INTELLECTUAL PROPERTY SPOTLIGHT

INTRODUCTION

We are pleased to present the latest edition of our IP Law page, sharing important updates, key developments, and practical insights on Intellectual Property, all tailored to help you stay updated in the field of Indian Patent Law. Curated by our IPR Law Practice Group, the page is to keep you updated about the latest developments in this dynamic field.

DELHI HIGH COURT REINS IN OVER BROAD USE OF SECTION 3(I): A BOOST FOR PHARMACEUTICAL COMPOSITION PATENTS.

Medilabo RFP Inc. v. Controller of Patents

Delhi High Court • Judgment dated 24 November 2025

The Delhi High Court has once again stepped in to correct an increasingly common trend in patent examination- the mechanical expansion of Section 3(i) to reject well drafted pharmaceutical composition claims. In Medilabo RFP Inc. v. Controller of Patents, the Court set aside the Patent Office's refusal of a drug-composition application and sent it back for a fresh examination and disposal.

This decision reinforces an important message for innovators: a composition is a composition. It does not magically morph into a "method of treatment" simply because the specification explains what the drug is meant to do.

The Case at a Glance-

Medilabo had filed an application covering a drug composition of Rifampicin and Resveratrol for use in neurodegenerative conditions. During prosecution, the applicant amended the claims significantly by removing the trans-nasal administration language and dosage-regimen references. Despite this, the Controller refused the application under Section 3(i), reasoning that the claims were "implicitly" directed to a method of treatment because the specification discussed therapeutic use.

The Court found two major flaws:
1) The Controller assessed the application using the wrong set of claims i.e., the earlier version, not the amended, post-hearing claims.
2) Section 3(i) had been applied without a proper claim-based analysis, contrary to settled jurisprudence.

What the Court Held

1) Claims define the invention, not the examples, not the preamble, not the assumed end-use.
2) The Court reaffirmed that under Section 10(4)(c), the scope of the invention must be determined from the claims themselves. Medilabo's amended Claim 1 was a straightforward drug composition claim with no route of administration, no dosage regimen, and no treatment steps.
3) The Controller's reliance on the preamble ("for neurodegenerative disease") was held to be misplaced. A preamble does not become a claim limitation unless it adds essential structure, a principle repeatedly affirmed in several cases.
4) Specification illustrations cannot override clearly drafted claims.
5) Working examples, including those describing how a composition may be administered, do not convert a product claim into a method claim. They demonstrate feasibility not claim boundaries.
6) The refusal order lacked a reasoned analysis as the Controller had not explained how the amended claims fell under Section 3(i).

Fresh reconsideration ordered

The refusal was set aside, and the matter was remanded to the Patent Office for a fresh hearing and a fresh decision, within six months, without the Court expressing any views on the merits of patentability.

This Judgment is a strong reaffirmation of claim-centric examination. The ruling is another firm reminder that Section 3(i) cannot be used as a catch-all rejection for pharmaceutical inventions. Controllers must rely on claim language, not assumptions about therapeutic context.

This judgment fortifies the emerging jurisprudence that composition claims are patentable, even if they are meant for therapeutic use and only the processes which involve 'treatment steps' will fall within the ambit of Section 3(i).

Predictability for Industry

Pharmaceutical and biotech applicants gain greater certainty that composition claims will not be derailed merely due to the presence of therapeutic intent in the specification.

For applicants drafting or prosecuting composition claims particularly in the pharma and nutraceutical space, Medilabo is a welcome recalibration. It restores clarity to Section 3(i), discourages “implicit” readings into claims, and strengthens India’s move towards a more disciplined and internationally aligned patent examination framework.

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