



Indian Legal and Regulatory environment: The Pharmaceutical Industry

Gowree Gokhale & Dr. Milind Antani
Nishith Desai Associates

Abstract

In this paper Gowree Gokhale and Dr. Milind Antani, of Nishith Desai Associates, outline the legal and regulatory environment of the Indian Pharma Industry with particular detail to the current patent regime in the light of the recent amendments. They have attempted to bring forth the impact of this new regime on the existing players in the LifeSciences sector and the framework within which they can work.

Nishith Desai Associates, an international legal, tax and business counseling firm, cover a wide range of specialised disciplines including the Pharma, Biotechnology and nanotechnology sectors.

Legal and Regulatory environment: Indian Pharma Industry

Indian pharma industry witnessed fast growth in the recent years. It was feared that it could receive a set back after the advent of the product patent regime. But some of the top Indian companies were already geared to face the new regime by increasing their investing in product R & D and filing product patents across the globe by themselves. Players with smaller scale and no or low research capacity have begun to realize that they have to reorient themselves as contract manufacturers or contract R & D speceialists. India has now become a globally competitive pharmaceutical manufacturing location with lower cost, high caliber workforce and advanced technology.

In view of these new trends, we revisit the Drugs and Cosmetics Act, 1940, the legislation that regulates the Indian Pharma industry and discuss the new product patent regime in this article. We also briefly deal with the other legislations, regulations, and orders that affect the pharma industry.

Intellectual Property

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. 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, also accord protection of trade secrets.

The legislation that most affects pharmaceutical companies is the Indian Patents Act, 1970 ("Patents Act"). In addition, the following

¹Gowree Gokhale is the member of the intellectual property and technology law group as well as member of Biotechnology, Pharmaceutical Industry practice group of Nishith Desai Associates.

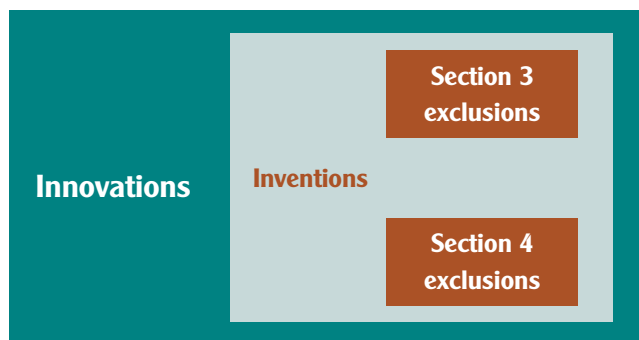
²Dr. Milind Antani, is a surgeon and lawyer, heads the Biotechnology, Pharmaceutical Industry practice group and member of Intellectual Practice Group at Nishith Desai Associates, an International law firm focusing on Tax, Corporate & Technology.

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, the law governing patents is the Patents Act, 1970 ('Patents Act'). In India's continued efforts to comply with its commitment under TRIPS the Patents Act has been amended thrice since 1995 by the Patents (Amendment) Act, 1999 ('First Amendment'), the Patents (Amendment) Act, 2002 ('Second Amendment') and Patents (Amendment) Act, 2005 ('Third Amendment'), respectively. Prior to the Third Amendment, President of India had promulgated Patents (Amendment) Ordinance, 2004 ('Ordinance'), which was later replaced by the Third Amendment. The legislation is supported by



the Patents Rule, 2003, ('Rules'). The following outlines the current Indian patent regime in light of the recent amendments.

Which inventions are patentable?

Not all innovations are "inventions" within the definition of the Patents Act. The term "invention" is defined under Section 2(1)(j) of the Patents Act as "a new product or process involving an inventive step and capable of industrial application." Thus, the traditional aspects of novelty, non-obviousness, and utility have been specifically included in the definition of the term "invention."

Novelty: If the invention was known or used by any other person or used or sold by the applicant to any person in India and/or outside India, then the applicant would not be entitled to the grant of a patent. Public use or publication of the invention will affect the validity of an application in India. The patent application must be filed prior to any publicity or prior knowledge. However, there is a 12-month grace period permitted in India, when a person has made an application for a patent in a convention country, and if that person or his legal representative (or his assignee) makes an application with respect to the same invention in India. The word "new" in the patent sense means new on a worldwide basis. Any earlier patent, earlier publication, document published in any country, earlier product showing the same invention, or earlier disclosure or use by the inventor will prevent the granting of a patent in India.

Not all innovations are "inventions" within the definition of the Patents Act. The term "invention" is defined under Section 2(1)(j) of the Patents Act as "a new product or process involving an inventive step and capable of industrial application." Thus, the traditional aspects of novelty, non-obviousness, and utility have been specifically included in the definition of the term "invention."

Inventions That Are Not "Inventions"

Section 3 of the Patents Act enlists the innovations that are not classified as inventions within the meaning of the Act. These may fall within the definition of the expression "invention," but the Patents Act expressly excludes them from the definition. Innovations that are not inventions within the meaning of the Patents Act, and accordingly are not patentable in India, include⁵:

- a method of agriculture or horticulture;
- a process for the medicinal or other treatment of human beings and animals;
- a mere discovery of any new property, or new use for a known substance, or a mere use of a known process, machine, or apparatus (unless such known process results in a new product or employs at least one new reactant);
- 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 is frivolous or which claims anything obviously contrary to well established natural laws;
- an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.

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. As stated earlier Section 3 of the Act, however, carves out certain exceptions. Thus only micro-organisms, which satisfy the patentability criteria may be patented in India.

²Don't take this for granted <eco-times/2005/Don%27t-take-this-for-granted-VV-GG(Apr10,05).pdf>, April 10, 2005

³Section 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"

⁴Section 2(1)(ac) of the Patents Act: "capable of industrial application in relation to an invention means that the invention is capable of being made or used in an industry,"

⁵Items relevant for this article have been enlisted

Further, 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.

Mashelkar Committee is at present examining the patentability of micro-organisms and limiting the patent protection only to the new chemical entities. Therefore, the patentability issue in relation to pharmaceutical products is still in the fluid stage.

Black Box Applications and Exclusive Marketing Rights

As required by TRIPS, by virtue of the First Amendment 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 rights ("EMRs") with respect to the invention disclosed in the product patent applications.

EMRs could be granted for substances intended for use or capable of being used as medicines or drugs. However, EMRs could not be granted for chemical substances that are ordinarily used as intermediates in the preparation or manufacture of any of medicines or substances.

On September 5, 2003 India's Controller General of Patents, Designs, and Trade Marks granted the first ever EMR in India to United Phosphorous for the sale of its fungicide, which is sold under the brand "SAAF." 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.

India grants patent right on a first-to-apply basis. The application can be made by either (i) the inventor or (ii) the assignee or legal representative of the inventor. Foreign applicants are given national treatment.

The Third Amendment requires product patent applications in respect of which EMRs have been granted to be examined immediately for grant of patent.



Inventions for Which No Patent Can Be Granted

Section 4 of the Patents Act states that in respect of inventions relating to atomic energy and falling within the meaning of Section 20(1) of the Atomic Energy Act, 1962, no patent can be granted.

Who can be the applicant?

India grants patent right on a first-to-apply basis. The application can be made by either (i) the inventor or (ii) the assignee or legal representative of the inventor. Foreign applicants are given national treatment.

What is the process of registration?

Patent rights with respect to any invention are created only upon grant of the patent by the Patent Office following the procedure established by the Patents Act and the Rules. India follows a declarative system for patent rights. Below are the three types of applications that could be filed in the Indian Patent Office:

- Regular Application
- 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. The priority document has to be filed with the application.

- Patent Cooperation Treaty (PCT) National Phase Application

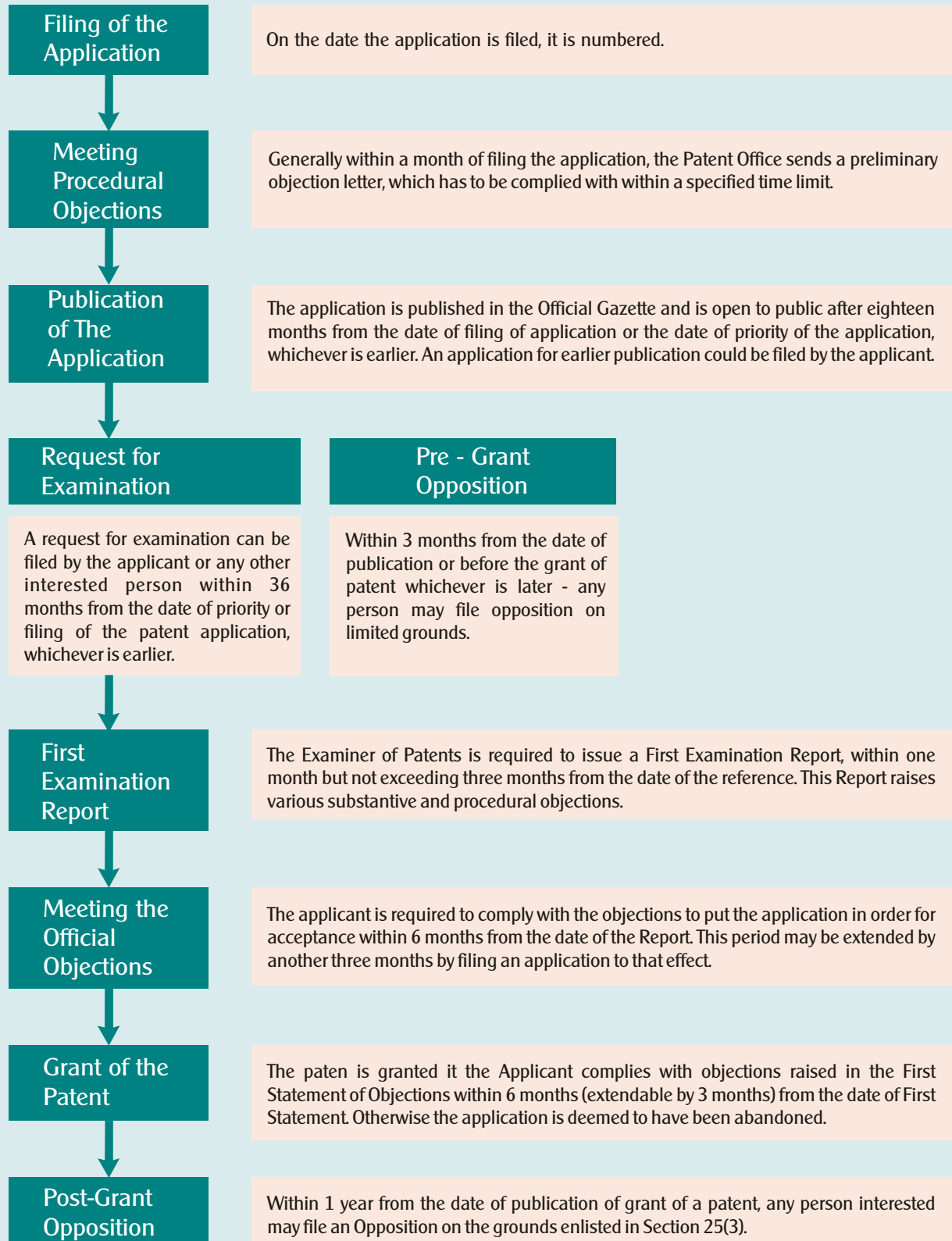
Because India is a PCT member country, a National Phase Application could also be filed in India.

The procedure for filing and obtaining patent in India is as shown on the next page.

⁶Section 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".

⁷Section 2(1) (k) of the Patents Act: "Legal representative means a person who in law represents the estate of a deceased person."

The procedure for filing and obtaining patents in India



Opposition Proceedings

The amended Patents Act allows 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. Opposition at two levels are likely to create delays in patent grant procedure.

What is the term of a patent?

Every patent granted under the Act shall be dated as of the date on which the complete specification was filed. Until recently, the term of the patent was fourteen years from the date of the patent, unless shown to be invalid. The Second Amendment prescribed a uniform term of 20 years for all categories of patents in compliance with Article 33 of TRIPS. There is no provision for an extension of the patent term.

Secrecy Provisions¹⁰

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. In spite 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.

Breach of this provision is considered as an offence.

Can the patent be surrendered?

A patentee may surrender his patent under Section 63 at any time by giving notice to the Controller in the prescribed manner.

How can the patent be cancelled / revoked?

Either the Appellate Board or the High Court (on a counter-claim in a suit for infringement of the patent) may pass orders for revocation of a patent. In an infringement action, the defendant can raise the grounds for cancellation as defenses and at the same time file a counterclaim for revocation. The grounds on which the patent can be revoked include wrongful procuring, false suggestion or representation in obtaining, failure to disclose foreign applications, prior secret use, prior grant, lack of novelty, or obviousness. The Controller of Patents also has the power to revoke the patent if, despite the grant of a compulsory license, the reasonable requirements of the public with respect to the patented invention remain unsatisfied or if the patented invention is not available to the public at a reasonable price.

Assignment / Mortgage / License of Patent

An assignment of a patent or of a share in a patent, a mortgage, license, or the creation of any other interest in a patent is only valid if the following conditions are satisfied:

- There is a written agreement embodying all the terms and conditions governing rights and obligations of parties; and,
- An application for registration of such an agreement is filed with the Controller of Patents within six months from the execution date of the agreement or within an extended period of not more than six months.

However, the agreement, when registered, is effective as of the date of its execution.

Compulsory Licensing

The Patent Act provides for the grounds on and procedures by which a compulsory license will be granted. The Second Amendment adds an entire chapter to the Patents Act on the working of patents, compulsory licenses, and revocation of licenses. After this amendment, the grounds on which a compulsory license will be granted are:

- Reasonable requirements of the public with respect to the patented invention have not been satisfied; or,
- The patented invention is not available to the public at a reasonably affordable price; or,
- The patented invention is not worked (i.e. not used or performed) in the territory of India.

The following factors are also to be taken into account: a circumstance of national emergency; a circumstance of extreme urgency; or a case of public non-commercial use, which may arise or is required, as the case may be, including public health crises such as those relating to Acquired Immuno Deficiency Syndrome (AIDS), Human Immunodeficiency Virus (HIV), Tuberculosis, Malaria, or other epidemics.

However, the Patents Act does not provide the definitions of the following expressions: "circumstance of national emergency"; and "a circumstance of extreme urgency." Therefore, the courts would be required to interpret these expressions on a case-by-case basis.

Any person interested in working the patented invention may apply to the Controller of Patents after three years have passed from the date of the sealing of the patent for a compulsory license. While examining the application, the Controller also considers such aspects as the nature of the invention; the time that has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make full use of the invention; the ability of the applicant to work the invention for public advantage; and the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted.

A new provision 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.

⁸However, term of a patent in respect of an invention relating to a process or method of manufacture of a substance intended to be used or capable of being used) as food, medicine, or as a drug was for period of seven years from the date of the patent.

⁹Section 53 of the Patents Act

¹⁰Sections 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

The amendment seeks to implement the agreement on Para 6 of Doha Declaration on TRIPS and public health. The amended provision will allow Indian companies to produce and export AIDS drugs to African and South East Asian countries.

Rights of the applicant post publication

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.

Infringement

In the Patents Act, 1970, what constitutes an infringement of a patent is not defined or stated. Therefore, whatever action violates or infringes upon the monopoly rights granted to the patentee under Section 48 of the Act is deemed infringement. In the case of a product patent, the following actions would amount to infringement: making, using, offering for sale, selling, or importing for these purposes, the product in India without the permission of the patentee. In the case of a process patent, the following would amount to infringement: using, offering for sale, selling, or importing for these purposes, the product obtained directly by that process in India without the permission of the patentee. In patent infringement suits, the damages are not granted for the use of the patented invention during the period prior to the date of acceptance of the patent application. In a patent infringement action, the defendant can file a counterclaim for a revocation of the patent. As a result, the main suit and the counterclaim are heard together.

What acts do not constitute infringement?

The Second Amendment has inserted Section 107A in the Act, which incorporates Bolar provision and provision for parallel imports. Section 107A states that the following acts do not constitute infringement

- Any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information required under any Indian law, or law of a country other than India, that regulates the manufacture, construction, use, sale or import of any product;
- The importation of patented products by any person from a person who is duly authorized by the patentee under the law to produce and sell or distribute the products.

Bolar Provision: In view of introduction of the product patent regime, this provision will gain importance. 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: A machine, though patented in India, can be imported (without the consent of the patentee) from the patentee's agent, say, in China, who manufactures it at a lower cost with the consent of the patentee.

Protection of Indian manufacturers: Product patents granted in pursuance of black box applications have been treated differently to

protect the interests of Indian 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.

Reversal of Burden of Proof

The Second Amendment also inserted Section 104A concerning the burden of proof in infringement suits. The section provides that in any suit for infringement of a process patent, the defendant may be directed to prove that the process used by him to obtain the product that is identical to the product of the patented process, is different from the patented process. Such direction may be passed by the court if:

- the subject matter of the patent is a process for obtaining a new product; or,
- there is a substantial likelihood that the identical product is made by the process, and the patentee or a person deriving title or interest in the patent from him, has been unable through reasonable efforts to determine the process actually used.

However, before obtaining such a direction, the plaintiff (claimant) has to prove that the product is identical to the product directly obtained by the patented process.

Remedies in the Case of Infringement

In the case of infringement of the Indian patent, the patentee can file a suit in the appropriate court, which may be a District Court or a High Court. In such a suit the plaintiff can seek an injunction and damages or order for an accounts for profits from the potential infringer of the patent. Where the defendant proves that at the time of infringement he was not aware of and had no reasonable ground to believe that the patent existed, an order for damages or accounts for profits is not granted. Therefore, the patentee should take steps to convey to the general public that his product or process is patented. In an infringement suit, infringing goods, materials, and equipment used for their production can be seized, forfeited, or destroyed. The courts can appoint suo motu, or on application of a party to the suit, scientific advisors to assist the court or to submit a report on a specified question.

The Patents Act does not provide for criminal action in case of patent infringement.

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 petrochemicals is re-examining the issue.

¹¹Section 64 of the Patents Act.

¹²Section 68 of the Patents Act. Section 69 describes the procedure for the recording of interest.

Impact of TRIPS on the Indian Pharma Industry

Erstwhile patent law endorsed reverse engineering that allowed expensive drugs available in the foreign market to be reproduced cheaply and made available to the Indian public. Though Indian pharma majors like Dr. Reddy's and Ranbaxy have already started investing in research and development, smaller Indian firms who relied mainly on reverse engineering are likely to bear brunt of the new law. Smaller firms fear that they will be at a disadvantage as they have limited capital and technology to invent new drugs that can be patented and exploited by them. Currently, major structural changes are taking place at global drug development and production arena. This is happening mainly due to exponential increase in the cost of drug development, shortening of product life and stiff competition from generic drugs. All these factors would lead the Indian firms to shift of paradigm of functioning. The Indian firms will be required to change their thinking, planning and focus of functions. Indian industry will obviously face stiff competition from the MNCs. The trends that are likely to evolve with respect to Indian players are:

- Some of the big Indian players are likely to spend more on R & D, which will lead to the development of new drugs. Some promising players may also benefit by foreign investments.
- Indian companies may not be able to pay royalties, which the MNCs may demand in respect of their patented molecules. Indian companies which are currently manufacturing certain molecules will be required to cease their activities once the patents are granted in respect of the same molecules (applications for which were pending in the black box).
- Since MNCs are now assured of protection of their IP in India, they would be willing to transfer technology to Indian players. There will be an inclination towards collaboration between Indian industry and the MNCs in the following areas:
 - Contract Manufacturing outsourcing, where MNCs would transfer its technology to Indian manufacturers and get the drugs manufactured in India. It is estimated that the contract manufacturing market for global companies in India will touch \$900 mn by 2010.
 - Licensing: Indian firms will have to capitalize on the opportunity which might be created to obtain a license to produce drugs, as global pharma companies that do not have any significant stake in Indian market will not hesitate to give license, to Indian firms. However, MNCs with subsidiaries in India are likely to introduce patented drugs only through their subsidiaries. Further, the in-licensing of partially developed products to Indian companies and in turn out-licensing of fully developed products by such Indian companies to MNCs would be on the rise.
 - Contract research: India is all set to become the hub for R&D activities considering the cost effectiveness and presence of skilled human resource and fast developing infrastructure. India is already seeing an inflow of funds into research and development, both from local investors and multinational organizations.
 - Clinical trials to be carried out in India by international companies. There is a strong possibility of the Indian pharma industry seeing many partnerships, collaborations and acquisitions. The large patient pool and low cost investigators too would be playing a major role in this space. It is estimated that the outsourced clinical research market in India will

increase to \$500 mn by 2010. Quintiles, a leading pharmaceutical service provider, and other such CROs are examples of an establishment of research organizations.

Due to the existence of a product patent regime and existence of factors such as availability of skilled manpower at lower costs, India has a potential of emerging as a major exporter of new pharmaceuticals. However, in the initial stage MNCs are likely to be apprehensive of the extent of and the speed at which they may be able to protect their IP in India. As discussed earlier, MNCs may increase their focus on India by creating subsidiaries or entering into collaborations or licensing arrangements with Indian companies. At the moment the choice of MNCs has been to establish fully owned R&D subsidiaries in India for their activities in India. Considering the above trends, the need of the hour is to create favorable conditions and environment for contract enforcement and effective protection and enforcement of IP within the country.

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. 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 the 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 after 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.

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. By recent amendment to the definition of the term "drug", certain medical devices have been also brought under the ambit of the Drugs Act and new regulations are being framed in respect of their manufacture, import and clinical trials. 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:

■ 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, 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.

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). 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.

■ Importing a drug into India

Most pharmaceuticals are freely importable under the provisions of the EXIM Policy. 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.

■ Manufacture/Import of New Drugs

The term "New Drug" 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. 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.

(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."

¹⁹In 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."

²⁰Infra, Discussions on the EXIM Policy.

²¹New 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.

²²See, http://www.nic.in/cpc/pharma10_fl1.htm (accessed on January 4, 2002).

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. Drugs 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.

Labeling

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 the 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."

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 Organization, 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.

²²Rule 122-DAA of Drug Rules

The Biomedical Research on Human Subjects (Promotion & Regulation) Bill

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 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 unformed 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.

Drug Price Control Order, 1995

The Drug Price Control Order ("DPC Order") has been promulgated under the Essential Commodities Act, 1955 ("ECA") 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"), 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.

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 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.

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.

²³Section 3 of the Essential Commodities Act, 1955.

²⁴National Pharmaceutical Pricing Authority, at <http://www.nppaindia.nic.in/> (accessed on August 31, 2002).

Fiscal incentives available to commercial research and development companies

Weighted tax deduction of 150 % (Section 35(2AB) of the Income Tax Act)

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 1½ times of such expenditure. This deduction was restricted for expenses incurred on or before March 31, 2005. This was last extended by the Finance Act of 2005, till March 31, 2007, and has not since been extended. 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.

Import - export exemptions

Further, such in-house R&D units recognized by DSIR in the area of pharmaceutical and bio-technology sector are eligible for duty free import of specified goods (comprising of analytical and specialty equipment as per list 28) for R&D; and duty free import of specified goods (comprising of analytical and specialty equipment as per list 28) for production; and duty free import of pharmaceutical reference standards³.

Section 80-IB(8A) of Income Tax Act

- Section 80-IB (8) of Income Tax Act ("ITA") provides for deduction from total Income for the purposes of computation of Income tax to companies engaged in scientific research and development. However, such an exemption is only available to a Research and Development ("R&D") Company which has sought an approval from the Department of Scientific and Industrial Research ("DSIR"), which is the prescribed authority to grant approvals and regulate such R&D Companies under the present section, before March 31, 1999.

- A new section was introduced in the Finance Act 2001, under which a 100% exemption for a period of ten consecutive years on the profits and gains from the business of carrying on scientific research and development was made available to R&D companies. The approval to avail of the exemption is extended till April 1, 2007. DSIR is the approving authority for such companies under the present section, and the ITA Rules prescribe certain conditions which need to be fulfilled to be granted such an approval. They include:

- The main objects of the company should be exclusively scientific and industrial research and development. Has adequate infrastructure to undertake R&D activities. Is registered in India.

Contributions made to other institutions

The 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.

Service Tax

The Finance Bill of 2006 has expended the definition of the taxable service - "technical testing and analysis", to include "clinical testing of drugs and formulations". Hence, clinical trials are taxable at the rate of 12.24 % (increased from 10.25% in the Finance Bill 2006). However, if the clinical trials are being performed by a Contract Research Organization ("CRO"), or any other entity/persons, and the same is exported, there would be no service tax payable as the service would be treated as "export of service", which is not taxable. ■



About the Authors

Dr. Milind Antani

Dr. Milind Antani heads the Biotechnology, Pharmaceutical Industry practice group and member of Intellectual Practice Group at Nishith Desai Associates, a prominent International law firm focusing on Tax, Corporate & Technology. He has had 14 years of active practice as an ENT surgeon at Gujarat. He has graduated from Baroda Medical College, MS University, Vadodara, Gujarat. He obtained his degree in Law (LLB) from Sardar Patel University, Vallabh Vidyanagar, Gujarat.



Gowree Gokhale

Gowree is Senior Associate at Nishith Desai Associates. Her areas of specialization include the intellectual property and technology law, litigation, BPO, human resources law, Biotechnology, Pharmaceutical Industry related laws. She holds a Bachelors degree in Social and Legal Sciences, a Bachelors degree in law, and diploma in taxation laws - from the University of Pune (India); and a Masters degree in Commercial Laws (Intellectual Property rights, Labor and Tax) and Consumer Protection Law - from the University of Bombay. She is a Solicitor registered with the Bombay Incorporated Law Society. She is also a registered patent agent and trademark attorney. Gowree is a member of the Bar Council of Maharashtra & Goa.

¹As per notification No. 26/2003-customs dated 1st March, 2003 (item at Sl. No. 248(1))

²As per notification No.26/2003-customs dated 1st March, 2003 (item at serial No.248(2))

³As per notification No.26/2003-Customs dated 1st March, 2003 (item at serial No.138);