How pharmaceutical patents are treated in India

Sharad Vadehra and Kshitij Saxena of Kan and Krishme discuss how India's patent office interprets pharmaceutical patents, recent court decisions and how applicants can improve their chances in prosecution

In what ways is Indian law on pharmaceutical patents different from other countries?

The test for patentability of an invention is as much the same as in other countries. The Indian Patents Act provides that to be patentable an invention apart from satisfying the criteria of novelty, inventiveness and industrial applicability should not fall under the categories as mentioned in Section 3 and Section 4. Section 3 of the Indian Patents Act provides the inventions which are not patentable in India and therefore can be considered as an additional bar for grant of a patent. Section 4 further provides that inventions relating to Atomic Energy are not patentable. In other words, the invention must be patent eligible i.e. must not fall within the scope of Section 3 or Section 4 before being considered for patentability. Here it is to be noted that the exceptions to patentability under Section 3 and 4 may be categorized into an absolute exception and limited exception. While Section 4 provides for an absolute bar to patentability on inventions relating to Atomic Energy, Section 3 provides that subject to fulfilment of certain condition(s) as mentioned therein, the invention is patentable.

What specific provisions apply to the patentability of pharmaceuticals in India?

Section 2(1)(j) of the Indian Patents Act defines *"invention"* as a new product or process involving an inventive step and capable of industrial application. The inventive step is defined in Section 2(1)(ja) and Section 2(1)(l) defines the term "new invention". Further, Section 3(d) of the Act aims to prevent "evergreening" of patents by providing that only those pharmaceutical derivatives that demonstrates significantly enhanced efficacy are patentable. Section 3(e) allows invention where the applicant is able to prove by way of data that the components of a combination are working together and are not working independently of each other and show some synergistic effect. Further, Section 3(i) of the Act excludes from patentability methods of treatment of the humans or animals by therapy or surgery, or methods of diagnosis performed on the human or animal body. This exclusion applies only to methods of treatment and diagnosis and not to the device/apparatus/instrument used in such methods.

How are these interpreted by the patent office and examiners?

There are various concepts embedded in the above mentioned Section of the Indian Patents Act which the Patent Office interprets based upon the Court decisions, guidelines and manuals of the patent practice. It is to be noted here that for assessing novelty and inventive step in India, there are limited case laws emanating from the Indian Courts. However, novelty and inventive step are being interpreted in the same manner as interpreted worldwide. During practice, if the cited documents are same then the arguments as presented in other countries are usually accepted by the Controllers/Examiners as far as novelty and inventive step are concerned.

Section 3(d) is the most controversial section when it comes to patents on Pharmaceutical inventions. Section 3(d) stipulates that an incremental invention, based upon an already known substance, having established medicinal activity shall be deemed to be treated as a same substance, if the invention in question fails to demonstrate significantly improved efficacy with respect to that known substance.

As regards the interpretation of Section 3(e) is concerned, the Patent Office usually identifies whether there are any functional interactions between the components of a composition/formulation and whether a combined technical effect higher than the sum of the technical effects of the individual features of the each component is achieved. It is to be noted that the synergistic effect should not be interchangeably used as far as efficacy is concerned and the applicant needs to be careful also about submission of the synergistic data.

As far as the interpretation of Section 3(i) is concerned, the Patent Office outrightly rejects any claim directed towards a method of treatment irrespective of any in-vivo or in-vitro treatment. This exclusion applies only to methods of treatment and diagnosis and not to the device/apparatus/instrument used in such methods.

What are the latest relevant decisions from the courts on these issues?

The Novartis judgement on the issue of efficacy is the most prominent decision in the context of pharmaceuticals. The decision has been widely discussed and the impacts thereof are seen in the routine proceedings of the Patent Office. The *Novartis judgment* has interpreted efficacy as "therapeutic efficacy" for pharmaceutical inventions. However, it fails to define the same in terms of other chemical inventions. In the *Novartis Judgment,* the Supreme Court of India (SC) has not considered an increase of 30% in Bio-availability as efficacious. The SC observed in paragraph [189] *"whether or not an increase in bioavailability leads to an enhancement of therapeutic efficacy in any given case must be specifically claimed and established by research data"*. This led to a further debate as to how the efficacy should be defined. Should it relate to only bio-availability or there are other criteria too to define efficacy? For example heat stability or humidity resistance of a drug could be well within the qualifying criteria to overcome the objections relating to Section 3(d). Further, reduction in side effects, toxicity, New Drug Delivery System, quantity of dosage forms, frequency, and manufacturing efficiency could be other parameters to define efficacy.

Another important judgement is Roche v Cipla where Indian company CIPLA in its counterclaim contended that the granted patent to Roche did not have any inventive step and also lacked novelty because same

Sharad Vadehra

Sharad Vadehra is the Managing Partner at Kan and Krishme. He joined the profession in the year 1989, and is among the few attorneys in the country with both technical and legal qualifications.

Sharad specializes in Intellectual Property Laws, Media, Entertainment, Sweepstake and Promotions, Marketing, Commercial disputes and Litigation and has more than 26 years' experience in these fields and in handling such matters for both domestic and international companies (including Fortune 500 companies) and research institutions. Sharad has prosecuted, defended, opposed/or enforced directly or in supervisory capacity over 20,000 patent matters in India and abroad. He has been a speaker in over five hundred institutions and corporate bodies in India and overseas, and is the author of the book *Indian Patent Law and Practice* published by Chosakai in Japan in Japanese language.

Sharad has often been consulted by the Government of India when any new guidelines or rules are being framed with respect to the Indian Patent Act and Rules.

Sharad, along with other colleagues founded the FICPI India group in the year 2009 and has been very closely associated therewith. He is presently the president of the FICPI India. He has recently been appointed the coordinator for CET 9 in FICPI for all Asian Countries including but not limited to India, Japan, S. Korea and China. He has recently been elected as Vice President of APAA India and he will be playing an active role in organizing the APAA Congress to be held in New Delhi in the year 2018. He is one of the founding members of GALA and is the Past President of its Asia Pacific branch. He holds the membership of FICPI; APAA; AIPLA; AIPPI; INTA; LES; CII and Delhi High Court Bar Association.

Kshitij Saxena

Kshitij Saxena is a Registered Patent Agent and an Advocate. He is working as a Managing Associate and Heads the Chemical Department of the firm.

Kshitij has over 12 years of experience in the practice and is actively involved in work which includes advising clients on various IPR issues, conducting FTO searches, prior art searches, IP due diligence and handling of the work covering the entire gambit of the life cycle of the Patent, Design and Trade Mark Applications. He also handles and advises on contentious and non-contentious issues on IPR. As a Head of the Chemical Department, he is responsible for supervision and guidance on legal and technical aspects of all patent matters handled by the firm in Chemical field.

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features of the invention had already been disclosed in prior art. CIPLA failed to prove its allegations in absence of any substantive evidence. CIPLA also challenged the validity of the granted patent under Section 3(d). The Court, however, has stated that CIPLA had to prove that the granted patent of Roche was a new form of a known substance which CIPLA had failed to do so.

Are there any pending cases that are likely to affect the law?

The Supreme Court recently accepted the petition of CIPLA against the order of the Delhi High Court wherein CIPLA is being held for infringing the patent of Roche. CIPLA filed this petition seeking the appointment of scientific expert and simultaneously challenging the order passed by the Delhi High Court. CIPLA contended in the Supreme Court that Delhi High Court has erred in holding that its product Erlocip was infringing the Roche's patent as the product was subject matter of a rejected patent application in India and had been in public domain. The Supreme Court in its proceeding may decide over the issues such as novelty, inventive step and on the issue of Section 3(d).

What can applicants in this area to do maximize their chances during patent prosecution?

An applicant should be aware of the fact that Indian Controllers take the written opinion in an international application quite seriously and in case the written opinion of *ISR and IPRP are* not favourable, the threshold to satisfy the controller/examiner's increases. The applicant must be aware that the Indian Patent Office can see and review all the information on the corresponding foreign applications in other jurisdictions such as USPTO, EPO and JPO. Further, it is also to be noted by the applicant that in case any document is not available in English language, the Patent Office has the required resources for translation of the same and the publication of that document in other languages may not avoid the citation of the same against an invention in India. Keeping in mind that the novelty and inventive step concepts are same all over the world, an applicant is required to prepare the argument in a more concrete manner.

Further, in case of pharmaceutical inventions where the applicability of Sections 3(d) and 3(e) is likely to arise, the applicant is required to be prepared with the necessary and relevant data in hand such that should there be an objection; the said data may be provided to the controller to overcome the objection.

Specifically for the objection relating to Section 3(d) an applicant should ascertain as to whether the claimed invention actually falls within the purview of a new form of a known substance or not. If not, the applicability of Section 3(d) does not arise and an argument needs to be presented as to why the claimed invention is not falling within the ambit of new form of a known substance. For instance, New Chemical Entities do not fall under this category. The applicant in such a case must respond stating that applicability of Section 3(d) does not arise. On the other hand, in case the answer is in the affirmative, an applicant should provide enhanced therapeutic efficacy data (comparative details) of the prior substance and with the claimed substance. If the invention relates to a process, it has to be seen whether the process employs at least one new reactant or results in a new product.

As far as claims related to method of treatment are concerned, the applicant should draft the claims in a manner so that the essence of the claims appears to be that of a product claim rather than a method or treatment or method of diagnosis. It is to be noted here that that these claims would be difficult to amend after the filing of the national phase entry since any amendment in the claims should not go beyond the scope of the earlier filed claims. Accordingly, care must be taken in drafting the claims during the international phase where the applicant intends to file the application in India within the specified period. It is to be noted here that pursuant to the amendment in the Patents Rules, 2016, an applicant can now delete the claims at the time of national phase entry and hence the applicant should delete the non-patentable claims at the time of national phase entry to save the cost and future objection. The applicant should be aware that only deletion is allowed and not the amendment at the time of national phase entry in India.

Further, the applicant must submit the details of the corresponding foreign applications including the details of the prosecutions history, oppositions and the documents cited against the corresponding foreign applications. The detailed particulars of corresponding foreign filing under Section 8(1) includes name of the country, date of filing of the application (date of national phase entry in case of PCT applications), application number, status of application, publication date/publication number of application and grant date/grant number of application in prescribed Form-3. As per the recent case laws on this issue, it is to be noted by the applicant that this is a continuous obligation onto the applicant and as a practical solution to the cumbersome requirement of filing Form-3, it is generally suggested that the applicant may file a final updated Form-3 at the time of filing response to the first examination report to show bona fide of the applicant that there is no deliberate/intentional omission by the applicant, instead of filing a fresh Form-3 every time there is change of status of any of the corresponding foreign application.

The Act also requires that an applicant to submit details relating to processing of the corresponding foreign applications under Section 8(2). It is suggested to voluntarily file documents/information if on a later date before the grant of Indian Patent, there is a claim rejection or narrowing down of claims (vis-a-vis claims pending in Indian Patent Office) in major countries such as US, Europe, Japan, Korea etc. The documents which need to be filed to comply with the requirement of Section 8(2) includes Search Report or Examination report; response to office actions submitted by the applicant along with the claims amended/allowed/rejected together with English translation thereof, if applicable. If translation of entire documents is not available, English summary of office action(s), search report(s), etc. shall suffice.

The applicant must note here that the non submissions of the details as regards the corresponding foreign applications as mentioned above is a ground available to a party in a pre-grant or post-grant opposition as well as in any revocation proceeding over a granted patent.