

# Understanding the inventive step for pharma and bio-pharma inventions in India

Rajeev Kumar and Pankaj Musyuni of LexOrbis discuss the importance of the inventive step and the ways of establishing it.

The Indian pharmaceutical and bio-pharmaceutical industry has an important position in providing medical and alternative therapies worldwide. Both sectors have the potential to provide the most advanced and cost-effective supplies globally and to work in parallel to provide an optimum solution. Additionally, ongoing research in the pharma/bio-pharma sector for combating diseases is vital for public health and, subsequently, patent protection is equally important for the researchers.

In India, patent protection is available subject to the establishment of the pre-requisite patentability criteria of novelty, inventive step, and capability of industrial application for any invention, whether product or process. Among these criteria, establishing an inventive step is a benchmark which implies that the invention must not simply be an obvious and alternate development of what is already available. Consequently, the said criteria are much harder to comply with, and exist to establish the right balance, promoting and rewarding real inventions and avoiding undesirable patent monopolies for unworthy inventions. To ensure this, India adopted a peculiar definition for assessing inventive step under Section 2(1)(ja) of the Patents Act, whereby inventions are judged based on the establishment of the technological advancement, economic significance, or both.

Claims in pharma/bio-pharma inventions are usually directed to cover new chemical entities, compositions/formulations, technology-based inventions such as specific combinations, dosage forms, new forms of known substances such as salts, ethers and esters; polymorphs; solvates, including hydrates; clathrates; stereoisomers; enantiomers; metabolites and pro-drugs;



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conjugates; pure forms; particle size; complexes, isomers, and mixtures thereof. Also, claims may be drafted for kits, selection inventions, process or method, and product-by-process inventions. Since these inventions have different styles of claims to cover the nature of the invention, the obviousness issue is usually checked by evaluating the combined prior arts and checking what a skilled person would extract from the available knowledge and its interpretation. In general, the invention must be considered as a whole to check whether it is beyond the ability of a person skilled in the art to perform.

Whilst examining these inventions, the Indian examiners usually check various factors, not limited to the hindsight approach, the reasonable expectation of success, and "obvious to try" factor apart from the technical advancement, which is generally considered in the form of identification of a problem and its solution, or unexpected results obtained by the proposed invention. The application of the hindsight approach by the examiner is common in such inventions where the invention relates to a new polymorph or a novel formulation with varying excipients, and different modes of delivery or release mechanisms such as delayed-release, sustained-release etc. are in question. It is assumed by the examiners that these inventions are obvious and can be prepared retrospectively. Contrary to the said assumption, the fact remains that developing a new product or formulation is not based on mere theory; trial and error and intensive experimentation are also required in getting a useful invention. Further, a reasonable expectation of success is usually examined in the context of the prior art not having any teaching or motivation to attempt the present invention in the absence of undue experiments. A classic

example of such an invention would be the case whereby an enantiomer is obtained by purification of a racemic mixture. Similarly, the consideration for "obvious to try" approach is largely misunderstood for pharma/bio-pharma inventions despite the fact that the technology and expected outcome in product and formulation development is unpredictable. Additionally, the formulation inventions are interpreted as inherently obvious concerning choosing the variable excipients and assuming that the result for efficacy would be predictable, which again is not possible without conducting experiments.

Whilst looking for the judicial interpretation regarding the inventiveness of patent applications in India, there are only a handful of cases, and only one by the Hon'ble Supreme Court in the case of *M/s. Bishwanath Prasad Radhey Shyam v. M/s. Hindustan Metal Industries*. The Court stated that minor modification in the patented invention would make it obvious to any skilled worker based on the knowledge available at the date of the patent. About "inventive step" the Supreme Court laid down the following principles that need to be kept in mind. For the determination, several forms of the question have been suggested "...whether the alleged discovery lies so much out of the track of what was known before as not naturally to suggest itself to a person thinking on the subject, it must not be the obvious or natural suggestion of what was previously known"; in other words, the obvious to try test has been tested to check that the patent in question lacked inventive step. A similar approach has been used by the Delhi High Court in the case of *F. Hoffmann-La Roche Ltd. v. Cipla Ltd.*, wherein the Court relied on the *Bishwanath* case (supra) case and observed that "*the same (person ordinarily skilled in the art) cannot be read to mean that there has to exist other qualities in the said person like un-imaginary nature of the person or any other kind of person having distinct qualities...*"

Though usually adopted by the examiners, it is pertinent to understand that while applying the hindsight approach it is essential to understand that one must avoid the approach as laid down in the *Bishwanath* case (supra) "*Had the document been placed in the hands of a competent draftsman (or engineer as distinguished from a mere artisan), endowed with the common general knowledge at the 'priority date', who was faced with the problem solved by the patentee but without knowledge of the patent invention, would have arrived at the invention*". A similar interpretation was held in *F. Hoffmann-La Roche Ltd. & Anr. v. Cipla Ltd.* RFA(OS) 92/2012, wherein the High Court held that, while conducting an inquiry into obviousness, hindsight is impermissible; the legal conclusion must be reached on the basis of facts gleaned from the



## Résumés

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prior art and should not include knowledge gleaned from patent disclosure. Teachings in the prior art document have to be considered as a whole. Teachings away from the patent claim are treated as non-obvious. To inquire into obviousness, two-fold inquiry is required i.e. motivation to select and motivation to modify.

In addition, the test for obviousness has been precisely dealt with in case of *Hoechst v. Unichem Laboratories and Ors*, wherein the Bombay High Court held that "... an invention usually involves three stages, (1) the definition of the problem to be solved, or the difficulty to be overcome, (2) the choice of the general principle to be applied in solving the problem overcoming the difficulty; and (3) the choice of the particular means to be used... merit in any one of these stages, or in the whole combined, may support the invention, and it is, therefore, probably more important to consider the advance in knowledge due to the inventor rather than to examine in detail the variations from the former product". In another important matter of *F. Hoffmann-La Roche Ltd & ANR versus Cipla RFA (OS) Nos.92/2012 & 103/2012*, the Court identified some steps to determine obviousness/lack of inventive steps to be conducted, which include:

- (1) to identify an ordinary person skilled in the art;
- (2) to identify the inventive concept embodied in the patent;
- (3) to impute to a normal skilled but unimaginative ordinary person skilled in the art what was common general knowledge in the art at the priority date;
- (4) to identify the differences, if any, between the matter cited and the alleged invention, and ascertain whether the differences are ordinary application of law or involve various different steps requiring multiple, theoretical and practical applications; and
- (5) to decide whether those differences, viewed in the knowledge of alleged invention, constituted steps which would have been obvious to the ordinary person skilled in the art, and thus rule out a hindsight approach.

Among other examples in a judicial context, whilst analyzing the inventive step, another famous case for the test of obviousness was decided by the Intellectual Property Appellate Board in *Enercon vs Aloys Wobben ORA/08/2009/PT/CH*, Oder No. 123 of 2013. In particular, paragraph 43 of the decision explains that that the "coherent thread leading from the prior art to the obviousness" or, in other words, "the reasonable expectation of success embedded in the prior art which motivates the skilled person to reach to the invention, is the most crucial determining factor in ascertaining inventive step".

In India, the evaluation of the technical advancement of patent applications is somewhat clear, focusing on exhibiting technical advancement of the claimed invention and consideration of economic advantages or advancements alone or together. Although factors such as reducing the manufacturing costs, operational costs and maintenance costs involved in any product development or employed process are also essential, they are influential in the case of a proposed invention that is technically weak when comparing with prior arts. Additionally, the outcome of the invention as an unexpected result is helpful even when it might appear that it would have been obvious to choose the combination of excipients at the time of invention. Further, an invention is not obvious if it produces results that would not have been expected before the researcher started testing the invention. Such results will often be the basis for the

non-obviousness of a pharma/bio-pharma invention. In general, the identification of a problem and providing a solution can be the invention wherein the inventive step resides in the identification of a previously unappreciated and unrecognized problem. While the solution to the problem might be obvious once the problem has been identified, the invention might nonetheless be nonobvious if, upon examination, it is identified that the invention would have been obvious to a person skilled in the art before the inventor identified the problem.

Though the patents are subject to the territorial regime, it is also essential to have them consistent with public health strategies and the economy. Patents are considered a fundamental incentive to innovative activities in the pharma and bio-pharma sectors; hence they need to be safeguarded. Of late, India has been witnessing an increase in patent enforcement activities and patent filings. As evident from the annual report of 2017-18 published by the Office of the Controller General of Patents, Designs, Trademarks and Geographical Indications, India, there was an increase of 5.3% in the overall filing of patent applications. That said, the report further indicated that the total number of patents granted during the year was 13,045. Out of the total granted patents, 3,318 patents were granted to applications relating to chemicals, 773 to pharmaceuticals, and 505 to the biotech domain. Further, along with various initiatives, the Indian Patent Office continually works to reduce the backlog and expediate the examination procedure.

Upon a random analysis of the decision issued by the Patent Office, it appears that analysis of the inventive step for pharma/bio-pharma inventions is primarily subjective. One major reason for different opinions would be the differing subject matter expertise of the examiners. Sometimes, the data disclosed and presented in the specification is the primary reason for biased interpretation.

While understanding that inventive step is the most common issue raised in prosecution and litigation, assessing inventive step, examining the prior arts, identifying the differential features, and defining the skilled person are the primary concerns for examiners and patent practitioners which are still open for wide and varied interpretation. Going forward, more clarity, and refined tests on the assessment of the inventive step are expected, as the number of cases filed and decided in this regard increases.

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