INDIAN PATENT OFFICE RELEASES GUIDELINES FOR APPLICATIONS RELATING TO PHARMACEUTICAL INVENTIONS

The pharmaceutical sector in India is the third largest in terms of volume and is growing with substantial investment in research and development. The sector is amongst the few that has shown marked growth, as high as 81 percent, during the recent economic slowdown.

India's Patent Law reinstated product patents for the first time since 1972, by way of enactment of an amendment dated 1 January 2005. The legislation took effect on the deadline set by the WTO's Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, which mandated patent protection for both products and processes for a period of 20 years. It was only after this amendment that pharmaceutical products became patentable in India.

Indian Patent law has requirements of novelty and inventiveness that are similar to the requirements across the globe. However, it is to be noted that only a product or a process is eligible to qualify for an invention in India under Section 2(1)(j)[1]. Besides this restriction, Indian Patent law has provisions prohibiting the patenting of inventions that otherwise may have qualified under the universal requirement of novelty and inventiveness. Sections 3(d)[2], 3(e)[3], 3(i)[4], 3(j)[5] and 3(p)[6] of the Patents [Amendment] Act, 2005, being unique provisions of the Indian Patent Law, are considered to be the stumbling blocks for patenting pharmaceutical inventions in India.

Lack of clear explanation in regards to the codified Sections, lack of adequate case law, the presence of different practices followed by the Examiners and the absence of explicit guidelines for examination and grant of pharmaceutical patents in India, makes it difficult for an applicant to obtain Patents in India for pharmaceutical related inventions.

To resolve this issue and to streamline the process of examination of patent applications, the Indian Patent Office has recently issued guidelines for examination of Patent applications for various domains in line with guidelines issued by foreign patent offices. In the recent past the Indian Patent Office issued guidelines for the examination of inventions related to biotechnology, traditional knowledge and computer related inventions. More recently, the Indian Patent Office has issued finalized guidelines for the examination of pharmaceutical related inventions. The guidelines are aimed at providing clarity with respect to the application of various provisions of the Indian Patents Act in respect of pharmaceutical inventions. The absence of any guidelines in this respect as well as the absence of any case law on most of the aspects of the Indian Patents Act has resulted in an atmosphere of uncertainty among stakeholders, which has created difficulties for applicants.

Therefore, in such a scenario, the guidelines are a welcome step to bring uniformity in examining patent applications in the field of pharmaceuticals. The guidelines have covered various areas where both the examiners and applicants were unclear as to how to handle a particular situation in view of the complexity of an invention and the applicability of various provisions of the Patents Act.

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The guidelines can be commended for explaining in detail as to how an examiner would ascertain novelty or inventive step and/or non-obviousness. The guidelines bring clarity as to when an objection for lack of novelty and obviousness can be raised and thus will eventually help applicants to understand why an objection has been raised and how the same can be addressed in a positive manner.

The guidelines have similarly clarified many aspects of examination of pharmaceutical related inventions. However, there still remain some sticky points which may, if not addressed, create problems going forward and may prove to be an Achilles heel of the guidelines.

Problem Areas:

The proposed guidelines regarding Markush claims are well defined, so as to bring clarity in examination and thereafter allowing or disallowing claims with a Markush structure. However, the draft guidelines contain a requirement regarding Markush claims stating that a "*test conducted for each embodiment is provided*", which seems to create complex requirements that is beyond the scope of the legislative requirement of Section 10(4)(b)[7] of the Indian Patents Act. Based upon the comments provided by stakeholders, the final guidelines amended the said requirement to state that a "test conducted for the representatives of such embodiments known to the applicant is provided".

It is to be noted that incorporation of the requirement of a "*test conducted for each embodiment be provided*" in the draft guidelines was not only likely to discourage applicants due to involvement of huge costs in carrying out tests for each embodiment, but would also create a situation where otherwise well drafted patent applications may be objected to for lack of disclosure. However, there still remains vagueness as to what embodiments would be considered as representative embodiments. Further, if an applicant has provided test results for a few embodiments, the question is whether or not the Controller still requires demonstration of test results for a specific embodiment if it is stated that said embodiment is structurally similar to those embodiments for which results have been provided.

The Indian Patent Office must follow the general principle adopted world-wide for obtaining patent protection for a class of compounds having a common structural element and, thus, plausibly also having such a common property or activity, even if not all the compounds falling within the scope of the Markush claim have been exemplified or tested.

Besides this, the Indian Patent Office very often objects to claims exclusively enabled by their description and not by the working examples. This practice results in restricting protection to claims which are supported by working examples along with the disclosure in the description of the invention.

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The approach of restricting claims is beyond the scope of legislative requirement for support in the description of a claimed invention, which does not make any specific requirement for support in the working examples for the purpose of enablement of a claim. It is felt that the guidelines lack clarification in this regard.

Another problematic area where further elaboration is perhaps required is the interpretation of Section 3(i)[4] of the Patents Act, which prohibits patenting of "*method of diagnostic treatment to render human or animal free of disease or to increase their economic value or that of their products*" rather than a method of diagnosis or method of detection per se.

The guidelines also fail to provide clarity and explanation with respect to the acceptability of method of treatment or diagnosis performed outside the human or animal body. The treatment or diagnosis performed outside the body (in-vitro), such as diagnostic tests performed on blood or other samples removed from the body, should not be prohibited by Section 3(i)[4] of the Patents Act, and are patentable subject matter as is the practice in other countries.

The pharmaceutical guidelines have also raised serious apprehension by direct incorporation of the "Guidelines for processing of Patent Applications relating to traditional knowledge and biological material" by way of reference. The existing guidelines for traditional knowledge have gone beyond the scope of Section 3(p)[6] of the Indian Patents Act, especially the Guiding Principle 3[8], which is detrimental to applicants' interests. This has the effect of rendering many pharmaceutical inventions non-patentable, which otherwise are patentable. The guidelines will render such inventions obvious and thus non-allowable merely due to the presence of a single known constituent in a composition without considering the fact that various other active ingredients are present or there is a disclosure of a specific ratio of ingredients giving a synergistic effect. Therefore, such direct incorporation of guidelines for traditional knowledge into the guidelines for pharmaceutical subject matter will greatly impede patenting of pharmaceutical related inventions by substantially increasing the scope of Section 3(p)[6] of the Indian Patents Act, and therefore needs to be addressed appropriately.

The guidelines, while interpreting the requirement of Section 3(d)[2] and Section 3(e)[3] of the Indian Patents Act, mentions that 'any test conducted and results obtained for such an effect shall be disclosed at the time of filing', including a detailed report pertaining to the test conducted, such as in vitro or in vivo test, and experimental results with inference to such a test shall be provided in the description. This has the potential to be interpreted that such tests for an embodiment should be included in the specification at the time of filing of the application. Such tests could be efficacy data, therapeutic efficacy data or synergistic/unexpected properties exhibited by the claimed invention. Therefore, the

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inclusion of the said clause in the guidelines is in contradiction of Section 599 of the Indian Patents Act, whereby amendment of a patent application can be made by way of explanation. Moreover, it is not always possible to include efficacy data (therapeutic efficacy for pharmaceutical related inventions) and synergistic data in the complete specification at the time of drafting and filing an application or during national phase entry, since such data/studies are often generated after the drafting and filing of the patent application. It is to be noted that pharmaceutical inventions are filed at the initial stages of discovery and development of a drug and it is only at a later stage that the clinical research data is collated after clinical trials relating to therapeutic efficacy are conducted.

The in vitro data or animal-model based in vivo data, as well as computer-assisted simulations, are frequently used for establishing the safety and efficacious nature of pharmaceutical products and are normally relied upon as a basis for drafting a patent application. Additionally, for safety and/or regulatory reasons, the human clinical trials of pharmaceutical products are carried-out at the last stage. The above- stated reasons being supported by the land mark judgment in *Novartis* vs. *Union of India*, where the Supreme Court of India did not raise any such requirement that such data should be present in the complete specification at the time of filing of the Application in India, is a clear demonstration of such flexibility being allowed.

The applicant in such situations should be given an opportunity to incorporate further test results, by way of explanation, as permitted under Section 59[9] of the Indian Patents Act, in order to meet the requirement of data which could be efficacy data, therapeutic efficacy data, or synergistic effect data as required under Section 3(d)[2] and Section 3(e)[3]. It is pertinent to mention that though the guidelines appear to require an applicant to provide a detailed report pertaining to the test conducted and experimental results in the description at the time of filing of an application, Examiners in the Indian Patent Office in practice have started to accept research data even during the later stage of prosecution of the application. Further, the absence of examples and explanation in the guidelines with respect to claims directed to pharmaceutical products viz. kit, dosage forms, and compositions having biological materials with the end product being capable of use as a pharmaceutical product, should also be addressed. This will not only help the examiner in the examination of claims directed to these aspects, but also the applicant during prosecution to understand an objection and propose a suitable explanation.

The pharmaceutical subject matter guidelines will facilitate growth of the pharmaceutical industry and stake holders across the globe will be well informed of the intricacies of Indian Patent practice and can accordingly equip themselves to handle the complexities arising therefrom. This initiative will go a long way in clarifying various aspects of the examination of pharmaceutical inventions. However, ambiguities, uncertainties and apparent conflict with statutory provisions are likely to be reduced only

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by the gradual evolution of the Indian patenting system, reinforced by an increase in the case law covering different aspects of Indian Patent practice.

1. ***Section 2(1)(j) "invention" means a new product or process involving an inventive step and capable of industrial application;***

2. ***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 employ 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.

3. ***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;***

4. ***Section 3(i) any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings or any process for a similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products;***

5. ***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;***

6. ***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;***

7. ***Section 10(4)(b) disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection;***

8. ***Guiding Principle 3: In case an ingredient is already known for the treatment of a disease, then it creates a presumption of obviousness that a combination product comprising this known active ingredient would be effective for the treatment of same disease"***

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9. Section 59. Supplementary provisions as to amendment of application or specification.—(1) No amendment of an application for a patent or a complete specification or any document relating thereto shall be made except by way of disclaimer, correction or explanation, and no amendment thereof shall be allowed, except for the purpose of incorporation of actual fact, and no amendment of a complete specification shall be allowed, the effect of which would be that the specification as amended would claim or describe matter not in substance disclosed or shown in the specification before the amendment, or that any claim of the specification as amended would not fall wholly within the scope of a claim of the specification before the amendment.

(2) Where after the date of grant of patent any amendment of the specification or any other documents related thereto is allowed by the Controller or by the Appellate Board or the High Court, as the case may be,—

(a) the amendment shall for all purposes be deemed to form part of the specification along with other documents related thereto;

(b) the fact that the specification or any other documents related thereto has been amended shall be published as expeditiously as possible; and

(c) the right of the applicant or patentee to make amendment shall not be called in question except on the ground of fraud.

(d) in construing the specification as amended, reference may be made to the specification as originally accepted.

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