



Intellectual Property Practice

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Newsletter

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The Patents (Amendment) Bill, 2003 - Highlights

Editorial

January 1, 2005 India moves towards a fully TRIPS compliant patent administration and with that the stage is set to usher in the product patent regime.

This transition beckons a reorientation in the way pharmaceutical companies do business in India. So far the process patent regime prevented the knowledge based pharmaceutical companies from taking strategic advantage of their Intellectual property assets. But undoubtedly, Patents are the single, most efficacious and indispensable tool to secure strategic competitive advantage in the market.

The impact of TRIPS compliance is becoming increasingly visible, on the pharmaceutical industry in India. The generic manufacturers are likely to add emphasis on research and development, resulting in a shift, from working around molecules to developing new molecules. The grounds acquired by the Indian generic medicine manufacturers under the protected environment of limited term process patent regime for over 30 years have to be transformed into the foundation to start carrying out new molecule research.

The near future may witness strategic alliances between knowledge based pharmaceutical companies and the Indian generic manufacturers. Alongside, the survival issues for the small domestic pharmaceutical companies may crop up. However, one cannot expect drastic changes in the way the market operates even after the introduction of a fully TRIPS compliant product patent regime. Availability and affordability of life saving drugs will continue to be a key public interest issue in a country like India with over a billion people.

As we stand on the threshold of this significant change, this newsletter focuses on 'product patent regime vis-à-vis pharmaceutical industry in India'. It dwells briefly upon several issues that confront the pharmaceutical industry as well as the patent system in India. Hope this issue proves to be congruent with the current concerns of the industry and legal fraternity in India and abroad.

We sincerely appreciate your comments on the articles and notes included in this special edition of our Newsletter. Please feel free to email us with your comments at mail@lexorbis.com.

We thank you for finding time to read this Newsletter. ●

The Lex Orbis Publication & Research Group

Product Patent Regime and Pharmaceutical Industry in India - The Challenges Ahead

The Prologue

With the nearing of the TRIPS deadline, the pharmaceutical industry in India is gearing up to face new challenges. The product patent regime is no longer the challenge - it is a reality that the Indian pharma industry has accepted.

The new set of challenges stem from the deeper implications of the imminent product patent regime. With the exception of a few, most Indian pharma companies are unfamiliar with the nuances of complex patent prosecution strategies. The research-based pharmaceutical companies, on the other hand, have first hand knowledge of successfully designing and implementing, sophisticated patent prosecution strategies. Therefore, the first hurdle for the Indian pharma industry is unevenness in the domain knowledge on patents. One of the ways to overcome this is to learn the use of patents as a business tool. The unrealistic defence against the global norms on patents is perhaps the most critical post-TRIPS challenge faced by the Indian pharmaceutical industry.

This article attempts to analyze the implications of the TRIPS compliant patent regime. The key issues discussed in this article are:

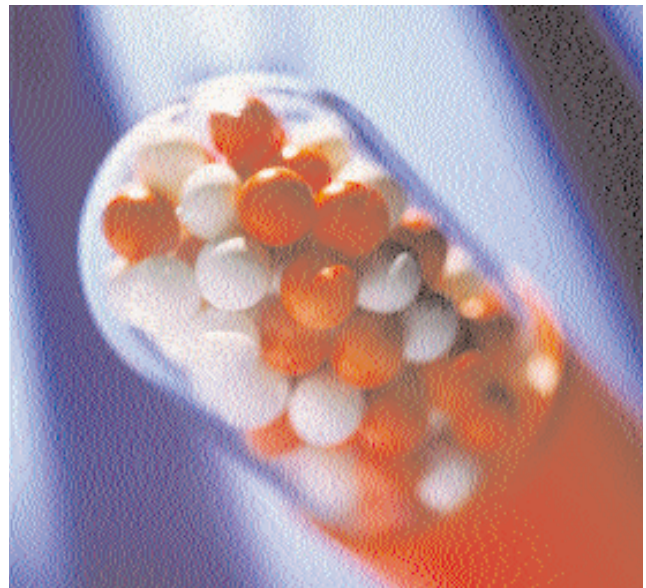
- (a) The scope and extent of patentability of pharmaceutical products;
- (b) Evergreening - the patent term extension strategies; and
- (c) Implications of Compulsory Licensing provisions

Scope and Extent of Patentability – Pharmaceutical Products

Article 27 of the TRIPS Agreement harmonizes the subject matter of patent in a broad manner. However, the exclusions permitted under the TRIPS Agreement have created wide variance in the Indian Patent Act, 1970 ('the Act'). Complying verbatim with Article 27, Section 2(1)(j) of the Act provides that 'invention means a new product or process involving inventive step and capable of industrial application'. Section 3 of the Act explicitly excludes certain categories of inventions from the scope of patentability. Critical categories include-plants, animals, parts of plants and/or animals, seeds, essentially biological processes, mathematical or business methods, computer program per se, inventions based on traditional knowledge, methods of treatment, diagnostic, therapeutic, and surgical methods. Section 2(1)(j) and Section 3 are inextricably linked with

each other; any addition in the latter would result in the constriction of the former.

While Section 3 per se poses a direct conflict with the general mandate of Article 27 of the TRIPS Agreement, some of these restrictions can in fact stay on, provided they come under the general exceptions under the TRIPS, as provided in Art. 27 (2) and (3). One needs to closely watch the dialectics of Section 2(1) (j) and Section (3) of the Act in view of the substantive provisions contained in Art. 27(1) and the exceptions to patentability provided under Article 27(2) and (3) of the TRIPS Agreement.



Patentability of Pharmaceutical & Related Inventions

A general reading of Section 2(1) (j) (which defines patentable inventions) with Section 3 of the Act (that provides the list of subject matters excluded from patentability) do not clearly indicate if it is possible to interpret these provisions to exclude certain aspects of pharmaceutical inventions from the scope of patentable subject matters. A section of the Indian pharma industry even today argues that a distinction has to be drawn between primary and secondary patents in the field of pharmaceutical inventions. According to them, primary patents are the ones directed at new molecules and secondary patents cover new combinations, optical isomers, active metabolites, polymorphs, 'prodrugs', new uses and so on. The question here is whether it is permissible under the TRIPS to draw such a distinction.

The Government of India seems to be adopting a balanced

approach in addressing this issue. In the proposed Patents (Amendment) Bill, 2003, it is proposed to substitute the words "new use of known substance" with the words "mere new use of a known substance" in Section 3(d) of the Act. The interpretative scope of this is yet to be seen. It could eventually lead to the acceptability of 'Swiss-type' new use claims.

The patentability of diagnostic methods under Section 3 (i) of the Act poses another important question with respect to the possible distinction between 'in vitro' and 'in vivo' methods of diagnostics. The Patents Amendment Bill, 2003 has not introduced any distinction between 'in vitro' and 'in vivo' methods of diagnosis. While 'in vitro' methods of diagnosis would involve tests on samples taken from the body and performed outside the body, (like taking blood samples and testing for diagnosis of a disease like malaria), the 'in vivo' methods of diagnosis would include performing the methods on the human body (like CT scanning of the body). Section 3(i) of the Act provides that any

patent prosecution procedures, pharmaceutical companies develop 'bullet proof' patent portfolios around million dollar drug molecules. Typically, multiple patents are secured covering a variety of inventive aspects in respect of a basic invention without attracting double patenting rejections. This plurality of patents directed at divergent inventive aspects can at times lead to the extension of patent terms, provided the national patent law allows such flexibilities.

On a rough estimate, the Mail Box contains over 5000 patent applications filed under Sec. 5(2) of the Act. Therefore, these 5000 patent applications presumably contain claims directed at 'substances capable of being used as food, medicine or drug'. The number of new drug molecules discovered in the last 5 years is roughly estimated at 40-45. That being the case, a certain section of Indian pharma industry argues that a majority of these patent applications are claiming secondary inventive aspects. Here again the basic question is, the extent to which, the patent statute can declare inventive aspects as

Post Grant Opposition - Pros & Cons

Introduction of post grant opposition in the proposed Patents (Amendment) Bill has raised a nation wide debate. Latest reports in media indicated that the group of ministers that reviewed the Patents (Amendment) Bill intends to retain the options of both, post and pre grant oppositions. While this position may lack legal logic it is aimed at balancing the interest conflicts of various stakeholders.

As per the current practice, once a patent application is accepted, the notice of acceptance will be advertised in the Gazette of India and the application will be open for opposition for a period of 4 months from the date of advertisement of the acceptance of the complete specification. This

opposition period of 4 months is extendible for 1 month. The bill proposes to amend this provision. As per the proposal, opposition will be after the grant of patent. Any interested person can oppose a patent within 1 year from the date of grant of a patent. The Controller of Patents, by order in writing, will constitute an Opposition Board to hear the opposition. The Controller shall order for the maintenance, amendment, or the revocation of the patent based on the recommendations of the Board.

Post grant oppositions was successfully experimented in United Kingdom. It infact shifts the burden of rechecking the validity of patents from the government to public. ●

process for the diagnostic or other treatment of human beings or any process for a similar treatment of animals is not patentable. In view of this, 'in vitro' diagnostic methods may be considered as a patentable subject matter.

The above being the position, the exact nature and scope of patentable inventions in the field of pharmaceutical arts will become clear only when the amended law is put to use, and possibly reviewed by the Courts of Law. Hopefully the textual law will acquire more clarity in the days to come when the Judges opine what it means and contains.

Patent Term Extension Strategies (referred to as 'Evergreening of Patents')

'Evergreening' or what the pharmaceutical companies often refer to as 'life cycle-management plans' refers to patent term extension strategies. Using the intricacies of

unpatentable, while complying with the obligations under Art. 27 of the TRIPS Agreement.

According to the TRIPS Agreement, the term of protection for patent is 20 years counted from the filing date. As a patent prosecution and management strategy, 'Evergreening' enables patent term extension by developing a portfolio of patents around a basic invention. The child patents may be directed at any one of the various ancillary inventive aspect explained in the earlier section.

Adding new claims to a basic patent disclosure is permissible in certain jurisdictions. This is achieved by the effective use of patent prosecution routes including continuation patent application, divisional patent application, continuation-in-part patent application, and application for patent of addition. It is also possible to build on chains of priority



from a basic patent disclosure to preserve novelty. The limitations or restrictions in the criteria of patentability and the exclusions of certain subject matters from the scope of patentability can impose serious limitations on patent prosecution strategies aimed at 'Evergreening'.

A number of fundamental issues come in sharp interplay when structuring patent prosecution aimed at 'Evergreening'. Unless the later applications disclose independent inventions (or inventive aspects), though linked to the invention disclosed in the basic application, the allowance of the later application(s) can lead to double patenting. On the other hand, inclusion of multiple inventive aspects (consequently multiple independent claims) in a single application can lead to 'unity of invention' issues. In India, the Patents (Amendment) Act, 2002 brought in an amendment to Section (10)(5) introducing 'single inventive concept'. However, the Indian patent offices are yet to start allowing multiple independent claims. Consequently, dividing out applications is considered a normal patent prosecution step. As the effective date of filing of a divisional application is the same as the date of filing of the basic application, this may not contribute to patent term extension or 'Evergreening'.

In the absence of multiple prosecution avenues, where the applicant has the scope of working around various prosecution routes, the Indian Patents Act is rather rigid as to the time lines for priority, patent term and patentable subject matters. Hence, 'Evergreening' may not acquire serious dimensions in India.

Compulsory Licensing

In the thirty years of the working of India's patents system, Compulsory Licensing provisions were never invoked. However, today it is the most widely debated topic in India. The Government of India and a number of other stake-

holders consider Compulsory License as a statutory tool to effectively protect 'public interest' from possible abuse of monopoly. One step ahead, many consider that Compulsory License will ensure a level playing ground between the owners of Intellectual Property Rights and their competitors.

The Patents (Second Amendment) Bill, 1999 (which later became the Patents (Amendment) Act, 2002 brought in substantial amendments in the provisions concerning Compulsory Licenses. The Patents Act, 1970 originally contained a Chapter titled 'Working of Patents, Compulsory Licences, Licenses of Right and Revocation'. The legislative intent

behind the inclusion of Compulsory Licensing provisions was evident from Section 83 of the 1970 Act. The Section contained the general principles applicable to the working of a patent aimed at curbing the potential abuse of monopoly by the patentee. The local working of inventions to the fullest extent and on commercial scales and preventing the patentee from creating import monopolies were the two fundamental principles recognized in the original Act. The recent amendment added clauses (c) through to (g) to the original set of principles. The new principles are addressed at striking a balance of interests between the technology owners and technology users, promoting socio-economic progress by technological development, protection of public health and the Government of India's rights in that regard prevention of unfair trade practices by abuse of monopoly rights by the patentee and the availability of the patented invention at affordable prices to the public.

The Act originally contained two important grounds for invocation of Compulsory Licenses. Any interested person could approach the Controller of Patents seeking a Compulsory License on grounds that (a) the reasonable requirements of the public with respect to the patented inventions have not been satisfied, and (b) patented invention is not available to the public at reasonable prices. The amended provision contained in Section 84 of the Act has included a third ground of 'local working' for seeking Compulsory Licenses. If the patented invention is not worked within the territory of India, it can be a ground to seek Compulsory License by any interested person. While explaining the meaning of 'reasonable requirements of the public', the law as it originally stood did contain a provision that the reasonable requirements of the public is deemed not to have been met, if for reason of the default of the patentee to manufacture in India the patented article, or not to give a license for the manufacture of the patented article the interests of the existing trade or indus-

try is adversely affected. In addition to the above, under Section 92 (1), the Central Government can issue notification for the grant of compulsory licenses, at any time after the sealing of patent, in the case of 'national emergency' or 'extreme urgency' or 'public non-commercial use'. The Controller of Patents is required to endeavor to ensure that the patented invention is available at the lowest price consistent with the patentees deriving reasonable advantage from their patent rights. Further, subsection (3) of the same Section provides that in circumstances of 'national emergency', 'extreme urgency' or 'public non-commercial use' including health crisis relating to AIDS, HIV, tuberculosis, malaria or other epidemic, the controller is not required to afford an opportunity of opposition to the patentee.

Difficulties may arise in the interpretation of the meaning and extent of the grounds on which Compulsory Licenses can be sought. The expressions 'National Emergency' and 'Extreme Urgency' are nowhere defined though it can be safely inferred that these terms refer to situations of grave magnitude.

National emergency can take the form of 'perceived terrorist attack using biological warfare'. For instance, in the year 2001 Canada overrode Bayer Corporation's patent over Ciprofloxacin and ordered production of a million tablets of generic version from a Canadian company. Ciprofloxacin was stockpiled as an antidote for any attack on the nation using the deadly Anthrax.

The amended provisions have in general broadened up the grounds for seeking Compulsory Licenses. Also the amendments have re-emphasized some of the basic principles behind the inclusion of Compulsory Licenses. The amendments are, therefore, a combination of policy statements

and a set of substantive augmentation of the earlier provisions respecting Compulsory Licenses.

While some implications of the Compulsory Licensing provisions are direct and predictable, some others are indirect, and far less apparent. The law says that Compulsory License can be granted to any interested person if the patentee does not make the invention 'available to the public' at 'reasonable prices'. What would be the nature and extent of 'making the invention available to public' for purposes of invoking Compulsory Licenses may lead to a contentious issue. These indirect and less apparent issues are likely to surface once the TRIPS compliant product patent regime comes into existence. Here again, the Court of Law may play a decisive role in explaining the pith and substance of the textual law.

Conclusion

While the discussion in this article is confined to the above three issues that the Indian pharmaceutical companies face in the anvil of the new TRIPS compliant regime, the transition from a limited term process patent regime to the product patent regime can have several other far reaching implications. The impact of this transition will become evident in the years to come. In the meantime, the Indian pharmaceutical industry must gear up to face the challenges. Creation of a level playing ground is possible the moment the domain knowledge of patents is even among all the players in the Indian market place. To begin with, the efforts to achieve parity in knowing the rules of the game can be confined to India. But sooner or later the Indian pharmaceutical companies will have to transform into knowledge-based organizations capable of producing research-based medicine at prices affordable to the Indian people. ●

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Currently - The Ten Most Valuable Patents*

Patent	Issued	Current Value (\$)	Assignee	Technology
6,517,866	2/11/2003	1,797,722,689	Pfizer Inc.	Pharma/Bio
6,500,987	12/31/2002	1,570,968,527	Teva Pharmaceutical Industries Ltd.	Pharma/Bio
6,566,344	5/20/2003	1,481,848,538	Idenix Pharmaceuticals, Inc.	Pharma/Bio
6,465,496	10/15/2002	1,408,931,126	Teva Pharmaceutical Industries	Pharma/Bio
6,452,054	9/17/2002	1,220,308,695	Teva Pharmaceutical Industries, Ltd.	Pharma/Bio
6,221,640	4/24/2001	1,194,927,644	Cubist Pharmaceuticals, Inc.	Pharma/Bio
6,071,970	6/6/2000	1,107,999,343	NPS Pharmaceuticals, Inc.	Pharma/Bio
6,319,919	11/20/2001	1,081,784,355	Davis; Bonnie (Syosset, NY)	Pharma/Bio
5,610,034	3/11/1997	1,071,288,767	Alko Group Ltd.	Pharma/Bio
6,022,716	2/8/2000	1,069,310,287	Genset SA	Pharma/Bio

* Source: Rick Neifeld, Patent Valuation from a Practical View Point, 2004

TM Disputes Involving Pharma Brands in India

AMOXIL

(Appellants)

(Beecham Group Plc. Vs. S.R.K. Pharmaceuticals 2004 (28) PTC391 (IPAB))

LYMOXYL

(Respondents)

The appellant was using the mark 'AMOXIL' in India since 1990. This mark was registered in India in 1972 in Class 5 in respect of pharmaceutical goods. The respondent started using the mark 'LYMOXYL' in India from 1985. The respondent filed the application for registration of the mark in 1987 in India in the same class with respect to similar goods.

The appellant brought an action against the respondent stating that the mark is deceptively similar. The only difference between the two marks is in the prefix 'LY' and 'M'. The rival marks are phonetically and deceptively similar and the goods are pharmaceutical goods under Sec. 12(1) of the Act.

The Intellectual Property Appellate Board (IPAB) held that the respondent dishonestly adopted the mark by copying it from the appellant who had got the mark registered long ago. Hence the respondent cannot claim honest concurrent use, by virtue of earlier use. The Appellate Board delivered a judgment prohibiting registration of the Trade Mark 'LYMOXYL'. •

FORTWIN

(Appellants)

(Ranbaxy Laboratories Limited vs. V. Anand Prasad & 4 Others 2004 (28) PTC 438 (IPAB))

OSTWIN

(Respondents)

The appellant was the registered proprietor of the mark 'FORTWIN' and had been using the mark since 1975. The respondent applied for registration of the mark 'OSTWIN'. Both the marks related to pharmaceutical compositions in respect of treatment of bones.

The appellant brought an action against the respondent stating that the mark is deceptively similar. The IPAB held that the prefixes are 'FORT' and 'OST' while both the marks end with the suffix 'WIN'. It was further held that since the rival goods are also pharmaceutical goods it might lead to serious consequences due to deception or confusion in the minds of the public. Hence on the possibility of harm being caused to common person the appeal was allowed. •

ARELON

(Appellants)

(Hoechst Aktiengesellschaft vs. Artee Minerals & Ar. 2004 (28) PTC 470 (IPAB))

ARTEELON

(Respondents)

The appellant was the registered proprietor of trademark 'ARELON'. This mark was registered in class 5 with respect to pharmaceutical goods relating to preparation for killing weeds and destroying vermin. The respondent filed an application for registration of the mark 'ARTEELON' in the same class with respect to pharmaceutical goods.

The appellant opposed the application for registration of trade mark filed by the respondents on the ground that the registration of the impugned mark would be contrary to provisions of Sections 9, 11, 12(1) and 18 of the Trade and Merchandise Marks Act, 1958.

The IPAB held that the rival goods were same and the only difference was the letters 'TE'. The Appellate Board further held that the possibility of confusion and deception is not ruled out and hence affirmed the order rejecting the application for registration filed by the respondent.

The IPAB further held that the benefit of use under Section 54 is given only in case of rectification proceedings when use of an associated trademark is deemed to be use of the registered trademark against which rectification proceedings are initiated for non-use of the mark. ●

PACITANE

(Plaintiff)

/

PARKITANE

(Defendant)

(Wyeth Holdings Corp. & Anr. vs. Sun Pharmaceuticals Industries Ltd. 2004 (28) PTC 423 (Bom))

In this case the plaintiff whose former name was American Cynamid Company and who was the proprietor of the trademark 'PACITANE' registered the mark in Class 5 of Pharma goods. The defendant was using the mark 'PARKITANE' with respect to similar goods. The plaintiffs filed a suit for infringement and passing off and sought various reliefs including interim injunction against the defendant for using the mark 'PARKITANE'.

The Court held that in both the cases the goods are similar, being pharmaceutical preparations for treatment of Parkinson's disease, the customers buying these goods are the same and the trade channels are the same. Since the defendant did not show any search of the Register before adopting the impugned mark, prima facie adoption of the mark was not honest. Further, the Court held that despite protests, if the defendants have chosen to continue to sell the products, it cannot be said to be acquiescence by the plaintiff. Therefore the Court held that injunction is to be granted in favour of the plaintiff.

The Court further held that in case of pharmaceutical products, the test is of possibility of confusion and not probability of confusion. The plaintiff have been in the field since 1950 and as such the balance of convenience is in their favour. The Court granted injunction in favour of the plaintiff. ●

LIPITOR

(Plaintiff)

/

LIPICOR

(Defendant)

(Pfizer Ireland Pharmaceuticals vs. Intas Pharmaceuticals and Another 2004 (28) PTC 456 (Del))

In this case the plaintiff had applied for registration of the mark 'LIPITOR' in Class 5 relating to pharma goods, a drug used for treatment of cardio-vascular diseases especially for reducing cholesterol. This mark has been in use by the plaintiff since 1947 all over the globe, but had not commenced marketing and selling its product 'LIPITOR' in India. The defendant adopted the mark 'LIPICOR' for a similar drug, which was manufactured and marketed in India by the defendants since June 2000. Therefore the plaintiff filed a suit in the court for a decree of passing off and also for payment of damages etc. It also prayed for grant of a temporary injunction in favour of the plaintiff and against the defendant.

It is assumed that the defendant did not incur any expenses towards research of the aforesaid drug and therefore it is possible for the defendant to manufacture, market and sell the same at a cheaper price than that of the plaintiff. It was further held by the Court that it is always possible for the plaintiff to be in India in the future as its application for registration is still pending in India. Therefore, the Court held that this is a fit case where an injunction, as sought for, is required to be granted.

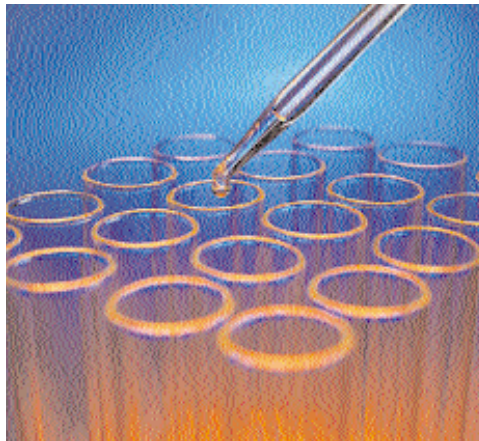
The Court granted a temporary injunction in favour of the plaintiff and against the defendant, restraining the defendants, their directors, partners, distributors, stockists, retailers and all others acting on their behalf from manufacturing, marketing, selling, offering for sale, advertising etc. the product under the trademark 'LIPICOR' or any other mark which could be said to be confusingly or deceptively similar to the trade mark 'LIPITOR' of the plaintiff, till the disposal of the suit. ●

Data Exclusivity - The Indian Perspective

Dilemma

Data exclusivity has triggered considerable debates and deliberations in the relevant industries in India, creating a deep divide between those who read 'data exclusivity' in Article 39(3) and those who confine the mandate of the Article only to 'data protection'. Article 39(3) is fraught with interpretational lacunas. The expressions "origination of which require considerable efforts", "unfair commercial use" and "necessary to protect the public interest"; are capable of several interpretations and by not defining the connotations of the aforesaid expressions, the TRIPS Agreement has left it to the subjective satisfaction of the Member States to construe the contents thereof. However, the implementation of the said provisions by other WTO Member States has made the international arena tilt unequivocally in favor of 'data exclusivity'.

In India, before granting marketing approval for any new drug, the regulatory authorities (Drug Controller of India) make it mandatory to submit extensive data to establish the safety and efficacy of the new drug. In order to generate this clinical and test data the originator has to spend several years in research and expend considerable sums of money. 'Data exclusivity' law prevents the regulatory authorities from allowing access to this data for certain duration, for the purpose of evaluating a generic application claiming bioequivalence with that of the pioneer drug. This provision may operate to the detriment of the generic applicant, as it must either wait for the data exclusivity period to expire or replicate the time consuming and expensive clinical trials for obtaining the marketing



approval for the drug. At the same time, granting marketing approval to the generic applicants, relying on the data of the originator, would result in heavy financial losses to the originator, which in turn would lead to decline in innovation and keenness to launch pioneer drugs in the market. Moreover, equity necessitates prohibition of free riding on the data arising out of the originators' industry.

In addition, data is also recognized as 'trade secret' on the ground that Article 39 falls in section 7 of the Part II of the TRIPS Agreement that is concerned with trade secrets and Article 1.2 of the agreement labels the subject matter protected by Section 7, as a category of 'intellectual property'. This data forms an indispensable tool in the trade of the drug developer. The applicant seeking the marketing approval would never disclose the data in the absence of regulation requiring such disclosure. Drug approval data can very well be treated as a 'trade secret' on the basis of secrecy or non-disclosure obligations of the member states.

Implication

In the short run, the Indian pharmaceutical industry, which has a strong generic base, may suffer disadvantages. The 'data exclusivity' legislation would be an embargo on free riding of data and hence would prevent rolling out generic equivalents. Several vociferous opposition is based on the ground that such legislation will invariably create market exclusivity. However from a different perspective, advantages of data exclusivity could outweigh the disadvantages. With the exception of a few

Term of Data Exclusivity

Countries	Term of protection (in years)	Name of the legislation/Regulations/FDA
Australia	5	Therapeutics Goods Amendment Act
Canada	5	Food and Drug Act
China	6	PRC Drug Administration Implementing Regulations
France	10	EU directive 2001/83, Regulation (EEC) 2309/93
Germany	10	EU directive 2001/83, Regulation (EEC) 2309/93
Japan	6	Japanese Drug Regulation
United Kingdom	10	EU directive 2001/83, Regulation (EEC) 2309/93
United States of America	5	The Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act

big pharmaceutical companies, the average allocation on R&D by drug companies in India is about 2 percent of the sales. This is a paltry amount for a research and technology intensive industry like the pharmaceutical industry. The inability to free ride may well result in substantial investment in R&D leading to excellent outsourcing opportunities for clinical trials, R&D and technical services.

Data exclusivity legislation, if enacted in India would provide necessary incentive to the originators to market their drugs in India without the fear of generic manufacturers and other multinational drug manufacturers free riding on their data. This may facilitate the flow of FDI and give a fillip to R&D.

According to the U.S. National Institute of Health (NIH), lack of data exclusivity in India is the primary reason why India only ranks 9th (compared to China which ranks 2nd), in funding given by the NIH outside of the U.S. U.S. pharmaceutical companies spent \$30 billion on R&D in 2001. Protection of test data is key to company decisions on location of clinical trials. The absence of data exclusivity legislation may prove to be a major impediment in setting up of contract research organizations (CROs) in India.

Conclusion

Data exclusivity legislation may become the bone of contention between the generic and the research based pharma companies. One of the consensus is that India provides for a short term (5 years) 'data exclusivity'. A Committee has been set up by the Government of India to look into this and suggest ways to amend the relevant law to ensure compliance with Art. 39 (3) of the TRIPS Agreement. Instead of reading conflict between the strong Intellectual Property protection and access to health care, attempt should be made to reconcile the two because without an effective intellectual property regime that offers incentives for investment, it would be difficult to improve the health care system in a developing country. If India has to match strides with the rest of the world, it must devise a solution that strengthens innovation and enriches the knowledge based pharmaceutical industry in India. ●

A Journey Called "TRIPS Compliance"

- | | |
|---------------|---|
| April 1994 | India signs the Marrakesh Agreement. Joins the WTO as a founding member. |
| December 1994 | The President of India on 31 December 1994 promulgates the Patents (Amendment) Ordinance, 1994.

[The Ordinance aimed at providing a 'Mail Box' mechanism in the Patents Act for receiving patent applications for pharmaceutical or agricultural chemical products (as required by subparagraph (a) of Article 70.8 of the TRIPS Agreement) and for the grant of exclusive marketing rights with respect to the products that are the subject of such patent applications (as required by Article 70.9 of the Agreement)]. |
| January 1995 | The WTO comes into force on 1 January 1995. India's TRIPS obligations begin.

The Patents (Amendment) Ordinance, 1994 becomes effective on 1 January 1995. |
| March 1995 | The Patents (Amendment) Ordinance lapses on March 26, 1995. During this period, 125 product patent applications had been filed through the 'Mail Box'.

A Patents (Amendment) Bill 1995 introduced in the Lok Sabha (Lower House) of the Indian Parliament in March 1995. The Bill passed by the Lok Sabha and then introduced in the Rajya Sabha (Upper House). |
| May 1996 | The Patents (Amendment) Bill 1995 referred to a Select Committee of the House for examination and report. The Patents (Amendment) Bill 1995 lapses with the dissolution of the 10th Lok Sabha on 10 May 1996. |
| April 1997 | Cases against India (for non-compliance of TRIPS) at the WTO by the United States and the European Communities. On 16 October 1997 the Dispute Settlement Body on request from the European Communities established a Dispute Settlement Panel. The Panel and the Appellate Body rule against India. |
| March 1999 | The Patent (Amendment) Bill, 1999 passed on March 26, 1999. [The Bill provided for 'Exclusive Marketing Rights' (EMR) and the 'Mail Box' with retrospective effect] |
| May 2002 | Patent (Second Amendment) Act, 2002 comes into force on May 20, 2003. |
| December 2003 | Patent (Third Amendment) Bill, 2003 introduced in Rajya Sabha on December 22, 2003. Dissolution of the Lok Sabha necessitates the re-introduction of the Bill. |
| January 2005 | The TRIPS deadline. |

'Swiss-Type' Claims and the Indian Patents Law

Novelty is one of the basic criterion of patentability, inventiveness and industrial applicability being the other two. If the use of a substance or a composition, for a specified medical purpose is new, a claim in a patent application directed at this use will be considered as novel, even if the same substance had previously been used in medicine for a different purpose. Satisfying the patentability criteria, a further or second medical use of a substance or composition can be protected by a claim to the use of the substance for the manufacture of a medicament for a specified medical use. Such claims are called 'Swiss-type' or 'Swiss-style' claims, as it was a decision of the Swiss Federal Intellectual Property Office in 1984 that first allowed patents with this type of claims.

The following illustration is aimed at further explaining the 'Swiss-type' claims. A claim for a second medical use can be as follows:

- 'The use of (substance X) in the manufacture of a medicament for the therapeutic and/or prophylactic treatment of (medical condition Y).' *This is the usual form of a Swiss-type claim.*
- 'The use of (substance X) in the preparation of (an anti-Y agent) in ready-to-use drug form for treating or preventing (medical condition Y).' *The expression "in ready-to-use drug form" was intended to mean, "as presented for sale", i.e. packaged.* 'The use of (substance X) in the manufacture of (an anti-Y agent) in a package together with instructions for its use in the treatment of (medical condition Y).'

However, a method of treatment claim can be disguised in the form of Swiss-type claims, for e.g.:

- 'The use of substance X in the treatment of disease Y.'

Swiss-type claims are, therefore, permissible only if the national patents law permits the patentability of new use for a known substance. Some of the major Patent Offices now allow such claims. In the US, claims addressed at methods of treatment are accepted. Since Swiss-type claims are drafted in a manner that is designed to avoid the prescription against the patentability of method of treatment claims, grant of such claims is not a requirement in the US. However USPTO accepts Swiss-type claims.

The European Patent Office (EPO) considers methods of treatment as not being capable of industrial application and consequently not patentable. However, subsequent to the

allowance of the 'Swiss-type' claims by the Swiss Patent Office, the Enlarged Board of Appeal of the European Patent Office (EPO) started accepting such claims. In *John Wyeth and Brothers Ltd's Application and Schering AG's Application* (1985), the Enlarged Board of Appeal of the EPO held that, whilst a claim to the method of use could not be permitted, a claim for the use of a product for the manufacture of a medicament for a specified new and inventive medical use (the Swiss-type claim) could be permitted on the basis that the novelty of the claim resided in the new therapeutic use and not the method of manufacture.

The Australian Patent Office started accepting the Swiss-type claims only in 1998, after a decision in *Bristol-Myers Squibb v Faulding*. This case involved two patents having claims directed at methods of administering a known anti-cancer drug (Taxol) at a particular dosage for a length of time that was demonstrated to be effective. It was held that the patents were invalid as they were directed to the treatment of a life threatening disease and allowing such patents would be 'generally inconvenient' and hence unpatentable under Australian practice. This decision, however, led to the change of practice of the Patent Office, allowing Swiss-type claims.

The Indian Patents Act, 1970 (the Act) does not allow claims directed to a new use for a known substance. Section 3(d) of the Act states that the mere discovery of any new property or new use for a known substance is not an invention and hence not patentable. The Act also does not allow claims directed at process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or animals.

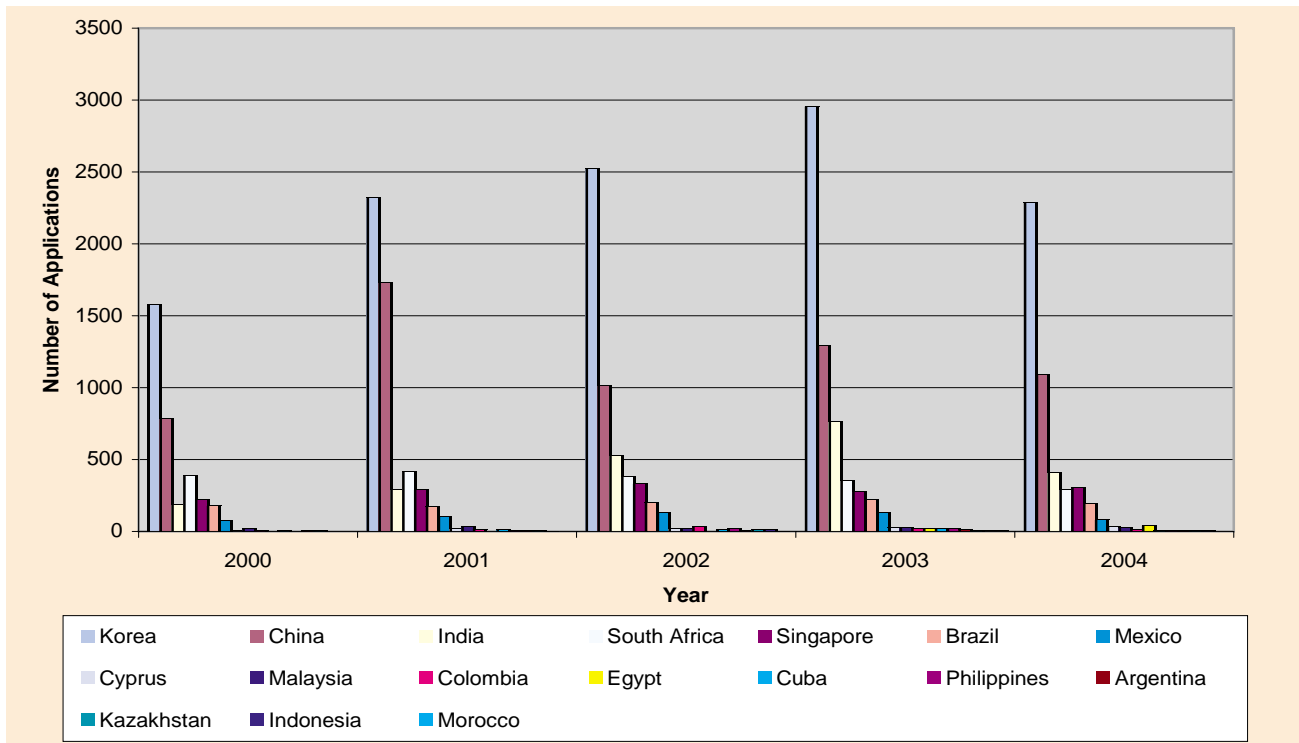
However, the currently pending Patents (Amendment) Bill, 2003 proposes to amend sub-section (d) of Section 3 of the Act to substitute the words 'new use' with 'mere new use'. This would imply that only a mere use of a known substance would not be patentable. As a corollary, a new use of a known substance, to produce a useful and non-obvious end result, would be patentable. Hence, a new use of a known substance (a drug) in a known or a new way to produce a non-obvious and useful result would be patentable. Therefore, it can be construed that the proposed amendment in the Patents (Amendment) Bill 2003 opens a way for the allowability of Swiss-type claims.

Considering the current status of R&D in India the protection of new uses may be advantageous for India. The trend of acceptance of Swiss-type claims has started in other developing countries. Malaysia has incorporated in its

patent law a provision for accepting claims drafted as uses of compounds to treat medical problems. Hopefully, an Examination Guideline by the Controller of Patents, may clarify the Indian position in the near future. In the alter-

native, the Intellectual Property Appellate Board is the appropriate forum to determine the intent behind substituting the words 'new use' with 'mere new use' in Sub-clause (d) of Section 3 of the Act. •

PCT Applications Filed by Developing Countries – As on September, 2004



Data Sources*

	2000	2001	2002	2003	2003 (Percent)	2003 (growth)	2004 (to date)
Republic of Korea	1580	2324	2522	2953	2.57%	17.10%	2,287
China	784	1731	1017	1293	1.12%	27.10%	1094
India	190	295	525	764	0.66%	45.50%	408
South Africa	387	419	384	355	0.31%	-7.60%	296
Singapore	222	288	330	281	0.24%	-14.80%	307
Brazil	178	173	201	220	0.19%	9.50%	192
Mexico	73	104	132	131	0.11%	-0.80%	80
Cyprus	5	18	18	29	0.03%	61.10%	36
Malaysia	19	38	23	28	0.02%	21.70%	28
Colombia	4	17	36	24	0.02%	-33.30%	12
Egypt	1	1	1	22	0.02%	2,100.00%	39
Cuba	4	14	11	20	0.02%	81.80%	8
Philippines	0	9	20	19	0.02%	-50%	4
Argentina	9	9	9	15	0.01%	66.70%	9
Kazakhstan	5	9	16	8	0.01%	-50.00%	5
Indonesia	1	2	10	7	0.01%	-30.00%	5
Morocco	1	0	2	7	0.01%	250.00%	1

*Source: www.wipo.int

The Patents (Amendment) Bill, 2003 - Highlights

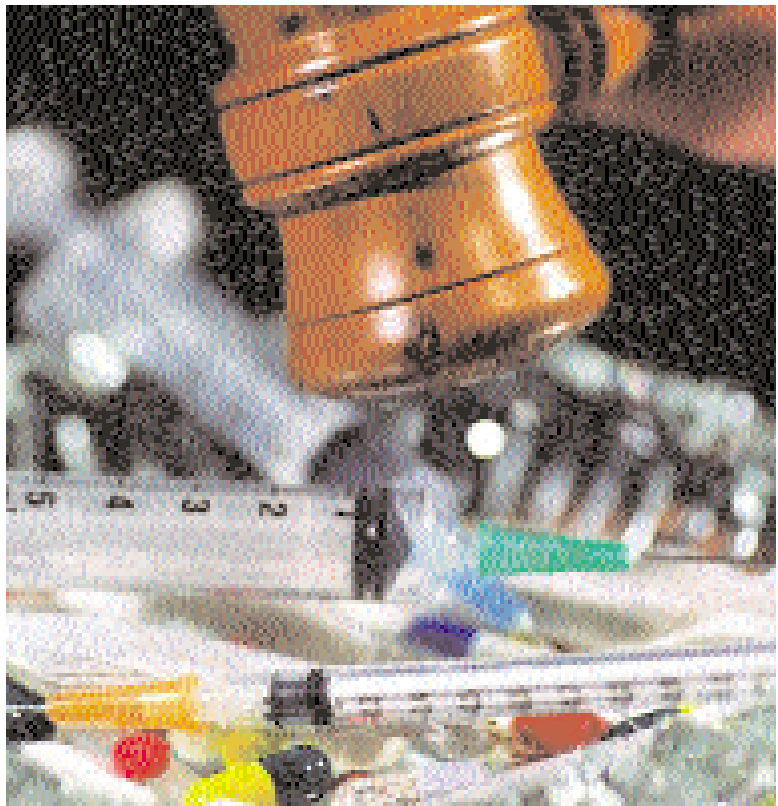
The Patents (Amendment) Bill 2003 aims at making the Indian patents law fully compliant with the Agreement on the Trade Related Aspects of Intellectual Property Rights (commonly known as the TRIPS Agreement). The bill was introduced in the Lok Sabha (the Lower House of the Indian Parliament) on December 22, 2003. The Lok Sabha was dissolved when the Bill was under review by a Parliamentary Standing Committee, necessitating its re-introduction. This is the 3rd in the series of the patents law amendments aimed at TRIPS compliance.

Before the Bill is reintroduced in the Parliament, it is undergoing review by a group of ministers. Following are the major amendments proposed in the Bill

- **Product patent** for all categories of inventions. The Bill seeks to omit Section 5 of the Patents Act, 1970 which provides for process patents for inventions in respect of 'food', 'drug', and 'medicines'. This amendment will make the Indian law compliant with Article 27 of the TRIPS Agreement.
- **Exclusive Marketing Rights** granted by the Controller of Patents will continue to be effective with the same terms and conditions on which it was granted.
- Every **Exclusive Marketing Rights** application will be treated as Request for Examination.
- Grant of **Compulsory Licenses** for export of medicines to countries which have "insufficient" or "no manufacturing capacity" to meet emergent public health situations. This provision is in line with Para 6 of the Doha Declaration on TRIPS and Public Health – an agreement reached at the WTO Ministerial Meet at

Doha on August 30, 2003.

- The **Intellectual Property Appellate Board** (IPAB) will have jurisdiction to adjudicate on revocations of patents. The IPAB will hear appeals from the orders of the Controller of Patents respecting revocation of patents. The High Court will have jurisdiction to adjudicate upon revocation of patents on a counter-claim in suits concerning infringement.
- **Representations** can be made by third parties during the prosecution of a patent application. The Bill pro-



poses to introduce a practice whereby a representation can be made in writing by third parties, to the Controller of Patents, stating the grounds on which the subject matter of a published patent application is considered unpatentable. •

If you have any suggestions, comments or queries, please feel free to email at: mail@lexorbis.com

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