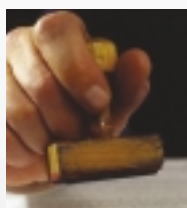


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India Moving Towards a TRIPS Compliant Patent Regime - Implications for the Pharmaceutical Industry

Preface

After independence in 1947, it took twenty-one years for India to enact a patent law. After joining WTO in 1995, India struggled through seven years of deliberations before it could amend its patent law to make it even partially TRIPS compliant. The last in the series of TRIPS compliant amendments in the national patent law was introduced in the Lok Sabha (the lower house of the Indian Parliament) on December 22, 2003. This Bill had been referred to the Department Related Parliamentary Standing Committee on Commerce. However, the dissolution of the Lok Sabha has necessitated the re-introduction of the Bill when the Parliament is convened after the general elections.

Introduction of Product Patents & Other Major Changes

The proposed Patents (Amendment) Bill, 2003 aims to achieve the following:

- (a) make the national law compliant with Art. 27 of the TRIPS Agreement;
- (b) provide for product patent protection for all categories of inventions;
- (c) repeal the provisions concerning Exclusive Marketing Rights (EMRs);
- (d) provide for a transitional provision to protect EMRs already granted;
- (e) introduce provisions to give effect to Para 6 of the Doha Declaration on TRIPS Agreement and Public Health; and
- (f) empower the IP Appellate Board to adjudicate upon revocation of patents.

The proposed Bill will introduce product patents covering 'all fields of technology' 'without discrimination as to the place of invention', 'the field of technology' and irrespective of 'whether products are imported or locally produced'. In all likelihood the product patent regime will change the way the pharmaceutical companies do business in India.

Exclusive Marketing Rights

At the time of joining the WTO, India did not have product patents for certain

categories of inventions viz., food, drug and medicine. As a WTO member, India was under an obligation to provide transitional protection for inventions in these fields.

In December 1994, India promulgated an Ordinance to amend the Patents Act to provide for a 'Mail Box' mechanism to receive product patent applications. However, the Government of India failed to substitute this Ordinance with a legislation passed by the Parliament. Consequently, a case was filed at the WTO by the US and the EU against India for not complying with its TRIPS obligations. India lost the case at the Dispute Settlement Panel of the WTO. India preferred an appeal against the decision of the Panel to the Appellate Body. The Appellate Body also decided the case against India by December 1997 and gave fifteen months time till April 1999 to comply with the TRIPS obligation respecting the transitional protection. The controversy ended when India amended its Patent law in March 1999 and introduced a new Chapter IVA dealing with Exclusive Marketing Rights. The Patent Rules 1972 was also amended in June 1999 to introduce Chapter IIIA to provide for filing and prosecution mechanism for Exclusive Marketing Rights.

EMR has been a key topic for deliberations in the Indian pharmaceutical business circles in the recent past. Very few companies have been able to meet the requirements set under the amended patents law. The details of the EMRs granted so far as well as EMRs applied for are given in Table A.

Clause 21 of the proposed amendment bill omits Chapter IV A of the Patents Act, 1970 that deals with Exclusive Marketing Rights. A new set of provisions has been proposed in the Bill to protect the EMRs already granted. The pending applications for EMRs will be treated as request for examination under Section 11B. All EMR related infringement suits pending before the courts will be treated as patent infringement suits once the new law takes effect.

Compulsory Licensing - the Balancing Act

The availability of medicines at affordable prices is a key public health concern. It was this key concern that compelled the Government of India to augment the reach and scope of compulsory licensing in the Patents Act. The Patents Act, 1970 contained detailed provisions respecting compulsory licenses. But these provisions were never put

Table A

Applicant	Title of the EMR/Patent Application and Related Drug Product	Brand Name	Status
Glaxosmithkline Beecham	Rosiglitazone (Novel compounds)	Avandia	EMR rejected
Glaxosmithkline Beecham	Novel compounds (name of drug product not available)	Not known	EMR Rejected
Novartis	Imatinib mesylate	Glivec	EMR granted (the first EMR in India)
Wockhardt	Nadifloxacin	Nadoxin	EMR granted
United Phosphorus	Combination of Carbedazim & Macozeb	SAAF	EMR granted (first EMR of an Indian company)
Nicolas Piramal	Aablaquine	Bulaquine	EMR application pending
Hoffman-La-Roche	Saquinavir mesylate	Invirase	EMR rejected
Eli-Lilly	Tadalafil	Cialis	EMR application pending
Astra Zeneca	Gifitinib	Iressa	EMR application pending
Astra Zenca	Ximelagatran	Exanta	EMR application pending
Wockhardt	Pharmaceutical compositions containing Benzoquinolizines	Not known	EMR application pending
Schering Plough	Biotech - interferon alpha	Not known	EMR application pending
Bristol-Myers Squibb	Gatefloxacin	Tequin	EMR application pending
Bayer	Moxifloxacin	Avelox	EMR application pending
Novartis	Zoledronic acid	Zometa	EMR application pending
Ranbaxy	Once-a-day oral controlled release form (name of drug product not available)	Ciprofloxacin	EMR application rejected
Eli Lilly	Tetracyclic derivatives, process for preparation and use thereof	Not known	EMR application pending

to use. However, in view of the introduction of product patents, the Government of India has made compulsory licensing provisions more stringent. Any interested person can apply to the Controller of Patents seeking a compulsory license if the 'reasonable requirements' of the public with respect to the patented invention is not satisfied, or the patented invention is not available to the public at reasonably affordable price, or when the patented invention is not worked in the territory of India. An attempt has been made to explain the meaning of an otherwise vague expression 'reasonable requirements' in Section 84(7). However, these explanations do not clarify the situations in which an interested person can invoke compulsory licensing provisions, leaving the expression 'reasonable requirements' ambiguous.

The Patents (Amendment) Bill, 2003 introduces a new section namely 92A in the principal Act relating to the grant of compulsory licenses for manufacture and export of patented pharmaceutical products in certain exceptional circumstances. This amendment is intended to implement Paragraph 6 of the Doha Declaration on TRIPS Agreement and Public Health. According to this provision, compulsory license will be granted to manufacture and export patented pharmaceutical products to a country, having insufficient or no manufacturing capacity in respect of that product, provided the applicant has obtained a compulsory license in that country for that product.

The provisions on compulsory licensing will have a bearing on the way the multinational pharmaceutical companies propose to do business in India after January 1, 2005. Making drugs available at affordable prices will be a key issue for multinational pharmaceutical companies. Those who do not have their own manufacturing units will need to enter into licensing arrangements with local counterparts. Indian pharmaceutical companies are likely to make use of the ambiguity in the provisions relating to compulsory licenses. The sub-clauses (a) through to (e) of Clause (7) of Section 84 are adequately ambiguous, giving the Indian companies the scope to use it to their advantage.

Parties aggrieved by the grant as well as the refusal of EMRs have filed cases at the High Court setting the scene for a large number of potential product patent litigations.

Conclusion

The scene has been set in India for an interesting era in the national patent system. The decade ahead will witness a vibrant phase of dialectics that will hopefully contribute to the emergence of a patent system capable of absorbing the often conflicting interests of the stakeholders — the Indian and the multinational pharmaceutical companies, the patent administration system and the people of India. ●

PCT - India in Limelight

In 2003 India's presence on the PCT map was highlighted with a substantial increase in the number of applications filed with the International Bureau of WIPO with India as the country of origin. The percentage increase in applications filed by applicants from India was 27.3 in 2003. The total number of international applications filed with India as the country of origin was 611, which is 0.6 per cent of all international applications filed. As far as developing countries were concerned India stood at the third spot behind Korea and China. India also figured among the top ten countries of origin in the list of number of applications filed with the International Bureau as the Receiving Office. The number of applications filed with the IB as RO from India stood at 249. ●

BARC Applies for Banana Juice Patent

The Bhabha Atomic Research Centre (BARC), a premier government research organisation has applied for a



patent on Banana juice. Now the technology is being upgraded for commercial exploitation. Banana is made into pulp, certain enzymes are added and the pulp is kept for about 2 days at certain fixed temperature and environment. Using a centrifuge, the liquid part is liberated from the pulp with the help of the enzyme. The liquid is then bottled as Banana juice. It has a storage life of a month and efforts are on to extend its shelf life. ●

Progressing Strides in Indian Trade Marks Law

The Indian trade marks law and practice underwent radical transformation in the recent past. The Trade Marks Act, 1999 notified on September 15, 2003 brought in a variety of progressive changes. This note summarises some of the important amendments introduced by the new law.

Service Marks are Now Registrable in India

Prior to the Trade Marks Act, 1999 service marks were not registrable in India. In the absence of service marks registration, a practice of filing service marks applications in Class 16 had evolved.

Collective Marks are Recognised

“Collective Marks” are recognised in the new law. A Collective Mark is defined as the one distinguishing the goods, or services of members of an association of persons from those of others.

Well Known Marks

Well-known marks find place in the new law. Well-known marks were recognised by the Indian Courts even prior to

the new Act. Accordingly, Sections 20 and 22 of the Companies Act have been amended to the effect that registration of a company, whose name is identical with or too nearly resembles a registered trade mark or a mark pending registration, would not be allowed. Further, if inadvertently a company has been incorporated with a name, which resembles a trade mark then on an application made by the proprietor of the Mark, the name of the Company can be changed. This makes it imperative to conduct a company name search to secure the brand name against any unauthorised usage.

Term of Registration & Renewal

The term of Trade Mark registration has been increased from 7 years to 10 years under the new Act and the mark can be renewed from time to time by making the requisite application.

Assignment Allowed Without Goodwill

As a landmark change, the 1999 Act permits a Trade Mark, whether registered or unregistered, to be assigned “in gross” — with or without goodwill.

The Trade Marks Act, 1999 notified on September 15, 2003 brought in a variety of progressive changes.

the amendment. To consider a mark as Well-known the Registrar is no longer mandated to consider whether the Mark has been used in India, whether it has been registered or whether the application has been filed in India. It is neither necessary that the Mark be well known to the public at large in India.

Shape of Goods and Packaging - the New Avenues of Registrability

Shape of goods is included in the definition of ‘mark’ under the new law. The inclusion of ‘packaging’ in the definition of mark has expanded the scope of registrable marks.

Colour Marks and Combination of Colours

Combinations of colours find specific mention under the new law. This is yet another step forward in expanding the registrability criteria for trade marks.

Trade Mark vis-à-vis Company Name

A Company name, which violates the trademark rights of another is recognised as a ground for infringement under

Suits Concerning Infringements

In a significant move, which is very material to overseas corporate entities having their offices in the metropolitan cities in India, the 1999 Act permits the plaintiff to file a suit in the District Court within the local limits of which it has its offices for gain or profit. This is a major deviation from the earlier position where a suit could be instituted only where the defendant had its principal place of business or offices for gain or profits or where the infringing activities had taken place.

Conclusion

The backlog of approximately 5 lakh unexamined trade mark applications has been brought down in a phased manner. The Registries have been modernized and search facility has been made available online at all the five Trade Mark Registries. In most cases the first office action is issued within 3-6 months’ time. The time to reply to the office action is 1 month. Typically the Trade Marks Registry fixes a hearing concurrently with the issuance of the office action. Renewal of Trademarks is being done instantaneously in straightforward cases. Overall these changes are indeed progressive. ●

The Intellectual Property Appellate Board

The establishment of the Intellectual Property Appellate Board (IPAB) marks the beginning of a new era in the Indian Intellectual Property Rights administration system. On September 15, 2003 the Trade Marks Act, 1999 was notified and the IPAB established. However, the IPAB became functional only in December, 2003 with the IPAB Rules being notified in the Gazette.

The primary purpose for the establishment of the IPAB is to provide an appellate forum to expeditiously adjudicate upon appeals from the orders or decisions passed by the Registrar of Trade Marks, the Controller of Patents and Registrar of Geographical Indications. The IPAB has also been conferred original jurisdiction in regard to rectification proceedings under the Trade Marks Act, 1999. The Geographical Indications Act empowers the IPAB to decide rectification applications in its original jurisdiction. As of now, the IPAB has been hearing appeals from the orders passed by Registrar of Trade Marks only. Applications and appeals from the orders, decision or directions of the Controller of Patents are not yet heard by the IPAB as the required notification under the Patents Act is awaited.

The orders subject to appeal before the IPAB are those passed by the Registrar of Trade Marks during rectification or opposition proceedings. Earlier such appeals were made to the High Courts. However, it is to be noted that appeals from infringement proceedings are solely under the High Court's jurisdiction and that the IPAB has no statutory power to try infringement proceedings.

The following are some of the salient features of the IPAB:

Composition of an IPAB Bench

Every Bench of the IPAB comprises a Judicial Member and a Technical Member. The Trade Marks Act and the Patents Act provide the particulars of the qualifications for appointment as a technical member of the IPAB.

Appeals to IPAB

An impugned order may be appealed against before the IPAB within a period of three months from the date of such order. However, the law also allows for condonation of delay subject to the satisfaction of the IPAB.

Exclusive Jurisdiction

The IPAB has been conferred exclusive jurisdiction to hear

appeals from the orders of the Registrar of Trade Marks, the Controller of Patents and Designs as well as the Registrar of Geographical Indications in respect of matters specified in the respective legislations.

Procedures - Non Applicability of Civil Procedure Code

The Code of Civil Procedure is not applicable to the proceedings before the IPAB. Earlier when the appeals were heard by the High Courts, procedural compliance used to consume much time and result in delayed disposal of the appeals. The simplified rules and freedom from CPC ensure faster disposal of matters before the IPAB.

Rules for Conduct of Proceedings

The IPAB has been vested with the powers to make its own rules for conduct of proceedings. A notification was passed on December 5, 2003, which laid out the Rules governing the proceedings before the IPAB i.e., IPAB (Procedure) Rules, 2003. The independence allowed to the Board is intended to aid in the faster disposal of cases and the convenience of the litigants.

Transfer of Cases

The Chairman has the power to transfer cases from one Bench to another either on an application by a party to the hearing or on its own. This discretionary

power will ensure fixing the place of hearing taking into consideration the convenience of the parties.

No Ex-Parte Injunctions

No ex-parte injunction is possible in proceedings before IPAB. The emphasis is on adjudication on merits.

Power of Review

The Board has been conferred the power to review its own orders. The Chairman has been given the authority to post the review proceeding before a Bench determined by him.

Appeals from IPAB

Orders passed by the IPAB are subject to appeal before the High Court.

Conclusion

The number of appeals and applications that have been heard and disposed of stands testimony to the promptness and optimism ushered in after the commencement of proceedings before the IPAB. The tabulated data respecting cases transferred to and decided by the IPAB is given in Table B. ●

Table B

Sl. No.	Remarks	No.
1.	Appeals/Applications Transferred to the IPAB from High Courts of Mumbai, Delhi, Madras and Calcutta	386
2.	New Appeals/Applications filed	36
3.	Number of Cases decided by the IPAB	53

Why Indian Patent Examiners Do Not Allow Multiple Independent Claims?

In the answer to this question lies an important aspect of Indian law — the wide gap between the legislative intent and the law in practice. The Patents Amendment Act, 2002 substituted sub-section (5) of Section 10 that deals with ‘single inventive concept’. The provision as it stands now reads as follows:

“The claim or claims of a complete specification shall relate to a single invention, or to a group of inventions linked so as to form a single inventive concept, shall be clear and succinct and shall be fairly based on the matter disclosed in the specification”.

The above provision acts as the basis to ascertain the form and content of claims in a complete specification. While the recitals respecting clarity, succinctness and support were present in the Patents Act 1970, the single inventive concept was added by the 2002 amendment. As per the amended provision, claims of a complete specification can be directed at a group of inventions linked so as to form a single inventive concept. Here arises the key question of putting this legal provision into practice.

An office action from the Indian patent office is almost a standard form single sheet having a cover letter setting out the time frame for reply, etc., on the front side and the reverse side having a number of one liner objections on predictable lines. This has been the practice of the

patent office for a considerably long time. One of the objections, typically, will be that ‘the claims are distinct’ and are ‘addressed at a plurality of distinct inventions’. This objection continues to be conspicuous in all office actions, if there is more than one independent claim whether directed at distinct inventions or not. In no office action will one find the Examiner substantiating his/her reasoning. So the onus is on the Applicant to prove that the claims are not distinct despite the fact that a plain reading of the claims will show that the inventions are closely linked to each other and dividing them out might lead to double patenting.

Therefore, it seems, the only reason for the Examiners to raise objections on the above lines is the existence of some sort of an un-codified convention that there can be only one independent claim in a patent application. Despite the inclusion of the ‘single inventive concept’ in the Patents Act, the Examiners continue to raise objections if there are more than one independent claims without in fact analysing whether the second independent claim recites features which are integral to the main invention claimed in the principal claim.

Here lies yet another example of the wide gap between the law on paper and the law in practice. Hopefully, soon there will be well-drafted Examination Guidelines to clarify what the law says and what the Examiner ought to do. ●

The Supreme Court Directs the Government of India to Challenge Monsanto Wheat Patent at EPO

International NGO Greenpeace along with the Research Foundation for Science, Technology and Ecology and the Bharat Krishak Samaj filed a Public Interest Litigation (PIL) in the Supreme Court of India. The PIL wanted the Government to challenge a European Patent for a wheat variety by crossing an Indian wheat variety Nap-Hal with another seed that had been granted to Monsanto. The Supreme Court on February 23, 2004 directed the Government of India to institute opposition proceedings at the EPO challenging the grant of the patent. ●

Towards A Data Exclusivity Law - The First Step

The government has constituted a high level inter-ministerial committee to consider steps to be taken in the context



of Article 39 of the TRIPS Agreement for the protection of undisclosed information. This has come in the wake of sustained efforts from multinational pharmaceutical companies in India, who have been advocating for enactment of data exclusivity laws in India. ●

Patents for Computer Related Inventions - the Indian Perspective

A direct reference to the patentability of computer related inventions finds place in the amended Indian patents law. Section 3 (k) of the Patents Act, 1970 states that a mathematical or business method or a computer program *per se* or algorithms are not inventions within the meaning of the Act.

A preliminary reading of this provision suggests that, what is not patentable is only computer program *per se* and all other computer program implemented inventions are patentable. Consequently a distinction must be drawn between what is computer program *per se* and what is not for purposes of patentability. In the absence of precedents or a manual of patent examination procedure, the Indian Patent Examiners use their subjective understanding to allow or reject patent claims reciting features of computer related inventions. This has resulted in an arbitrary system of examination of patent applications in the field of computing. It is, therefore imperative to develop a clear set of guidelines explaining what is patentable in India in the field of computing. In this connection it may be advisable to study the legal positions in other jurisdictions where this issue has been discussed in detail.

In the United States, the position is that computer software is patentable, if it produces a 'useful, concrete and tangible result'. (State Street Bank & Trust Co. v. Signature Financial Group Inc. 47 U.S.P.Q.2d 1596 [1998]). State Street Bank is the culmination of a long process of deliberations on the question of patentability of computer related inventions. In response to a number of decisions of the Court of Appeal for the Federal Circuit, in 1996 the United States Patent and Trade Office (USPTO) issued a set of 'Guidelines for Computer-related Inventions'. The USPTO explained that "Computer-related inventions" include inventions implemented in a computer and inventions employing computer-readable media. The Guideline further clarified that a computer or other programmable apparatus whose actions are directed by a computer program or other form of software is a statutory machine, a computer-readable memory that can be used to direct a computer to function in a particular manner when used by the computer is a statutory article of manufacture and a series of specific operational steps to be performed on or with the aid of a computer is a statutory process.

As per the current US position computer software or business methods do not fall within the exceptions to the statutory subject matter recognised under 35 USC 101.

In Europe, things took a slightly different course. A prelim-

inary reading of the European Patent Convention (EPC) shows that programs for computers as such are not patentable. Article 52(2)(c) excludes schemes, rules and methods for performing mental acts, playing games or doing business and programmes for computers. The rationale for the above exclusion provision in the EPC was that computer software as such is not of any technical nature and as per European traditions patentability requires a specific technical application. Therefore the key question in the European Context is whether the invention is of any technical nature. The EU position is that the invention 'must have a technical character or, in other words, must provide a technical contribution to the art'.

The distinction drawn between 'computer software as such' and 'computer program products' by the Technical Board of Appeal of the EPO is extremely significant. The Board viewed that a computer program claimed by itself is not excluded from patentability, if it, when running on a computer or loaded into a computer, brings about, or is capable of bringing about, a technical effect which goes beyond the 'normal' physical interactions between the program (software) and the computer (hardware) (EPO TBA Decision in T110/90, [1994] OJ EPO 55). In this case, coordination and control by software of the internal communications between programs and data files held at different processors in a data operating system was considered. Technical contribution could be considered as the difference between the technical features of the invention claimed and the prior art. This difference could be assessed by various approaches. As for example, a technical contribution can lie in an identified technical problem and the technical solution to that technical problem. It could be in the effects achieved by the solution. It could be in the technical features constituting the solution.

Consequently a program that causes, when run on a computer, the required technical effect would be regarded as an invention within the meaning of Article 52(1) EPC. As a further consequence, such a computer program may, in principle be claimed by itself or as a program product or as a record on a carrier.

Learning practical lessons from the comparative legal positions highlighted above, it is time for the Indian Patent Office to develop a set of clear guidelines on the patentability of computer software. In the absence of such clearly laid down examination guidelines, the law and practice of patents will lack uniformity and predictability. ●

How to Protect Geographical Indications in India?

Geographical Indications can be best explained by referring to some well known examples — *Basmati Rice, Darjeeling Tea, Scotch Whiskey, Venetian Glasses, Chinese Silk, Idaho Potatoes, Florida Oranges* to name a few.

What are Geographical Indications?

Geographical Indications are indications used to identify agricultural, natural or manufactured goods originating from a definite geographical territory having a special quality or reputation or other characteristics. Geographical Indications encompasses what is known as *Appellation of Origin*. An *Appellation of Origin* is a special kind of Geographical Indication used on products that have a specific quality that is exclusively or essentially due to the geographical environment in which the products are produced.

Can Geographical Indications be Registered in India?

Geographical Indications can be registered in India. An application to register a geographical indication must be made in Form G1-1 (for Indian applicants) or Form G1-2 (for foreign nationals). An application for goods falling in different classes by an Indian applicant must be filed in Form G1-3 and a Convention Application with goods falling in different classes must be filed in Form G1-4.

Where to File?

The application must be filed at the Office of the GI Registry in Chennai. The Applicant must furnish *inter alia* the following information/documents with the GI Registry:

- Geographical signification of the indication *vis-à-vis* the goods. The application must explain how the indication serves to designate the goods as a Geographical Indication;
- The application must also specify the class of the goods, the geographical area, the details of the appearance and the details of the producers;
- An affidavit deposing the applicant's right to become



- the registrant;
- The benchmark of the geographical indication;
- Special characteristics of the GI;
- Textual description of the boundary;
- Certified copy of the map of the territory;
- Growth attributes in relation to the GI;
- Special human skills involved;
- Number of producers; and
- Details of any inspection structures to regulate the use of the GI.

Examination & Grant

Upon filing a GI application, the GI Registry will allocate a filing number. The application will be examined to check whether it meets the requirements of the Act and Rules. The Registrar is empowered to constitute a consultative Group of experts to ascertain the correctness of the particulars furnished. The GI Registry will in due course issue an Examination Report.

Once the objections, if any, are removed, the submission of the applicant will be considered before accepting/rejecting an application. Thereafter, the application will be accepted and advertised in the Geographical Indications Journal.

Term of Registration & Renewal

The registration of a geographical indication is valid for a period of 10 years. It can be renewed from time to time for further period of 10 years each. ●

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

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