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Biochemical substances and the realm of S. 3(d) (Novozymes vs The Assistant Controller of Patents and Designs): Scope of applicability of Section 3(d) redefined by Madras High Court?

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I) Introduction

The science of biochemicals and the realm of Section 3(d) of Indian Patents Act!
Can there be a reconciliation between the two?

This question is a hot topic of discussion amongst the Indian biochemical patent community following the recent decision (Novozymes vs The Assistant Controller of Patents and Designs) pronounced by the Madras High Court on 20 September 2023. In a first-of-its-kind decision that may redefine the applicability of S.3(d) to the biochemical realm, the Court adopted a constrictive interpretation of the scope of substances that fall under the purview of S. 3(d) of the Indian Patents Act.

Invoking the doctrine of "*ejusdem generis*", the Court's interpretation of the applicability and scope of the statutory explanation provided under S. 3(d) in the context of biochemical substances has advanced a new twist to the tale – an unexpected and significant development to the inherent intricacies surrounding the interpretative framework of S. 3(d). Ultimately, the Court has ruled that S. 3(d) does apply to biochemical substances but that the Explanation to S. 3(d) does not apply to the claimed invention and that Novozymes appeal should be allowed in part. In so doing, the court relied on the Division Bench[1] and Supreme Court decision in Novartis AG[2], to arrive at its conclusion on the applicability of the substantive provision and the doctrine of "*ejusdem generis*" for the inapplicability of the Explanation to S. 3(d) to the claimed invention.

Until this case, the key determinants of S. 3(d) – "known substance" and "efficacy" have only been analysed through the lens of chemical/pharmaceutical inventions and its patent practitioners by the Indian courts. The present decision examines these key determinants in the context of biochemical substances. The scrutiny of S. 3(e) in the present case also sheds light on the standards required to be met for its applicability to composition claims.

II) Novozymes HC decision: A brief overview

1) Background of the Patent and invention at issue

In its decision dated September 20, 2023, the Court, setting aside the Indian Patent Office (IPO)'s

order partly, pronounced that the substantive provision in S. 3(d) applies to biochemical substances in principle but Explanation to S. 3(d) becomes inapplicable to the claimed invention in Indian patent application 5326/CHENP/2008 – pertaining to the variants of phytase, i.e. an enzyme or a biochemical. The appellant (Novozymes) had challenged the IPO's order (of 15.11.2016) in which the claims were rejected primarily on the grounds that the claimed invention in Claims 1 and 2 pertaining to the phytase variant with improved thermostability is a known substance not patent eligible under S. 3(d) and claims 8 to 11 (the composition claims comprising the phytase variant) falls within the scope of S. 3(e) because the composition is a mere admixture of ingredients.

2) Legal tenets governing the subject matter

S. 3(d) of the Indian Patents Act is a unique "Made in India" provision that is exclusive to the Indian jurisdiction and which acts an additional barrier to patentability of incremental inventions in the field of chemicals, pharmaceuticals, agrochemicals, biochemicals, biotechnology inventions etc. S. 3(d) mandates heightened standards of patentability for these technologies with an objective to prevent evergreening. This provision mandates that minor modifications carried out to existing substances/products (for instance, the parent compound) are not patentable unless they exhibit enhanced efficacy compared to the existing substance.

Under Indian patent law, the following are not inventions within the meaning of this Act – with S. 3(d) of the Indian patent Act reading as:

> 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 a known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

The Honourable Supreme Court of India, which adjudicated the landmark judgement on S. 3(d) in Novartis AG vs Union of India (Novartis SC judgement) in April 2013 concerning the chronic myeloid leukemia drug, Glivec® (active ingredient imatinib as a mesylate salt) clarified that S. 3(d) does not bar patent protection for all incremental inventions related to chemical and pharmaceutical substances, even though it rejected Novartis's patent application on the beta-crystalline form of imatinib mesylate (subject product, a polymorphic form). The Court carried out a known substance determination to hold that the subject product was a new form of a known substance, imatinib mesylate (the precursor substance, a salt) having known efficacy even though Novartis had contended that only imatinib free base was known from its earlier patent (US 5,521,184, referred to as Zimmermann patent) and not its mesylate salt form. The SC also restrictively defined the other key determinant, "efficacy" as "therapeutic efficacy" for pharmaceutical inventions.

In rejecting the patent application, SC held that that the improved physico-chemical properties of the beta crystalline form of imatinib mesylate, namely (i) more beneficial flow properties, (ii) better thermodynamic stability, and (iii) lower hygroscopicity, may be otherwise beneficial but

these properties cannot even be taken into account for the purpose of the test of section 3(d) of the Act, since these properties have nothing to do with therapeutic efficacy. On increased bioavailability, SC had ruled that Novartis had not provided evidence that 30% increase in bioavailability could result in enhanced (therapeutic) efficacy. Although SC clarified that physico-chemical characteristics which are not indicative of therapeutic efficacy of a new form of a known substance may not qualify as advantages to meet the efficacy criteria, the decision did not specify as to "what kind" of parameters or therapeutic advantages of a new form of a known substance shall suffice to meet the efficacy criteria, leaving room for further interpretation in future cases.

S. 3(e) of the Indian patent act excludes from patentability, 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. Accordingly, claims related to compositions obtained by mere admixture resulting in aggregation of the properties of the individual components are not patentable under S. 3(e) of the Act. Therefore, experimental evidence to substantiate that the combinative effect of the composition is greater than the sum of the technical effects of the individual components is mandated to rebut objections under S. 3(e).

3) Examination of key determinants of S.3(d) by the Madras High Court: "Known substance" and "Efficacy"

(A) Determination of "known substance" based on Statutory Explanation under S. 3(d)

a) Whether a "Known substance" in S. 3(d) is confined to pharmaceutical substances – The appellant contended that the key determinant "known substance" in the first limb of S. 3(d) is confined to chemical substances and more particularly, pharmaceutical substances. In addressing this question, the court referred to paragraphs 12 and 13 of Novartis Division Bench judgement and clarified that S. 3(d) is not limited in its application to pharmacology but its explanation is limited thereto and also referred to paragraphs 82, 87 and 157 of the Supreme Court publications of the Novartis judgement and pronounced that it does not follow from the determination of SC judgement that S. 3(d) applies only to pharmaceutical and agrochemical substances and not to biochemical substances.

b) Applicability of the Explanation portion of S. 3(d) to claimed invention (variants of phytase) and the doctrine of "*ejusdem generis*"- The appellant contended that that all the enumerated derivatives in the Explanation to S. 3(d) are derivatives of synthesized chemicals and not of biochemicals or chemicals found in a living organism. The court agreed with the appellant's contentions that the enumerated derivatives in the Explanation to S. 3(d) fall within the genus "derivatives of chemical substances" and invoking the doctrine of "*ejusdem generis*", the Court applied this principle to the expression "and other derivatives of known substance" to construe that the Explanation portion of S. 3(d) becomes inapplicable to the claimed invention, i.e. variants of phytase.

c) Sequitur of inapplicability of Explanation of S. 3(d) to the claimed invention – The court explained that the sequitur of the claimed invention not falling within the scope of the Explanation is that the claimed invention (variants of phytase) qualifies as a new form of a known substance even if it does not cross the filter prescribed in such Explanation; the filter being – "shall be considered to be the same substance unless it differs significantly in properties with regard to efficacy." The court further opined that that this does not mean that S. 3(d) becomes inapplicable to the claimed invention and it is the Explanation to S. 3(d) that does not becomes applicable in its entirety as underscored by its inapplicability to the third limb of S. 3(d) dealing with known

processes, known machines and not known substances.

(B) "What kind" of Experimental Data is required for meeting "Enhanced Efficacy" in the context of biochemical substances?

The court referred to Novartis SC judgement and held that increased thermostability data provided by the appellant in Example 8, Table 5 of the complete specification is indicative of enhanced efficacy as contended by the appellant. The IPO (respondent) contended that enhanced efficacy can only be correlative of enzymatic activity of the variants of phytase. According to the court, increased thermostability of the variants of phytase precludes denaturation and enables production, storage and sale in pellet form. It enhances the known efficacy of the enzyme in aiding digestion especially when used in animal feed. The court also held that there is nothing in the text or context of S. 3(d) which supports the interpretation that enhancement of known efficacy of the substance should be restricted to engineering or prospecting variants of phytase with inherently greater enzymatic activity over the reference phytase.

As to "how much" improvement in efficacy is required, the court further concluded that, as the practice guidelines also do not fix a numerical value to the margin of enhancement, the patent applicant has to establish that there is a reasonable enhancement of efficacy to the satisfaction of the Controller of Patents. The court held that as the measuring units, Improvement Factor (IF) were assigned numerical values which can be construed as a claim of efficacy and as no objections were raised to its materiality by the IPO, the claimed invention of the appellant satisfies the criteria of enhanced efficacy under S. 3(d).

4) Scrutiny of Section 3(e) requirement by the High Court

The court, referring to the Stempeutics decision[3] and contrasting with the view provided by this decision on the applicability of S. 3(e) to composition claims, held that there is nothing in S. 3(e) that limits its application to a composition claim that is obtained by aggregation of known ingredients as contended by the appellant and that the adjective "known" is used only in sections 3(d), 3(f) and 3(p) and is conspicuous by its absence in S. 3(e). Further, the court said that S. 3(e) does not appear to be limited in terms of independent claims and appears to exclude from patent eligibility any composition for a substance that merely exhibits the aggregate properties of its constituents. Therefore, the rejection of composition claims 8 to 11 by IPO is justified in the absence of evidence that the composition is more than the sum of its parts.

III) The Madras HC order: Practice pointers?

1) Scope of Explanation to S. 3(d)

In the instant case, the practice pointer is that the enumerated derivatives in the Explanation portion are all synthesised chemicals and not biochemicals. The decision therefore signposts that for future cases/reference, there may be a need to expand the scope of the Explanation portion to S. 3(d) by including in this provision possible illustrative derivatives for biochemical substances also. Alternately, the practice guidelines to S. 3(d) may be updated with possible illustrative examples for derivatives of biochemical substances also and more illustrations in respect of "other derivatives of known substances."

2) Variants of a Biochemical substance and "other derivatives of known substance" under S. 3(d)

Given that the instant decision has made a difference in assessment between chemical/pharmaceutical vis-à-vis biochemical substances, would the future cases carve out exceptions for arriving at known substance determination under S. 3(d) for variants of biochemical substances? The instant decision despite holding that the variant of phytase, i.e. a variant of a biochemical substance, does not fit into the Explanation portion of S. 3(d) (i.e. other derivatives of a known substance) has arrived at the determination that the claimed invention, i.e. the variants of phytase is a new form of a known substance. This adds a new dimension to the interpretative framework of S. 3(d) in the context of biochemical substances.

3) Experimental data on "Enhanced Efficacy" for biochemical substances

The instant decision, despite relying on Novartis SC judgment, had contrasted with its view on experimental data requirement and pronounced that physicochemical properties like thermal stability are indeed indicative of efficacy requirement in the context of a variant of a biochemical substance (in the instant case, a variant of phytase useful as animal feed). From a practice perspective, the question that emanates is what are the other physicochemical properties of biochemical substances the improvement of which might correlate to or can inherently result in enhanced efficacy? Should that be decided on a case-by-case basis or the practice guidelines need to be built for providing more clarity in this regard?

4) Definition of the term New Biochemical Substance

The instant decision has classified the different categories of biochemical substances. In this backdrop, from a practice perspective, there may be an imperative need to define NBS or a New Biochemical Substance and also formulate separate practice guidelines for patentability determination of biochemical substances (including the interpretative framework of S. 3(d) and S. 3(e) in the context of biochemical substances).

IV) Conclusion

While the instant decision has been welcomed by the patent community, the picture is not yet clear in India as to when S 3(d) will bite on inventions to biochemical substances. Future development of case law from the Courts and decisions by the IPO will inevitably refine the practice framework and interpretative framework of S. 3(d) in the context of biochemical substances. We await further developments with interest.

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