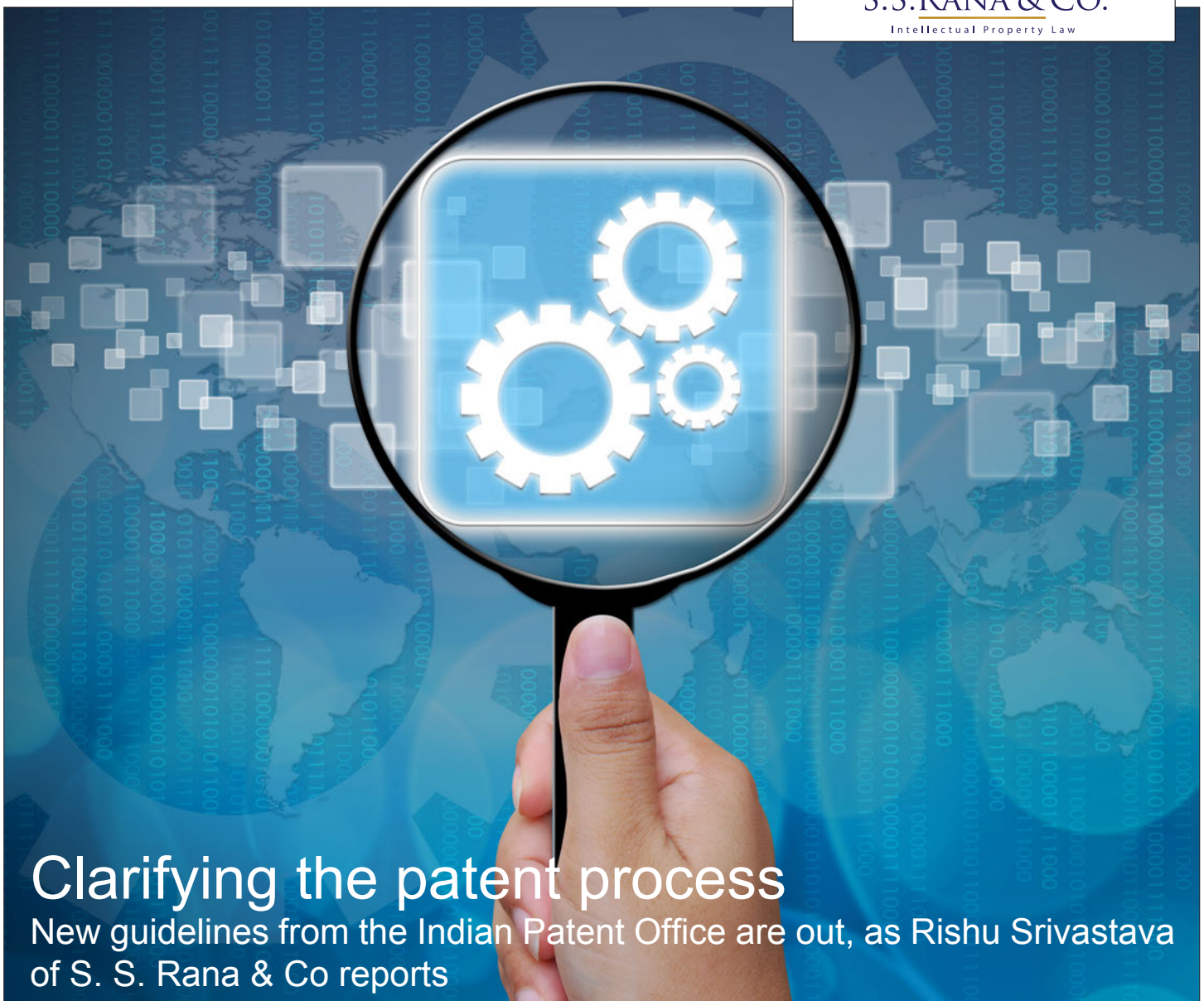

Clarifying the patent process

New guidelines from the Indian Patent Office are out, as Rishu Srivastava of S. S. Rana & Co reports

The patent system is imperative to fostering invention, innovation and for socio-economic growth of the nation. From being wielded as a defensive asset, to becoming a lynchpin in the intellectual property portfolio of an entity, patents have weaved into every facet of an organisation's strategic plan and economic policy.

This sentiment is echoed by various governmental policies and guidelines that underscore initiatives to stimulate the development of effective IP infrastructure that engenders consistent investment in R&D. Espousal of the reforms brought out by such guidelines and policies, when set against the backdrop of performance of key innovation sectors, highlight the significant role that it has played in the sustainable growth of the industry.

In conformity with the public policy objectives of the Patent Act, the Indian Patent Office has issued guidelines for processing patent applications relating to traditional knowledge and biological material, and biotechnology, and as well as draft guidelines for applications relating to pharmaceutical patent applications. These guidelines intend to establish uniform and consistent practices in the examination of patent applications of these allied subjects under the Patent Act 1970, by assisting examiners and controllers of the patent office by removing ambiguity and by clarifying the extent to which such applications had to be dealt under various provisions of the Patents Act.

The guidelines for the examination of pharmaceutical patents incorporate analysis of the courts, with the objective of helping to improve the examination standard and introduce harmonious practice among the technical officers of the system.

For examination of Markush claims

The guidelines directs examiners to raise objection under 'unity of invention' and insufficiency of the disclosure if while examining Markush claims any one of the following criteria is not met: whether the complete specification: (i) discloses all the possible embodiments covered under the claimed Markush formula; (ii) such embodiments share a common use or property; (iii) such possible embodiments share common structure; (iv) physical and chemical properties of claimed compound are disclosed; (v) test conducted for each embodiment is provided; (vi) at least one process for preparing the compounds is disclosed when more than one processes are claimed.

It would, however, be challenging for the applicant to conduct and do define all embodiments of the Markush formula, especially for a chemical structure with plurality of functionally equivalent chemical groups in one or more parts of the compound.

For prior art search

Examiners are directed to frame search strategies by combining parameters including keywords, compound searches, and so on, when conducting prior art searches. The guidelines also suggest using methods such as: molecular formula and structural formula searching; generic name searching (INN); and using International Patent Classification (IPC) for searching and identifying compounds.

Examiners are also directed to ask the applicant to disclose the INN of those pharmaceutical compounds where it is found that the applicant is claiming the second use/indication of an already known pharmaceutical compound.

Assessment of invention

The draft guidelines give explicit explanation and examples regarding the assessment of novelty, inventive step and obviousness of the chemical compound. It specifically prohibits consideration of the following types of claims, stating that they neither pertain to a product or a process: use of compounds in the treatment of; the process of preparing; in the composition of; and a product of a known substance for the treatment of new disease (which is nothing but a use/application claim).

Assessment of novelty

In addition to defining with examples the relevant sections of the Patent Act, with respect to 'new invention', 'priority date' and inherent anticipation, the guidelines specify implicit disclosure, stating that if the prior art discloses the claimed subject matter in such an implicit manner that it leaves no doubt in the mind of examiner as to the content of the prior art and the practical effect of its teaching, an objection regarding lack of novelty should be raised. It is further stated that the question of implicit disclosure is often a mixed issue of novelty and inventive step.

The draft guidelines also say that claims of combinations of pharmaceutical products should be dealt with under novelty as well, as quite often they escape the question of novelty and are dealt under the inventive step or relevant clauses of Section 3 of the act.

With respect to product-by-process claims, it is noted that they must also define a novel and unobvious product, and that its patentability cannot depend on the novelty and unobviousness of the process limitations alone, ie, the product must qualify for novelty and inventive step irrespective of the novelty or inventive step of the process.

Assessment of inventive step

The draft guidelines state that a surprising effect or synergistic outcome of combinations, prior art prejudice, and so on usually demonstrates the non-obvious nature of the invention. But it is clarified that enhanced effects cannot be cited as evidence of inventive step if they emerge from obvious tests.

In order to aid an examiner with objectively analysing inventive step, the following steps have been provided:

- Identify the inventive concept of the claim in question;
- Identify the 'person skilled in the art';
- Identify the relevant common general knowledge of the person skilled in the art at the priority date;
- Identify what, if any, differences exist between the matter cited as forming part of the state of the art and the inventive concept of the claim; and
- Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps that would have been obvious to the person skilled in the art or do they require any degree of inventive ingenuity?

The draft guidelines also elaborate the assessment of industrial applicability and the inventions that are not patentable under a provision of Section 3 of the Patent Act. Section 3(d) deserves special attention in the context of pharmaceutical inventions as it stipulates that an incremental invention, based on an already known substance, having established medicinal activity, will be treated as a same substance, and will fall foul of patentability, if the invention in question fails to demonstrate significantly improved therapeutic efficacy with respect to that known compound.

The guidelines reiterate comments in Novartis AG V Union of India (UOI) and Ors, stating that the Section 3(d) sets up a second tier of qualifying standards for chemical substances/ pharmaceutical products in order to leave the door open for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious grounds.

The guidelines further clarify that in the context of pharmaceutical patenting, the 'efficacy' should be understood as 'therapeutic efficacy'. While defining 'new product' in the context of Section 3(d), it is clarified that the test does not bar patent protection for all incremental inventions of chemical and pharmaceutical substances.

Sufficiency of description, clarity and support of the claims

The draft guidelines specify that while assessing the sufficiency of disclosure, non-disclosure of the source and geographical origin of the biological materials used in the invention should be treated as insufficiency of disclosure. It is further directed that if the declaration in a patent application for biological material from India is cancelled by the applicant, and the specification also states that the source and geographical origin of the biological material is not from India, the specification should be amended by including a separate heading/paragraph at the beginning of the description that the biological material used in the invention is not from India and should specify the country of source and origin.

It is also clarified that when claims seek to protect things that are not identified by the applicant at the time of filing the application, but that may be identified in the future by carrying out the applicant's process, such claims are not patentable on the ground of insufficiency of description.

The draft guidelines further direct examiners that while assessing the sufficiency of disclosure, it must be ensured that the best method for performing the invention is described so that the subject matter that is claimed, and not only a part of it, must be capable of being carried out by a skilled person in the relevant art without the burden of an undue amount of experimentation or application of inventive ingenuity.

If an application claims substance, composition or combination, a detailed report on the test conducted and experimental results with inference of such a test is required to be provided in the description. Test parameters, choice of testing method, mode of drug delivery, results obtained with explanation and inference, should also be provided in the specification.

The issuance of guidelines for examination of patent applications in the field of pharmaceuticals is certainly a positive step, taking into consideration that almost 25 percent of applications filed in India in 2012 to 2013 were in the field of drugs, chemicals and biotechnology. Similarly, 43 percent of the total patents granted were from these allied fields, clearly reflecting that pharmaceutical patenting is an extremely important aspect of India's patent system.

These guidelines will not only assist examiners but also applicants as to how the specification should be drafted and how to overcome the objections raised by the patent office.

This shall be more pronounced in the case of foreign applicants, as not only are the majority of patent applications filed by foreign entities in India, they do not have limitations and requirements as imposed by Section 3(d) of the Patent Act.

All the interlocking variables covered in the guidelines will encourage both national and international entities to effectively prosecute their patent applications in India. **IPPro**

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