companies to route their agreements through favourable tax treaty jurisdictions for IP such as Netherlands, Ireland etc. This is also a welcome move for non residents coming from non treaty jurisdictions as the domestic tax rate would now be line with the lower rate under the tax treaties.

Further, if such payments of royalties and FTS are effectively connected to a PE in India then such payments would be taxed as business profits on '*net income*' basis.

VI. Capital gains

Currently, capital gains are classified into short-term capital gains and long-term capital gains under the ITA. Shares of a company, securities listed on a recognized Indian stock exchange if held for more than 12 months are treated as long-term capital assets and if held for 12 months or less are treated as short-term capital gains. These gains are taxed as follows:

(i) Long-term capital gains arising on transfer of listed equity shares (including units of an equity oriented mutual fund) on a recognised stock exchange in India will be exempt from tax in India;

(ii) Short-term capital gains arising on transfer of listed equity shares (including units of an equity oriented mutual fund) on a recognised stock exchange in India will be taxed at the rate of 10%;

(iii) Capital gains realised on sale of listed equity shares not executed on a recognised stock exchange in India and other Indian listed securities or units of mutual funds (i.e. other than those falling under (i) and (ii)

above) would be taxed at the rate of 10% for long-term gains and as normal income in case of short-term gains;

(iv) Capital gains realised on sale of unlisted Indian securities would be taxed at the rate of 20% for long-term gains and as normal income in case of short-term gains.

The exemption on long term capital gains and reduction of rate for short term capital gains would be applicable only if the sale / transfer of the equity shares takes place on a recognised stock exchange in India. All transactions entered on a recognised stock exchange in India will be subject to a securities transaction tax ("**STT**") levied on the transaction value at the applicable rates. In case of purchase / sale of equity shares and units of an equity oriented mutual fund which is settled by way of actual delivery or transfer of the equity share/ unit, STT will be levied at the rate of 0.1% on both the buyer and seller of the equity share/ unit. For sale of equity shares and units of an equity oriented mutual fund settled otherwise than by way actual delivery or transfer of the equity share/ unit, STT will be levied at the rate of 0.02% on the seller of the equity share/ unit. Seller of derivatives would be subjected to an STT of 0.0133% while in case of sale of a unit of an equity oriented fund to the mutual fund would attract STT at the rate of 0.2%. The STT can be setoff against business income tax calculated as per the provisions of the ITA, provided the gains on the transactions are offered to tax as business income and not as capital gains.

VII. Minimum Alternate Tax

Where the tax payable by a company is less than 7.5 per cent of its book profits, the tax will be deemed to be 7.5% cent of such book profits as Minimum Alternate Tax ("**MAT**"). This is to ensure that every company pays a tax of at least 7.5% of its book profits. The Finance Act 2005 now allows for credit in respect of MAT paid for any assessment year beginning on or after April 1, 2006 against tax payable in subsequent years. However, carry over and set off will be allowed only up to five assessment years immediately succeeding the assessment year in which such tax credit becomes allowable. However, no credit is allowed in respect of MAT paid in any assessment year prior to the assessment year 2006-07.

VIII. Transfer pricing

India has enacted transfer pricing regulations and thus any international transactions between two associated enterprises would have to be on an arm's length basis.

IX. Structuring the investment into India

Investing in the Indian company through an intermediate holding company in a favorable jurisdiction offers various tax advantages. It helps in pooling offshore investments and also helps in globalization or restructuring at a later stage. India has favorable treaties with quite a few countries including Mauritius, Cyprus and Netherlands. It may be worthwhile considering a higher debt: equity ratio as there are no thin capitalization rules in India.

Indirect taxes

Customs duty

It is levied on the import of goods/equipment into India. Import duties are prescribed by the Customs Tariff Act. Specified life saving products can be imported at zero duty. The Finance Act 2004 removed restriction of minimum export obligation of Rs 200 million for availing exemption from customs duty for specified equipments used in R&D by bio-tech and pharmaceutical companies. The Finance Act 2004 also extended the concessional duty of 5% to all importers of Pharmaceutical Reference Standards. Finance Act 2005 has reduced the peak customs duty from 20% to 15% (excluding currently applicable education cess of 2%).

Sales tax

Sales tax is levied on the sale of movable goods by respective States. The Central Sales Tax Act regulates inter-State sales while intra-State sales are regulated by the local sales tax of the respective State. Sale in the course of import and export are exempt from the levy of sales tax under the Central Sales Tax Act. The Finance Act 2005 has amended the Central Sales Tax Act to include definition for "works contract" and computation of sale price in case of works contracts. The local sales tax is calculated as a percentage of the sale price and such percentage varies from 4-13% depending on the type of product being sold and the State which has jurisdiction to tax such a sale. Also refer to Value Added Tax hereunder.

Value Added Tax

20 Indian states have already shifted to the Value Added Tax ("VAT") system from April 1,2005 (Haryana being the first to introduce VAT in April 2003). The revenue neutral VAT rate agreed to by all the states is 12.5%. The States has also agreed 250 essential commodities and manufacturing inputs would attract a 4% tax, while 217 other items would attract the 12.5% rate. About 41 items like petrol, diesel, ATF, agricultural equipment and newspapers would be exempt from VAT while precious metals like gold and silver would attract only 1% tax. Sugar, textile and tobacco items would be out of the VAT net. The imposition of 12.5% VAT rate in lieu of sales tax is estimated to result in a 3-5% increase in the price of medicines[7].

Despite the introduction of VAT in several States, the Central Sales Tax has not been phased out as yet.

Service tax

The service tax regime was introduced *vide* Chapter V to the Finance Act, 1994 ("**F-Act**"). Subsequent Finance Acts, (1996 to 2004) have widened the service tax net by way of amendments to the F-Act. It is currently levied at the rate of 10% (excluding currently applicable education cess of 2% on tax) on gross basis on the specified taxable services enumerated in the F-Act, such as management consulting services, consultancy or technical services by a consulting engineer, business auxiliary services, *etc.*

[7] ICICI Securities, January- March 2003, Q4 FY 2003, Equity Research Group. P. 120.

The Finance (No. 2) Act, 2004 widened the services tax net to introduce service tax on Intellectual Property ("**IP**") services. IP services are defined as:

> "any right to intangible property, namely, trade marks, designs, patents, or any other similar intangible property, under any law for the time being in force, but does not include copyright, while intellectual property services is defined as, "(a) transferring, whether permanently or otherwise or (b) permitting the use or enjoyment of any intellectual property right".

However, the Central Board of Excise and Customs (the apex body for administration for indirect taxes, including service tax) vide circular dated September 17, 2004 has clarified as follows:

> "A permanent transfer of intellectual property right does not amount to rendering of service. On such transfer, the person selling these rights no longer remains a 'holder of intellectual property right' so as to come under the purview of taxable service. Thus, there would not be any service tax on permanent transfer of IPRs"

In March 2005, the government notified the Export of Services Rules ("**Rules**"). These Rules have become effective from March 15, 2005. As per the Rules, services taxable under the F-Act will be exempt from service tax where the same are exported outside India. In order to determine what constitutes export of services, the Rules have classified all the notified taxable services into 4 categories, and enumerated the conditions to be satisfied with respect to each of such categories. From the effective date of these Rules, the erstwhile exemption in respect of consideration received in convertible foreign exchange stands withdrawn.

Fringe Benefit Tax

The Finance Act 2005 has introduced the concept of Fringe Benefit Tax ("FBT") i.e. collective benefits which cannot be allocable per employee is subject to tax in hands of employer at the effective rate of 33.66%.

The term "fringe benefit" is defined as any privilege, reimbursement, free or concessional ticket for private journeys of the employees and their family members, etc. Other expenses or payments made by the employer in the course of his business on inter alia entertainment, gifts, conference, provision of hospitality, etc. would also be regarded as fringe benefits. Transport services provided to employees between place of work and residence, and canteen services in an office or factory are kept outside the purview of fringe benefits.

Taxable value of each of these benefits is separately prescribed. This tax is an additional tax and would be payable by the employer irrespective of whether he is subject to regular income tax under the ITA. This means that business undertakings, which are exempt from income tax on their income due to tax holiday, or incurring losses, would also be required to pay this tax. The employer would not get a tax deduction for such tax. There are detailed compliance requirements regarding filing of a fringe benefits tax return. It is also proposed that this tax would be separately assessable and would be subject

to advance tax, assessment, and interest and demand provisions similar to those applicable in respect of regular income tax returns.

Banking Cash Transaction Tax

In order to unearth black money and assets, the Finance Act 2005 has introduced the Banking Cash Transaction Tax ("BCTT") at the rate of 0.1% with effect from June 1, 2005. Accordingly, cash withdrawals by individuals in excess of INR 25,000 and INR 100,000 in case of others on a single day shall be subject to BCTT.

4. Legal & Regulatory Regime for Pharmaceutical Companies in India

The most important legislation that regulates Indian pharmaceutical industry is the Drugs and Cosmetics Act, 1940. There are several other legislations, regulations, and orders that also need to be considered including the Drug price Control Order. We have discussed the salient features of the legal and regulatory regime as specific to pharmaceutical industry herein below.

Drugs and Cosmetics Act, 1940

The Drugs Act and Cosmetics Act, 1940 ("**Drugs Act**") and Drugs and Cosmetics Rules, 1945 ("**Drugs Rules**") regulates the import, manufacture, distribution and sale of drugs in India. It provides the procedures for testing and licensing new drugs. The main object of the Drugs Act is to ensure the availability of standard quality drugs and cosmetics to the consumer. A drug is defined comprehensively under the Drugs Act to include a variety of substances[8]. The responsibility to enforce the Drugs Act is entrusted with both the Central Government and the State Governments. The Central Drugs Standard Control Organization, headed by the Drugs Controller General of India ("**DCGI**") is primarily responsible for coordinating the activities of the State Drugs Control Organization, formulating policies, and ensuring uniform implementation of the Drugs Act throughout India. Matters of product approval and standards, clinical trials, introduction of new drugs, and import licenses for new drugs are handled by the DCGI. Whereas, the approvals for setting up manufacturing facilities, and obtaining licenses to sell and stock drugs are provided by the respective State Governments.

The Drugs Act and the Drugs Rules provides procedure for obtaining approvals for the following activities:

1. Manufacturing a drug in India

   Manufacturing of any drug in India requires a license. A license is required for each such location at which drugs are to be manufactured,

8 Per Section 3 (b) of the Drugs Act : ""drug" includes —

(i) all medicines for internal or external use of human beings or animals and all substances intended to be used for on in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;
(ii) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;
(iii) all substances intended for use as components of a drug including empty gelatin capsules; and
(iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board."

and also for every drug to be manufactured at each of such locations. The license has to be renewed periodically. The Drugs Act also specifies other conditions for the grant or renewal of a license. A license (called loan license) to manufacture could be also obtained if the product is manufactured in the factory owned by another party.

Under the Drugs Act "manufacturing" includes any process (or part) for making, altering, ornamenting, finishing, packing, labeling, breaking up or otherwise treating or adopting any drug with a view to its sale or distribution. However, "manufacturing" does not include dispensing or packing at the retail sale level.

For a detailed analysis of the procedure for obtaining a manufacturing license and Loan License, please refer to ***Annexure I*** of this paper.

Annexure I

In a move to curb the spread and sale of counterfeit drugs, the Drugs Control Department of the National Territory of Delhi has made procuring of search reports from the Registrar of Trade Marks mandatory before approving any drug-manufacturing license under a particular brand name.

This initiative by the Delhi Drugs Authority is in pursuance of the observations in the decisions of the Supreme Court's decision in Cadila Health Care Ltd. vs. Cadila Pharmaceuticals Ltd. (decided on March 26, 2001)[9]. If adopted in the other states in India, this provision will eliminate the chances of approval of a deceptively similar and look-alike brand of drugs.

2. Importing a drug into India

Most pharmaceuticals are freely importable under the provisions of the EXIM Policy[10]. However, prior to importing certain drugs a prior license is required to be obtained from the Drug Controller of India. Such products cannot be imported after the date shown on the label as being that on which the potency would reduce or toxicity would increase beyond the standard permitted. A license is valid for a year, up to December 31st of the year following the year in which the license was granted, and has to renew thereafter.

For a detailed analysis of the procedure for obtaining an import license, please refer to ***Annexure II*** of this paper.

Annexure II

3. Manufacture/Import of New Drugs

[9] In paragraph 41 of the judgment, the Supreme Court observed: "*Keeping in view the provisions of Section 17-B of the Drugs and Cosmetics Act, 1940 which, inter alia, indicates an imitation or resemblance of another drug in a manner likely to deceive being regarded as a spurious drug it is but proper that before granting permission to manufacture a drug under a brand name the authority under that Act is satisfied that there will be no confusion or deception in the market. The authorities should consider requiring such an applicant to submit an official search report from the Trade Mark office pertaining to the trade mark in question which will enable the drug authority to arrive at a correct conclusion.*"

[10] Infra, Discussions on the EXIM Policy.

The term "New Drug"[11] is specifically defined under the Drugs Act and there are special provisions, which apply to the manufacture or import of new drugs into India. Part XA of the Drug Rules deals with import or manufacture of new drugs for clinical trials or marketing.

New drug development is knowledge intensive, time consuming and risky. The development process could broadly be divided in two major stages viz. pre-clinical and clinical. The objective of pre-clinical studies is to come up with a molecule that is effective against the disease vector and safe in animal testing. This is the Investigational New Drug ("**IND**") stage. This stage of investigation may take anywhere between 3 to 5 years and cost between US$100-150 million overseas or about Rs.400-Rs.600 million in India.[12] Pre-clinical investigations need an assembly of multi-disciplinary activities covering design and synthesis of new chemical compounds, bio-activity screening for both in-vitro and in-vivo testing, toxicity, pharmacokinetics, metabolism *etc*. Having established safety and efficacy in relevant animal models, the IND is administered to small population of healthy volunteers, in what is defined as Phase I of clinical trials. The purpose is to confirm safety of drugs in humans and establish a basis for progressing towards the next phase that would find out the efficacy of the drug in actual patients. The second phase clinical trials is carried out on a restricted population (numbers determined based on an approval protocol) and is used for proving efficacy in a disease category towards which the drug is targeted. The following phase of clinical trials (Phase III) is used for statistical validation and observing the long-term effect of administering the drug on a larger set of patients.

The Government announced amendments to the Drug Rules on January 1, 2002 to streamline procedures for manufacture and import of new drugs. According to the amended rules, institutions will be allowed to conduct clinical trials, whether for clinical investigation or experiment, for a new drug only after obtaining permission of the DCGI. Prior to this amendment, permission was mandatory only if the drug was sought to be marketed in India

11 New Drug means and includes:: A drug (as defined by the Drugs Act), including bulk drug substances, which has not been used in India to any significant extent under the conditions prescribed, recommended or suggested in the labeling thereof and has not been recognised as effective and safe by the Licensing Authority for the proposed claims; A drug, which is already approved by the Licensing Authority for certain claims, is now being proposed to be marketed with modified or new claims, namely indication, dosage etc.; A fixed dose combination of two or more drugs, individually approved earlier for certain claims, which are now proposed to be combined for the first time in a fixed ratio, or if the ratio of combination is already approved and marketed then the same is proposed to be changed, with certain claims, namely indication, dosage etc.

[12] See, http://www.nic.in/cpc/pharma10_f1.htm (accessed on January 4, 2002).

The procedure for obtaining a license with respect to a New Drug is given below:

File Application on Form 44 with Rs.50,000/- for obtaining a permission of Human Clinical Trial (Phase I) on a new drug.

Conduct Phase I Clinical Trial.

File Application for Phase II trial along with the results of Phase I trial with a Fee of Rs.25,000/-.

Conduct Phase II Clinical Trial.

File Application for Phase III trial along with the results of Phase I & Phase II trials with a Fee of Rs.25,000/-.

Conduct Phase III Clinical Trial.

File an application in Form 44, stating certain information and particulars about the New Drug with Rs.50,000/- with data as mentioned in **Appendix I of Schedule Y** to the Drug Rules including information relating to local clinical trials. Appendix I of Schedule Y require the following set of data to be submitted:

- Introduction *i.e.* description of drug and therapeutic class, Clinical and pharmaceutical information, Animal pharmacology, Animal toxicology, Human/ clinical pharmacology (Phase I),
- Exploratory clinical trials (Phase II),
- Confirmatory clinical trials (Phase III),
- Special studies
- Regulatory status in other countries,

Local trials are dispensed with in certain circumstances, for example:
All items above may not be required for all drugs. Some of the exceptions for are as follows:

- The trials are needed to be conducted on at least 100 persons spread over 3-4 locations in the country. However, the DCI may agree to dispense with the need for local clinical trials, if it is in the public interest and if it can use the data of trials carried out in other countries.
- Similarly, the submission of data related to animal toxicology, reproduction studies, teratogenic studies, perinatal studies, mutagenicity and carcinogenicity may be relaxed or modified in case the drugs are in use overseas for several years and there is

Product Standards

No drug can be imported, manufactured, stocked, sold or distributed unless it meets the quality and other standards laid down in the Drugs Act. For instance, for patented or proprietary medicines (medicines not listed in the Indian or other pharmacopoeia), the product should comply with the ingredients displayed in the prescribed manner on the label or container and such other standards prescribed by the Drugs Rules. General standards for all patent or proprietary medicines, tablets, capsules, liquid orals, injections and ointments have also been laid down. Drugs should not be misbranded, adulterated, or spurious.

The Central Government has the power to prohibit the import, manufacture or sale of any drug, including those that are deemed as "irrational drug combinations." For instance, the import and manufacture of Fenfluramine and dexfenfluramine is prohibited. Similarly, other banned drugs include fixed dose combinations of vitamins with anti-inflammatory agents, tranquilizers or analgesics or tetracycline and vitamin C.

OTC and Prescription Drugs

Under Indian law there is no category of drugs specified as 'OTC' drugs. The Drugs and Cosmetics Act specifies certain drugs to be sold only under prescription. The list of prescription drugs is quite large and covers all antibiotics, a number of painkillers, etc. The rest can be sold without prescription. However drugs can be sold in retail only by licensed outlets. Prescription drugs cannot be advertised in the general media.

In practice, a large number of prescription drugs are sold without prescription. Even in case of prescriptions, due to cost considerations, several customers buy less than the prescribed amount, or ask the chemist for a cheaper alternative.

The pharmaceutical industry has requested the Government to review this issue, and the Government has set up a committee of officials to draw up a list of OTC items. This would require an amendment of the Drugs Act.

Labelling

No drug can be sold or distributed or manufactured in India unless it is labeled in a manner provided by the Drugs Rules. The Drugs Rules lay down different labeling standards for non-homeopathic (Part IX), homeopathic drugs (Part IX-A) and biological and other special products (Part X). The Scheduled drugs under the Drugs and Cosmetics Act have to bear the Schedule under which they fall and have to specify the required warnings and satisfy some additional requirements.

In respect of non-homeopathic drugs the guidelines prescribe the pack sizes of drugs meant for retail sale, the contents of the label such as name of the drug, statement as to the net contents (in terms of weight, measure, volume), the contents of the active ingredient, license number, dates of manufacture, expiry, whether the medicine is for external or internal use, whether it is for human use or animal use, the name and address of the manufacturer and the address of the premises where the drug has been manufactured, the batch number, as

well as the drug license number under which it is manufactured (if manufactured in India)*etc.* In case of imported products the date of expiry of potency of the active ingredient and the import license number are also required to be stated.

The Standards of Weights and Measures Act, 1976 and the Packaged Commodities Rules, 1977 lay down some additional requirements in this regard.

Good Manufacturing Practices (GMP)

Schedule M of the Drugs Rules prescribes GMP guidelines which are in line with international guidelines of World Health Organisation (WHO).

Clinical Trials

"Clinical trial means a systematic study of new drug(s) in human subject(s) to generate data for discovering and / or verifying the clinical, pharmacological (including pharmacodynamic and pharmacokinetic) and /or adverse effects with the objective of determining safety and / or efficacy of the new drug."[13]

Rules 122DA to 122DC of the Drug Rules regulate application for permission to conduct clinical trials for new drug and investigational new drug in India. Schedule Y to the Rules states the requirements and guidelines on clinical trials for import and manufacture of a new drug. Schedule Y also lays down approval procedural for clinical trial and documents to be submitted with the application, responsibilities of sponsor, requirements of informed consent, responsibilities of ethics committee, and details of four phases of trials. Schedule Y also requires compliance of Good Clinical Practice Guidelines issued by the Central Drugs Standard Control Organisation, Director General of Health Services, Government of India.

For new drug substance discovered in India, the trials are required to be carried out in India right from Phase I. For new drug substance discovered in countries other than India, upon submission of Phase I data to the Licensing Authority, permission may be granted to repeat Phase I trials and/or to conduct Phase II trials and subsequently Phase III trials concurrently with other global trials. Phase III trials are required to be conducted in India before permission to market the drug is granted.

A new Bill titled as - "The Biomedical Research on Human Subjects (Promotion & Regulation) Bill", has been proposed by the Government to regulate and enforce ethical practices in scientific research on humans. It is likely to be introduced in the next session of Parliament.

The need for the Bill arose as currently only the commercial aspects of research on humans through clinical trials was being regulated under the Drugs Act, more specifically Schedule Y. Further, concerns were being raised as to the unethical practices in the industry. The current bill which relies heavily on the "ethical guidelines for biomedical research on human subjects" issued by the Indian Council of Medical Research (ICMR), aims to plug the holes and

[13] Rule 122-DAA of Drug Rules

encompass all kinds of research on humans. This would include clinical trials - both commercial and academic, as well as the entire range of research, including genomics, gene mapping, foetal tissue transplant, and stem cell research.

The Bill is driven by "ethical considerations" in research and its schedules contain the principles and processes, such as:

- ethical considerations
- ethical review procedures
- clinical trials
- clinical evaluation of devices
- diagnostics
- vaccines
- epidemiological studies
- stem cell research (including human genetics research)
- transplant research
- assisted reproductive technologies

It also covers stem cell research,a very controversial area of research which has been opposed in many countries. A further need to regulate this kind of research in India was felt as there are many cases of forced uniformed consents and clinical research on the illiterate and poor, which could lead to unregulated abortions, and the general flouting of medical ethics and scientific principles by doctors.

Currently the only regulator on human research in India is the Drug Controller-General of India who regulates commercially conducted clinical trials. The Bill proposes that the ethics committee of ICMR be designated as the national ethics committee, which will also be the technical adviser to the biomedical regulator. It also prescribes fines up to Rs 1 lakh and imprisonment of up to a year for norm violations.

Though, the Bill has been seen by some as a right move in the direction of bringing in more regulation into a much needed space, others feel that it would be causing a multiplicity of regulation, as there is the Drugs and Cosmetics Act already regulating clinical trials. Hence, it is felt that such a move would actually hinder the burgeoning market for clinical trials in India.

EXIM Policy

Imports and exports are regulated by the Foreign Trade (Development and Regulation) Act, 1992 along with the Customs Act, 1962 and the Export-Import Policy, issued by the Ministry of Commerce and Industry of the Government of India. As per Chapter 30 of the ITC(HS) classification of Export and Import items, all products in the category of 'Pharmaceutical Products' are now permitted to be imported freely. The only exception to this being 'waste pharmaceuticals' which still has certain import restrictions. However, import of certain pharmaceutical products is permitted subject to registration and other requirements as administered by the Drug Controller General of India under the provisions of Drugs Act.

Drug Price Control Order, 1995

The Drug Price Control Order ("**DPC Order**") has been promulgated under the Essential Commodities Act, 1955 ("**ECA**")[14] and is to be read with the Drugs Act. The DPC Order fixes the ceiling price of some active pharmaceuticals and formulations. The active pharmaceuticals and formulations, which fall within the purview of the legislation, are called scheduled drugs and scheduled formulations, respectively. The items in the schedule can be added or deleted. The authority set up under the legislation is the National Pharmaceutical Pricing Authority ("**NPPA**"),[15] which is responsible for the collection of data and the study of the pricing structure of active pharmaceuticals and formulations. Upon the recommendation of the NPPA, the Ministry of Chemicals and Fertilizers fixes the ceiling prices of the active pharmaceuticals and formulations and issues notifications on drugs, which are scheduled drugs and scheduled formulations. The NPPA arrives at the recommend prices for the scheduled drugs and formulations after collection and analysis of data on costing which includes data on raw material composition, packing materials, process losses, overhead allocation and apportionment, capacity utilization, technical data on manufacturing work orders and packing work orders. The government of India has the power under the DPC Order to recover the amounts charged in excess of the notified price from the company. There are also penal provisions for the violation of any rules and regulations under the ECA. Separate formulae have been prescribed for calculation of price for bulk drugs, drugs manufactured in India and drugs imported into India.

The Government can exempt certain products from price control if they are new drugs discovered in India or bulk drugs produced from the basic stage by a new process discovered in India or drugs manufactured by small-scale industries (capital investment below a certain level) and sold under their own brand names. Price control does not apply to formulations under the Indian system of medicine or homeopathic medicines or items to which the Drugs Act does not apply.

The Ministry of Chemicals and Petrochemicals is considering a dual system of drug price control in the upcoming Pharmaceutical Policy and Drug Price Control Order (DPCO), as follows: About 35 bulk drugs would continue to be under the cost-based formula, as devised by the NPPA under Pharmaceuticals Policy, 2002, while 279 drugs would come under the weighted average formula.

[14] Section 3 of the Essential Commodities Act, 1955.

[15] National Pharmaceutical Pricing Authority, at http://www.nppaindia.nic.in/ (accessed on August 31, 2002).

A 'special access programme' is also proposed whereunder anti-cancer and AIDS drugs, may also find its way into the policy. As many as 42 drugs are believed to be in this category which shall attract no excise tax from the government, traders would be asked to reduce their margins while companies would supply the drugs at concessional rates.

Advertising and sales promotion

Advertisements of drugs and pharmaceuticals are also strictly regulated. The salient features of the laws that regulate the advertisement of drugs and pharmaceuticals are set forth below:

Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954

This Act makes advertising of sex tonics and sex stimulants, abortion, contraception, uterine tonics and menstrual disorder regulators a cognizable offences. It also prohibits advertisements about diagnosis, cure, mitigation or prevention of 54 diseases and disorders listed in this Act such as cancer, diabetes, epilepsy, leucoderma, paralysis, sexual impotence etc. The bill-boards in Delhi, the local train railway compartments in Bombay, advertisement pages of news papers and glossy and not so glossy magazines, and now the electronic media, however, seem to be getting away with violations.[16]

Advertising Standards and Self-Regulation

Apart from restraint on advertising of prescription drugs, and making claims to provide prevention or cure of certain diseases under the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954, there are no legal constraints on advertising.

However, advertisements should not make unjustified claims, and complaints can be made to the Advertising Standards Council of India (ASCI), which has published the Code of the Advertising Standards Council of India ("Code"). ASCI is a voluntary association and is not a government body.

The Code applies to all forms of advertising and aims to maintain high standards of advertising. The Code has the objectives of ensuring truthfulness and honesty of representations and claims, safeguarding against misleading advertising, ensuring that advertisements are not offensive to general standards of decency, safeguarding against the indiscriminate use of advertising for products that are regarded as hazardous to society or to individuals to an unacceptable degree, and ensuring that advertisements observe fairness in competition so that the consumer's need to be informed about products in the market are balanced with generally accepted competitive behavior in business. If there is a complaint brought to the ASCI, it may ask the advertiser to withdraw or modify the advertisement in question if it deems fit. The ASCI, however, does not have effective powers of enforcement. The industry, advertisers, agencies and associations use the mechanism of ASCI, though its orders are not enforceable as that of the Court. If either of the parties is not satisfied they may take up the case in the courts under the relevant laws.

[16] http://www.healthlibrary.com/reading/vhai/july-aug/legis.htm (as visited on April 14,2003)

5. Intellectual Property protection and TRIPS

The protection of intellectual property rights in India which was one of the biggest concerns of global pharmaceutical companies seeking to enter India in the past has changed rapidly to adapt to a post-TRIPS and WTO scenario. Currently, There are well-established statutory, administrative, and judicial frameworks to safeguard intellectual property rights in India. India has complied with its obligations under TRIPS by passing necessary legislations and making amendments to the existing legislations. Well-known international trademarks such as Volvo and Whirlpool have been protected in India through judicial decisions even when they were not registered in India. Computer software companies have successfully curtailed piracy through court orders. Computer databases and software programs have been protected under copyright. Computer programmes having technical application to industry and computer programmes in combination with hardware can be now be patented in India. Though trade secrets and know-how are not protected by any legislation they are protected under the common law and through contractual obligations. The courts, under the doctrine of breach of confidentiality, accord protection of trade secrets.

The legislation that most affects pharmaceutical companies is the Indian Patents Act, 1970 ("**Patents Act**"). In addition, the following legislations have been enacted to fulfill the obligations imposed on it by TRIPS:

- The Trademarks Act, 1999.
- The Geographical Indications of Goods (Registration and protection) Act, 1999.
- The Protection of Plants & Varieties and Farmers Rights Act, 2001.
- The Biological Diversity Act, 2002.

Patent protection

In India's continued efforts to comply with it's commitment under TRIPS, the Patents Act has been amended thrice since 1995 by the Patents (Amendment) Act, 1999 ("**1st Amendment**"), the Patents (Amendment) Act, 2002 ("**2nd Amendment**") and Patents (Amendment) Act, 2005 ("**Third Amendment**"), respectively. The legislation is supported by the Patents Rule, 2003, ("**Rules**"). The Third Amendment has introduced a much awaited product patent regime in India, which is discussed in detail later.

Invention

The term *Invention* is defined under Section 2(1) (j) of the Patents Act as "a new product or process involving an inventive step[17] and capable of industrial application[18]."

In India, the patent rights in respect of any invention are created only upon grant of the patent by the Patent Office following the procedure established by

[17] *Section 2(1) (ja) of the Patents Act: "inventive step means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art."*

[18] *Section 2(1)(ac) of the Patents Act: "capable of industrial application in relation to an invetion means that the invention is capable of being made or used in an industry."*

the Patents Act and the Rules. India follows declarative system in respect of patent rights. India grants the patent right on the first to apply basis. The application can be made by either (i) the inventor or (ii) the assignee[19] or legal representatives[20] of the inventor.

Convention Application

India has published a list of convention countries under Section 133 of the Patents Act and is also a member of the Paris Convention. The convention application has to be filed within one year from the date of priority and has to specify the date on which and the convention country in which the application for protection (first application) was made. Priority document has to be filed with the application. Since India is a member of the Patent Co-operation Treaty, a National Phase Application could be also filed in India.

By the 2nd Amendment Act the following have been added to the innovations which are not inventions within the meaning of the Act:

- plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals ;
- an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.".

Recent Amendments

The Patents Act has been amended to include the following provisions of TRIPs Agreement:

- The term of the patent has been extended to 20 years from 14 years;
- As required by TRIPS, by virtue of the 1st Amendment (which had retrospective effect from January 1,1995) pending the introduction of the product patent regime, the Patents Act had a provisions for:
    - Acceptance of product patent applications. Such applications were to be kept in what is known as the "Black Box" until January 1, 2005, when such applications would be examined for the granting of a patent.
    - Pending such grant, the applicant could apply for the grant of exclusive marketing rights21 ("**EMRs**") with respect to the invention disclosed in the product patent applications.
- In infringement suits over 'process' patents the 'burden of proof' is reversed.

[19] *Section 2(1) (ab) of the Patents Act: "Assignee includes an assignee of the assignee and the legal representative of the deceased assignee and references to the assignee of any person include references to the assignee of the legal representative or assignee of that person".*

[20] *Section 2(1) (k) of the Patents Act: "Legal representative means a person who in law represents the estate of a deceased person."*

[21] *EMRs entitle the holder to possess the exclusive rights by himself, with his agents, or with his licensees to sell or distribute in India the article or the substance on and from the date of approval granted by the Controller for a period of five years, or until the date of the patent application's grant or rejection, whichever is earlier.*

- The Third Amendment has deleted Section 5 of the Act, which barred patent being granted in respect of substances:
    - intended for use or capable of being used as food, medicine, or drugs; or,
    - prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and inter-metallic compounds).

Thus, product patents will now be allowed in India. The black box applications for product patents will be examined beginning January 1, 2005. The provisions for Exclusive marketing rights (EMRs) have been removed effective January 1,2005. The applications for patent in respect of which EMRs were granted will be examined for the grant of patent immediately on the commencement of the Third Amendment. All suits relating to infringement of the EMRs granted before January 1, 2005 will be dealt with in the same manner as if they were suits concerning infringement of patents under the Patents Act.

Section 3 of the Act, carves out certain exceptions from the patentable inventions. Under Section 3 (j) Plants and animals in whole or any part thereof (other than micro-organisms) including seeds, varieties and species and essentially biological processes for the production of plants or animals – cannot be patented. This is in line with Article 27.3 of TRIPS. Thus micro-organisms, which satisfy the patentability criteria may be patented in India.

Section 3(d) as amended by the Third Amendment clarifies that mere discovery of a new form of a known substance, which does not result in the enhancement of the known efficacy of that substance is not an invention and therefore not patentable. For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances are to be considered to be the same substances, unless they differ significantly in properties with regard to efficacy. Therefore, Swiss Claims will not be allowed in India.

Exclusive Marketing Rights granted

On September 5, 2003, Controller General of Patents, Designs and Trade Marks granted the first ever EMR in India to United Phosphorous for sale of its fungicide. On November 11, 2003 Novartis India, an Indian subsidiary of Swiss drug manufacturer became the second company and the first pharmaceutical company to be granted an EMR. Novartis was granted an EMR on 'Gleevec', its breakthrough anti-cancer drug.

Some of the other amendments are discussed hereinbelow:

Infringement: If a patented invention is made, constructed, used sold or imported 'solely' for uses reasonably related to the development and submission of information required under any law (Indian or foreign) that regulates such activities, then such acts do not amount to an infringement. This provision, known as the Bolar provision will gain importance in view of introduction of the product patent regime in India. Bolar provision allows manufacturers to begin the research and development process in time to ensure that affordable

equivalent generic medicines can be brought to market immediately upon the expiry of the product patent.

Parallel Imports : Import of patented products in India from a person authorized by the patentee to sell or distribute the product does not amount to an infringement.

Protection of generic manufacturers: Product patents granted in pursuance of black box applications have been treated differently to protect the interests of generic manufacturers. Enterprises which have made significant investment and were producing and marketing the concerned product prior to January 1,2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent, are protected and the patentee cannot institute infringement suits against them but would be entitled to receive reasonable royalty from them. It is not clarified as to how the reasonableness of royalty would be determined. This provision would prejudice the rights of a patentee in respect of exploitation of its patent.

Enforcement: The global community has been viewing India as a 'poor patent enforcement' territory. Two provisions have been introduced that are likely to give a fillip to the patent enforcement mechanism. First being insertion of Section 104A, which is a "reversal of burden of proof" provision, in compliance with Article 34 of TRIPS. This is an exception to the normal rule, that is, the person who makes any claim or allegation has to prove it. In 'process patent' infringement suits, the defendant will have to prove that he has used a process different than the 'patented process' to arrive at an identical product produced by a 'patented process'. Second, an amendment to Section 108 of the Act will enable the court to order seizure, forfeiture or destruction of infringing goods and also materials and implements, used for creation of infringing goods.

Compulsory License: One of the most controversial amendments has been on compulsory licenses ("CL"). Now, CL can be also granted if the invention has not been worked in India or if the invention has not been worked in India on a commercial scale due to imports into India. New grounds for grant of CL have been inserted, that is, circumstances of national emergency; a circumstance of extreme urgency; a case of public non-commercial use, public health crises, relating to AIDS/ HIV, TB, malaria or other epidemics. With the advent of the product patent regime, the number of applications for CL is likely to rise and the real impact of the new CL provisions will then be realized.

A new provision[22] has been inserted in the chapter of Compulsory License. The provision provides for grant of license to manufacture and export the patented product to any country having insufficient or no manufacturing capacity in the pharmaceutical sector to address public health problems provided a compulsory license has been granted in that country or if such country has allowed importation of the patented pharmaceutical products from India. The amendment seeks to implement the agreement on Para 6 of Doha Declaration on TRIPS and public health. The amended provision will allow Indian

[22] *Section 92A*

companies to produce and export AIDS drugs to African and South East Asian countries.

Change in the Procedure for grant, publication and opposition of patent as amended by the Third Amendment:

- All the applications would be published after expiration of 18 months, except on the grounds of secrecy or when the application is abandoned or withdrawn. The applicant could make an application for earlier publication.
- The stage of acceptance and advertisement of the application for opposition has been replaced by the stage of grant of patent.
- The new provisions allow both pre-grant and post-grant opposition. The pre-grant opposition can be filed anytime after the publication of the patent application but before a patent is granted. The post-grant opposition can be filed within a period of one year from the date of publication of the granted patent. The grounds on which pre-grant opposition and post-grant opposition can be filed are similar.

Rights prior to the Grant: From the date of publication of the application until the date of the grant of a patent, the applicant has the like privileges and rights as if a patent for the invention has been granted on the date of publication of the application. However, applicant is not entitled to institute any proceedings for infringement until the patent has been granted. Prior to the Third Amendment, only upon acceptance of the application did the applicant enjoy like privileges and rights.

Secrecy Provisions[23]: Any person resident in India is not allowed to apply for grant of patent for any invention unless either of the following two conditions is satisfied:

- Obtaining written permission of the Controller of Patents. The Controller is required to obtain consent of the Central Government before granting such permission for invention relevant for defense purpose / atomic energy. The application is to be disposed of within 3 months. OR
- Patent application for the same invention has been first filed in India at least six weeks before the application outside India and there is no direction passed under Section 35 for prohibiting /restricting publication/ communication of information relating to invention.

This section is not applicable in relation to an invention for which an application for protection has first been filed in a country outside India by a person resident outside India. Inspite of this exclusion, this provision is likely to delay the filing of US applications since US applications are required to be filed by the inventors and not assignees of the inventors.

[23] Sections 35 to 43 of the Patents Act; Can you keep a secret? <eco-times/2005/Can-you-keep-a-secret-Feb-14-2005.htm>, February 13, 2005

Data Exclusivity:

When the Indian government was in the process of introducing the 2nd Amendment to the Patents Act, 1970 in 2002, the MNCs had approached the Government with the recommendation to introduce a data exclusivity provision in line with Article 39.3 of TRIPS. However, the Government had refused to accede to such a request. Currently, a committee headed by secretary, department of chemicals and petrochemocals is re-examining the issue.

Trademarks

In India, trademarks are protected both under the statutory law and the common law. The Trade and Merchandise Marks Act, 1940 was the first legislation in this regard in India, which was replaced later by the Trade and Merchandise Marks Act, 1958 (TM Act, 1958). The Trade Marks Act, 1999 (TM Act, 1999) has now been enacted in compliance with the TRIPS obligation, which has replaced the TM Act, 1958, effective September 15, 2003. The TM Act, 1999 allows for the registration of service marks and three-dimensional marks as well. India follows the Nice Classification of goods and services, which is incorporated in the Schedule to the Rules under the TM Act, 1999 24. The pharmaceutical products are covered under Class-5, cosmetics under Class-3 and the veterinary preparation would fall under Class-1 and Class-5.

The TM Act provides for procedure for search of trademarks. It is a prudent practice to conduct the search for conflicting trademarks (whether registered or pending) before using or applying for any trademark. This avoids potential litigation or opposition.

Any sign to be registrable as a trademark must fulfill certain conditions. The TM Act, 1999 has laid down absolute and relative grounds of refusal of trademark registration. These grounds are akin to the provisions of the UK Trade Mark Act of 1994. The trademark can be registered even if the mark is proposed to be used in India i.e. even if prior to the date of application no goods have been sold under the applied trademark. The term of registration and renewal is renewable 10 years. Foreign companies can license their trademarks in India under the proper license / Registered User Agreement.

The concept of "**well-known trade mark**" has been recognized under the TM Act,1999. This would prohibit registration of a mark which is merely reproduction or imitation of a well-known mark - even in respect of different goods or services.

A trademark can be used without registration and can be protected under common law but not under the statutory law. Recently Indian courts have held, that copying of international names (even if the products that are not made in India by the owner) is not permissible. Several international companies are engaged in trademark litigation in India, including IBM, Apple, Microsoft, Dunhill, Whirlpool, Sony and Cartier could obtain injunctive orders against the infringers.

[24] *Classes of Goods and Services: Classes 1 to 34 cover goods while classes 35 to 42 cover services.*

Biological Diversity Act, 2002 ("Biodiversity Act")

This Act aims to ensure the conservation of biological diversity in India, sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of biological resources. "Biological diversity" means the variability among living organisms from all sources and the ecological complexes of which they are part, and includes diversity within species or between species and of eco-systems. "Biological resources" means plants, animals and micro-organisms or parts thereof, their genetic material and by-products (excluding value added products) with actual or potential use or value, but does not include human genetic material. Only selective provisions of the Biodiversity Act, 2002 namely, definitions provisions, provisions relating to the constitution of the National Biodiversity Authority ("NBA") and rule-making powers of Government have been brought into force with effect from October 1, 2003. NBA will regulate the commercial/other uses of biodiversity by both Indian and non-Indian entities. Prior to applying for any IPR in respect of biological resources the applicant will be required to obtain approval of NBA.