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Indian IP Spotlight

Patent Office Examination Guidelines for Pharmaceuticals Applications

Neeti Wilson†

Anand and Anand, B-41 Nizamuddin East, New Delhi 110 013

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The Indian intellectual property scenario is developing at a very fast rate in India and one finds some or the other newspaper headline related to the same. This section is devoted to presenting the current Indian IP news in the limelight to keep the readers abreast of the latest trends. The spotlight for November 2014 is on the latest Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals issued by the Office of the Controller General of Patents, Designs and Trademarks. Any comments or suggestions may be sent to IPneeti@outlook.com or neeti@anandandanand.com.

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The recent guidelines for examination of patent applications in the field of pharmaceuticals issued by the Office of the Controller General of Patents, Designs and Trademarks on 29 October 2014 is yet another step towards transparency and uniformity or practice among the four patent offices for patent examination. These guidelines are the fifth in a series of documents to be used for examination of patent applications issued by the Indian Patent Office.

The Indian Patent Office has been streamlining its various procedures including examination of patent applications for the different types of inventions. The Patent Office has issues guidelines for examination of patent applications in the area of Biotechnology, Traditional knowledge, Computer related inventions and recently in the area of Pharmaceuticals.[1] These guidelines set the tenor of scrutiny that said subject area inventions would need to go through before monopoly rights of twenty years is granted to the patentee.

Pharmaceutical Patenting in India

In view of the prominent position of Indian pharmaceutical industry in the world, the patenting of inventions in the pharma sector in India has always been in the limelight. The Indian Patent Act allowed patents to be granted for pharmaceutical products only after 2005 when India became fully TRIPS compliant. The pharma product patents granted from 2005-06 to 2009-10 have been specifically listed at the Indian Patent Office website and with a number of 3488 granted patents indicates a healthy rate of grant in said five year period of about 700 patents a year.

Pharma patent proceedings have never been out of news in India ever since the product patents were allowed, be it the granting of first compulsory licence in product patent regime by the Patent Office[2], later upheld by the Intellectual Property Appellate Board (IPAB)[3], challenge of the constitutional validity of Section 3(d)[4], first complete trial decision in patent infringement suit by High Court[5], or the interpretation of patentability criteria in terms of therapeutic efficacy by the Supreme Court.[6]

Examination of Patent Applications

The Indian Patent Office (IPO) examines all patent applications as per the technical and formal requirements prescribed in the Patent Act. The jurisdiction of IPO being divided into four zones with an office in Chennai, Delhi, Kolkata and Mumbai each, the IPO published a 'Manual of Patent Office Practice and Procedure' for providing guidance to the Examiners as well as the stakeholders as to how the applications would be dealt with by the Patent office.

To supplement the general manual, the patent office thereafter issued guidelines in specific technical fields: (i) Guidelines for Examination of Biotechnology Applications; (ii) Guidelines for Processing of Patent Applications relating to Traditional Knowledge and Biological Material; (iii) Guidelines for Examination of Computer Related Inventions; and most recently the Controller General of Patents, Designs & Trade Marks launched (iv) the Guidelines for examination of patent applications in the field of pharmaceuticals after extensive consultation with stakeholders.

Pharmaceutical Patent Examination Guidelines

The guidelines lay emphasis on the following criteria of patentability in India:

(1) Novelty
(2) Inventive step/non-obviousness
(3) Industrial applicability
(4) Assessment whether inventions not patentable under Section 3
(5) Sufficiency of description (clarity and support of the claims) and
(6) Unity of invention

Prior Art Search for Pharmaceutical Compounds

The guidelines emphasizes the case of claims of the pharmaceutical compounds involving derivatives of known compounds having established pharmaceutical activities which have already been assigned generic names (International Non-Proprietary Names, INNs). When the patent specification under examination discloses such INNs, the examiner is required to search the prior art on the basis of such INNs as well. Further, if the claims are for second use/indication, the examiner is directed to not only follow the regular search methodology but also ask the applicant to convey the INN of the said pharmaceutical substance. If the applicant does not disclose the INN even on the request, the examiner should try to find out the INN and use the same in the search strategy. However, it has been clarified to the stakeholders that the application would not be refused on account of non-disclosure of the INN by the applicant. It is interesting to note that the patent office website has a list of 8179 INN names issued by the Trademark Registry.

Selection Patents

The pharmaceutical inventions such as New Chemical Entities and specifically compounds are the most important type of claims and though the guideline has detailed reference to the 'Markush structure' there is no reference to 'selection inventions', which are equally common in the pharmaceutical field.

The IPAB which is the binding authority for the Patent Office recognised that selection patents are valid and may be properly considered. Its Order[7] in particular stated as follows:

Particularly in chemical patents the concept of "selection patent" where the inventive step (also novelty) is demonstrated by way of an inventive selection of even a new, unexpected or unpredictable single member having surprisingly advantageous properties previously not known from a known series of a family disclosed in the art can be accepted in the Indian law also. For its applicability in the instant case, the following minimum requirements as per the guidelines by different authorities aforesaid were shortlisted:

- Whether there is any statement in the specification where the nature of the invention concerns with some kind of selection
- Whether the selection is from a class of substances which is already generally known
- Whether the selected substance is new
- Whether the selection is a result of any research by human intervention and ingenuity opposed to mere verifications
- Whether the selection is unexpected or unpredictable
- Whether the selected substance possesses any unexpected and advantageous property

Non-patentable Pharmaceutical Inventions

The Guidelines specifically elaborate the provisions under the Indian Patent Act which Section 3 specifies that are not patentable inventions within the meaning of the Act: (i) Section 3 (b): an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment; (ii) Section 3 (c): the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature; (iii) Section 3 (d): the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy; (iv) Section 3 (e):

a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance; (v) Section 3 (i): any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products. (vi) Section 3(j): plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals; (vii) Section 3 (p): an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.

Conclusion

Pharmaceutical patents have always been a sensitive issue in India with the Indian generic industry being proactive in opposing the innovator patent applications and the strict examination standards followed at the IPO. The new Guideline is intended to bring more clarity on the practice and procedure in the pharmaceutical sector however with the proviso that in case of any conflict between these Guidelines and the Patents Act, 1970 and the Rules made thereunder, the provisions of the Act and Rules will prevail. At the same time, the Patent Office is to update the guidelines from time to time as and when new judgments on patent matters are passed by the judicial authorities in India.

References

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