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India: Making It Trips Way - India's New Patent Regime

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Patent is a monopoly or exclusive right granted by State in favour of an inventor in respect of an invention. It is granted to the person who is entitled for it and who fulfills the prescribed conditions imposed by state for such grant. It may also be described as an official document which gives the patentee right of ownership of an invention.

The fundamental object behind the Patent Law is to encourage scientific research, new technology and industrial progress. The price of the grant of the monopoly is the disclosure of the invention at the Patent Office, which after the expiry of period of monopoly, passes into public domain. A patent is granted only to those inventions that are novel, having an inventive step and industrial applicability.

Historical background of Patent Law in India

The origin of the term of Patent can be attributed to the term "Letters Patent" which were issued under great seal of the king of England addressed by the crown to the subjects conferring certain rights and privileges on one or more persons. These were in respect of inventions and were, referred to as the grants made by the crown to a subject enabling the grantee to prevent all persons other than himself and those whom he authorizes for making, using or vending that which is the subject-matter of "Letter Patent". In other words, "Letters Patent" were grant of a form of trade monopolies. It was a document granting some right or privilege, issued under Governmental seal and open to public inspection.

Introduction of Patent Law in India took place in 1856 whereby certain exclusive privileges to the inventors of new inventions were granted for a period of 14 years. However the formal Patent protection in India was introduced by way of Patent Act, 1911. Thereafter, various acts appeared on the façade of the patent law pattern.

Presently, the provisions with respect to Patents in India are governed by The Patents Act 1970 as amended by The Patents (Amendments) Act, 2005 and The Patents Rules, 2003 as amended by The Patents (Amendments) Rules, 2005. Both Act and the Rules are an outcome of various amendmeds made in the Patent Act 1970 and Patent Rules 2003 done mainly to meet the requirements of TRIPS so as to tune up the Indian patents regime with International standards and meet India's obligations under International agreements.

The main rationales responsible for triggering 2005 amendment is that India being a signatory to Trade Related Intellectual Property Rights (TRIPS) agreement earlier known as GATT have to mandatoraly introduce product patents for drugs, food products and chemicals (food, medicines and drugs) by 01.01.2005.

Some of the Prominent Amendment that are being carried out are:

1. Provision relating to inventions where only methods or processes of manufacture were patentable has been omitted, so as to allow product patent protection regime in addition to existing process patent regime in all fields of technologies including the areas of food; medicine and drugs**,** which were not allowed earlier;

2. Computer Programme per se is not patentable other than its technical application to industry or a combination with hardware.

3. Provision for publication of patent application has been introduced. Now the application is deemed to be published after the expiry of 18 months from the date of filing or from the date of priority, whichever is earlier. Further an option for an early publication of application is also made available to the applicant.

4. Provision relating to time period for putting an application in order for grant has been reduced significantly from 12 months to 6 months which upon request may be further extended to 3 months. However those applications which have been examined before the 1st day of January, 2005 the time period for putting an application in order for grant remains the same i.e. 12 months from the date on which the first statement of objection is issued to the applicant to comply with the requirements.

5. Deletion of the provisions relating to Exclusive Marketing Rights (EMRs) (which has become redundant), and introduction of a transitional provision for safeguarding EMRs that already granted or for which the applications are still pending:

a. Every application to which EMRs is granted before the day 1 of January 2005 should continue to be effective with the same term and conditions on which it was granted and shall be examined for the grant of patent immediately on the commencement of this Act.

b. All suits relating with the infringement of EMRs shall be dealt in the same manner as if they were suits concerning infringement of patents.

c. Every application for grant of EMRs filed before the 1st January 2005 shall be deem to be treated as request for examination for grant of patent.

6. Provisions related to pre-grant and post grant opposition have been amended.

a). Pre-grant opposition

Pre-grant opposition can be filed anytime after publication but before the grant of patent. Earlier the time period was 4 months from the date of advertisements of the acceptance of a complete specification.

The Pre-grant opposition would now be allowed on the following grounds:

(a) that the applicant for the patent or the person under or through whom he claims, wrongfully obtained the invention or any part thereof from him or from a person under or through whom he claims;

(b) that the invention so far as claimed in any claim of the complete specification has been published before the priority date of the claim:

(i) in any specification filed in pursuance of an application for a patent made in India on or after the 1st day of January, 1912;

or

(ii) in India or elsewhere, in any other document Provided that the ground specified in sub-clause (ii) shall not be available where such publication does not constitute an anticipation of the invention by virtue of sub-section (2) or sub-section (3) of section 29.

(c) that the invention so far as claimed in any claim of the complete specification is claimed in a claim of a complete specification published on or after the priority date of the applicant's claim and filed in pursuance of an application for a patent in India, being a claim of which the priority date is earlier than that of the applicant's claim;

(d) that the invention so far as claimed in any claim of the complete specification was publicly known or publicly used in India before the priority date of that claim.

Explanation - For the purposes of this clause, an invention relating to a process for which a patent is claimed shall be deemed to have been publicly known or publicly used in India before the priority date of the claim if a product made by that process had already been imported into India before that date except where such importation has been for the purpose of reasonable trial or experiment only;

(e) that the invention so far as claimed in any claim of the complete specification is obvious and clearly does not involve any inventive step, having regard to the matter published as mentioned in clause (b) or having regard to what was used in India before the priority date of the applicant's claim;

(f) that the subject of any claim of the complete specification is not an invention within the meaning of this Act, or is not patentable under this Act;

(g) that the complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed;

(h) that the applicant has failed to disclose to the Controller the information and undertaking regarding foreign application(s) or has furnished the information which in any material particular was false to his knowledge.

(i) that in the case of convention application, the application was not made within twelve months from the date of the first application for protection for the invention made in a convention country by the applicant or a person from whom he derives title;

(j) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention;

(k) that the invention so far as claimed in any claim of the complete specification is anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere,but on no other ground and the Controller shall, if requested by such person for being heard, hear him and dispose of such representation in such manner and within such period as may be prescribed.

b) Post-grant opposition

A new provision is also inserted which provides for post-grant opposition, which can be filed any time after the grant of patent but before the expiry of a period of one year from the date of publication of the grant of a Patent. However, the opposition would now be allowed on the following grounds:

- that the patentee or the person under or through whom he claims, wrongfully obtained the invention or any part thereof from him or from a person under or through whom he claims;
- that the invention so far as claimed in any claim of the complete specification has been published before the priority date of the claim:
    ii. in any specification filed in pursuance of an application for a patent made in India on or after the 1st day of January, 1912; or
    iii. in India or elsewhere, in any other document:

c) that the invention so far as claimed in any claim of the complete specification is claimed in a claim of a complete specification published on or after the priority date of the claim of the patentee and filed in pursuance of an application for a patent in India, being a claim of which the priority date is earlier than that of the claim of the patentee;

d) that the invention so far as claimed in any claim of the complete specification was publicly known or publicly used in India before the priority date of that claim.

Explanation. - For the purposes of this clause, an invention relating to a process for which a patent is granted shall be deemed to have been publicly known or publicly used in India before the priority date of the claim if a product made by that process had already been imported into India before that date except where such importation has been for the purpose of reasonable trial or experiment only;

e) that the invention so far as claimed in any claim of the complete specification is obvious and clearly does not involve any inventive step, having regard to the matter published as mentioned in clause (b) or having regard to what was used in India before the priority date of the claim;

f) that the subject of any claim of the complete specification is not an invention within the meaning of this Act, or is not patentable under this Act;

g) that the complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed;

h) that the patentee has failed to disclose to the Controller the information and undertaking regarding foreign application(s) or has furnished the information which in any material particular was false to his knowledge;

i) that in the case of a patent granted on convention application, the application for patent was not made within twelve months from the date of the first application for protection for the invention made in a convention country or in India by the patentee or a person from whom he derives title;

j) that the complete specification does not disclose or wrongly mentions the source and geographical origin of biological material used for the invention;

k) that the invention so far as claimed in any claim of the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere.

6. Provisions relating to acceptance of complete specification, advertisements of acceptance of complete specification and effect of acceptance of complete specification have been omitted. There will now be direct grant of Patent.

7. Provision relating to the requirement of sealing of Patent has been omitted.

8. Patent of addition shall now be granted after the grant of the patent for the main invention.

9. No proceedings can be initiated for infringement of Patent committed before the date of post grant publication of the application.

10. With respect to the pharmaceutical products compulsory license shall be available for manufacture and export to any country having insufficient or no manufacturing capacity in the this sector for the concerned product to address public health problems, provided compulsory license has been granted by such country or such country has, by notice or otherwise, allowed importation of the patented pharmaceutical products from India.

11. Provision relating to supplementary provisions as to convention applications are amended to provide that in case of convention application, the applicant shall furnish, when required by the controller, in addition to the complete specification, copies of the specifications or corresponding documents filed or deposited by the applicant in the patent office of the convention country. This should be verified to the satisfaction of the controller and submitted within 3 months period from the date of communication by the controller. Earlier, these were required to be certified by Head of Patent Office of convention country.

12. Provisions relating to advertisements have been replaced by publication in Official Journal published by Controller of patents.

13. Provisions relating to registration of assignment of patent have been amended. The new law provides that 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 shall not be valid unless the same were in writing and the agreement between the parties concerned is reduced to the form of a document embodying all the terms and conditions governing their rights and obligations and duly executed meaning thereby that only documentation is required and registration of assignment with Controller is not compulsory.

14. Importing Patent invention for specific purpose is not infringement,such as in case of: -

a) Making, constructing, using or selling a patented invention solely for uses reasonably related to development and submission of information required under any law.

b) Importation of patent products from a person who is duly authorised by any law to sell, produce or distribute the product will not be infringement of patent rights.

15. India's old patent laws did not allow a "new use" for a known substance to be patented. This was to prevent drug manufacturers from making variations on the same drug and extending the patent life beyond the original 20 years. Such practice prevented delays to the entry of generics into the market. The new Act provides that "mere new use" for a known substance cannot be patented. The effect of this amendment is that even though the substance itself is known and comprises part of the state of the art, it would now be patentable if something more than mere new use could be shown.

16. Processing time limits for examination of patents have also been reduced from 48 months to 36 months.

17. Another modification is the introduction of a provision that patent rights for mailbox applications will only be available from the date of grant of patent, and not retrospectively from the date of publication. As a result, many Indian companies will be saved from infringement attacks by the multinational majors, who might get patents for drugs which Indian companies are selling. However the patent holder will be entitled to receive reasonable royalty from such 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 patent.

18. Provision relating to seeking permission of the Controller, in the prescribed manner, before applying for the grant of patent outside India by any person Resident in India is now extended to all kinds of Patents. Earlier it was required only for inventions relating to defense or atomic energy. However this section is not applicable on persons resident outside India who have already filed an application for the invention in a country outside India.

Conclusion:

Under the new patent regime venturing in pharmaceutical sector is made encouraging to multinational corporations due to their enormous R&D budgets. The Indian pharmaceutical majors will also have to pool in greater amounts in the field of R&D in order to search for new molecules to compete with the inflow of the multinational corporations. However the smaller pharmaceutical companies will face hurdles in their way due to their smaller budgets for R&D, they may have to think positively for mergers or collaborations to increase their budget size or alternatively may take up assignments from the major players.

The present Act is skillfully drafted in order to meet India's major obligations under international agreements. Apart from major changes, one of the positive aspects of the present Act is that by amending the various sections rigidity in the time-line is replaced by greater flexibility. The present legislation will have great impact on the overall society as well as economy of India. The new Act would encourage Indian pharmaceutical companies to emphasize R & D based innovative growth. Complying with WTO membership requirements would open up trade with the world for India. It would result in more economic activity and more employment. The Indian pharmaceutical and biotech industry offers a huge scope for outsourcing of research. Now with the right legal framework in place for the protection of the results of such research, India could become a global research hub.

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