Chemical Patents: Peculiarities of Indian Patent Laws

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India has been rising the charts of World Bank's ease of doing business ranking from 100 in 2017 to 63 in 2019, it has become one of the top ten most preferred country foreign investment. Patent filing in India has also increased from 47854 patent applications in 2017-18 to about 50667 patent applications filed in 2018-19. Patent applications filed in the field of chemical sciences constitutes the highest numbers, in 2017-18 about 6343 chemical patent applications were filed. India is considered as 'world's pharmacy', being the biggest manufacturer and supplier of generic medicines, India is an important jurisdiction for chemical and pharmaceutical patents. This being the case, the present articles provides a glimpse into the peculiarities of the Indian patent laws in respect of the chemical and pharmaceutical patents.

Types of Claims allowed:

Section 2 (1)(j) of the Act, defines an "invention" as a new product or process involving an inventive step and capable of industrial application. Thus from the plain reading of section 2(1)(j), it is clear that only products and/or processes, which are novel, inventive and industrially applicable are considered to be inventions.

Claims directed to the use of product/process are not considered as invention according to the definition of invention provided in the act, therefore, use claims are not allowed. Also, the claims directed to the application of the claimed product/process are not considered as inventions and thus not allowed.

Also, Swiss claims or second medical use claims are not allowed in India in view of the provisions of Section 3(d).

The types of claims allowed under the product and process categories are, but not limited to, following:

I. Product claims: i. Pharmaceutical product:

1. New Chemical Entities;
2. Formulations/Compositions;
3. Combinations;
4. New forms of known substance such as salts, ethers and esters; polymorphs; solvates, including

hydrates; clathrates; stereoisomers; enantiomers; metabolites and pro-drugs; conjugates; pure forms; particle size; isomers and mixtures thereof; complexes; derivatives of known substances; and

ii. Kits;

iii. Product-by-process

II. Process/method of manufacturing claims;

Markush Claims:

As per the practice of the Indian Patent office and the "Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals", while examining the Markush claims, the complete specification is critically examined to see whether:

1. it discloses best representatives, as known to the applicant, of the possible embodiments;
2. such embodiments share a common use or property;
3. such possible embodiments share common structure;
4. physical and/ or chemical properties of best representatives of such embodiments known to the applicant are disclosed;
5. test conducted for the representatives of such embodiments known to the applicant is provided;
6. in case of product claims at least one process for preparing the compounds has been disclosed enabling the whole scope of the invention.

If any one of the above condition (i) to (vi) is not met, Markush claims are objected to as lacking 'unity of invention' and/or insufficiently disclosed.

According to the patent office practice, the compounds are said to have a common structure where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have only a small portion of their structures in common, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art. The structural element may be a single component or a combination of individual components linked together.

Inventions not patentable:

Section 3 of the Indian Patents Act lays down a threshold for patent eligibility. Section 2(1)(j) provides a theoretical definition of an invention while Section 3 illustratively outlines what are not inventions. The section relevant to chemical and pharmaceutical inventions are discussed herein below.

1. **Section 3(c):** said section reads as follows:

"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"

Thus said section clearly excludes 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 from the scope of patentability. Compounds which are isolated from nature are not patentable subject-matter.

2. **Section 3(d):** said section reads as follows:

"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."

Section 3(d) is the most notorious section in the Patents Act for the chemical and pharmaceutical inventions and was brought in to avoid ever-greening of patents. Said section stipulates that the incremental inventions should involve enhanced efficacy over the already known substance.

In accordance with Section 3(d) of the Act, new form of a known substance or a derivative of an already known substance, having known efficacy 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 compound.

In other words, the law in relation to section 3(d) is that if there is a known substance that known substance should have known efficacy. It is not enough for Section 3(d) to be attracted to show that there is some known compound in the prior art which allegedly bears some structural resemblance to the claimed compound. The prior art should also provide the known efficacy of the said known compound. The rule of law in this regard is clear. The obligation is not on the applicant for a patent to show how the claimed compound has better efficacy over a compound for which there is no established or proven efficacy and carry out tests to do this.

The Hon'ble Supreme Court in Novartis Vs Union of India and Ors, MANU/SC/0281/2013, Paragraph 103, held, *"We have, therefore, no doubt that the amendment/addition made in section 3(d) is meant*

especially to deal with chemical substances, and more particularly pharmaceutical products. The amended portion of section 3(d) clearly 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".

While interpreting the term "*efficacy*", the Hon'ble Supreme Court in the Novartis case held that in the context of the pharmaceutical patenting the "efficacy" should be understood as *"therapeutic efficacy".* In Paragraph 180 of Novartis order, Supreme Court held as follows:

"What is "efficacy"? Efficacy means "the ability to produce a desired or intended result". Hence, the test of efficacy in the context of Section 3(d) would be different, depending upon the result the product under consideration is desired or intended to produce. ***In other words, the test of efficacy would depend upon the function, utility or the purpose of the product under consideration.*** *Therefore,* ***in the case of a medicine that claims to cure a disease, the test of efficacy can only be "therapeutic efficacy".*** *.....It may be noted that the text added to Section 3(d) by the 2005 amendment lays down the condition of "enhancement of the known efficacy". Further, the explanation requires the derivative of "differ significantly in properties with regard to efficacy". What is evident, therefore, is that not all advantageous or beneficial properties are relevant, but only such properties that directly relate to efficacy, which in case of medicine, as seen above, is its therapeutic efficacy."*

The forms provided in the explanation of section 3(d) are considered as same substance unless they differ significantly in property with regard to "therapeutic efficacy. Hence, the mere change of form with properties inherent to that form would not qualify as "enhancement of efficacy" of a known substance. In other words, the explanation is meant to indicate what is not to be considered as therapeutic efficacy.

Further, in Roche vs Cipla (RFA (OS) Nos.92/2012 & 103/2012), Delhi High Court had held in Para 29 as follows:

"... Now, Section 3(d) assumes that structurally similar derivatives of a known substance will also be functionally similar and hence ought not to be patentable. What is of crucial importance is that this is not a provision that merely bars certain subject matter from patentability. On the contrary, it provides that if the new form of the known substance is found despite a structural similarity to demonstrate a better functionality i.e. enhancement of the known efficacy', it would qualify for assessment under Section 2(1)(j) as if it were a new product involving an inventive step and it would thereafter be up to the applicant for the patent to demonstrate the patentability of this substance in accordance with Sections 2(1)(j) and (ja). This provision is not a patent term extension or an evergreening provision but in fact recognizes incremental innovations in pharmaceutical patents."

According to the interpretation of the Delhi High Court, first the decision has to be made whether or not the subject matter of the invention falls under the exclusions of section 3(d), if the answer is no, it would qualify for assessment under Section 2(1)(j) as if it were a new product involving an inventive step and it would thereafter be up to the applicant for the patent to demonstrate the patentability of this substance in accordance with Sections 2(1)(j) and (ja). Thus, graphically represented, the same would be:-

Enhanced Efficacy *New Product*

Substance ----------->Inventive Step ----------->Pharmaceutical substance

In view of above, it is very important for the applicants to demonstrate enhanced efficacy in the specification by way of experimental data. In case such data is not available, post filing data is also acceptable.

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;"

Section 3(e) of the Act, is critical in case of the composition or formulation inventions. According to said section, mere placing side by side of old integers so that each performs its own proper function independently of any of the others is not a patentable combination, provided where the old integers when placed together, some working interrelation produces a new or improved result, then there is patentable subject matter.

Compositions obtained by mere admixing and resulting in aggregation of the properties of the individual components are not patentable under section 3(e) of Act. However, in a composition if the functional interaction between the features achieves a combined technical effect which is greater than the sum of the technical effects of the individual features, it indicates that such a composition is more than a mere aggregation of the features. Further, polymer compositions are not considered as admixtures as they involve chemical interactions among the components of the composition.

4. **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"

Section 3(i) of the Act, is critical in case of inventions or subject matter relating to the method of treatment which includes 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. In the field of pharmaceuticals, it is noticed that method of treatments are often claimed in the guise of composition/dosage claims.

Many a time's, method of treatment claims or dosage claims are converted into to composition claims during prosecution. However, the allowability of such amendments is doubtful as such claims are examined as per Section 57 read with section 59 of the Act, which lay strict guidelines on the nature of amendment.

Unity of invention:

Section 10(5) of the Act, requires that claims or groups of claims should relate to a single invention, or to a group of inventions linked so as to form a single inventive concept. If claims relate to a plurality of distinct inventions, it may be objected on ground of lack of unity of invention. To fulfil the requirement of unity of invention each claim of a complete specification should share a single common technical relationship which is inventive called the "special technical feature".

Chemical and pharmaceuticals inventions may claim huge number of chemical compounds by Markush structures, chemical compounds as intermediate and final products, compositions comprising different chemical components, processes for their manufacture, their uses or applications, even devices or apparatus used for carrying out specific processes in a single application. In such cases, applicants have to show sufficiently that the different sets of claims are related by "special technical feature".

Conclusion:

While filing patent applications relating to chemical inventions, it is necessary to take into consideration the afore-discussed provisions, particularly the excluded subject matter. In case the specification has claims relating to the excluded matter, said claims may be deleted to reduce the official fee as they will have to be deleted during the prosecution of the application. Also, try to provide sufficient data I the specification to demonstrate the enhanced technical effect of the invention. Filing of post filing data is permissible, preferably in the form of an expert declaration.

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