EXECUTIVE BENCH BRIEFING FOR FOREIGN PATENT COUNSEL

# Decoupling Section 3(e) Formulation Eligibility from Inventive Step

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**EXECUTIVE SUMMARY & KEY TAKEAWAY**
Section 3(e) evaluates quantitative non-additive synergy in multi-component compositions in vacuo. It must never be conflated with prior art obviousness under Section 2(1)(ja). Emipirical synergy data clears Section 3(e) threshold eligibility.

## 1. Decoupling Level 2 Eligibility from Level 3 Obviousness

A systemic examination error in life sciences and chemical patent prosecution before the Indian Patent Office is the improper blending of Section 3(e) formulation eligibility with prior art obviousness under Section 2(1)(ja).

Section 3(e) is a Level 2 threshold statutory filter evaluated in vacuo, requiring quantitative non-additive synergy. In FER objections, Controllers frequently issue combined objections stating that a multi-component formulation is 'a mere admixture because the individual components are known in prior art.' This logic is statutorily defective.

## 2. Evidentiary Standards for Section 3(e) Non-Additive Synergy

Section 3(e) excludes 'a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof.' To clear Section 3(e), an applicant must demonstrate that the combined formulation exhibits non-additive, synergistic efficacy:

Observed Combination Effect (E_AB) > Expected Additive Sum (E_A + E_B)

Experimental evidence demonstrating non-additive therapeutic efficacy, unexpected stability, enhanced bioavailability, or synergistic reaction yield satisfies Section 3(e) as a matter of threshold law.

## 3. High Court IPD Precedents on Formulation Eligibility

Recent Delhi High Court IPD jurisprudence holds that once non-additive synergy is demonstrated by empirical data submitted in the specification or in response to an FER, Section 3(e) eligibility is established, and examination must proceed strictly under Section 2(1)(ja).

## 4. The 4-Step Response Matrix for Chemical & Pharma Claims

1. Separate Eligibility from Prior Art: Clarify that Section 3(e) evaluates interaction between components within the claimed composition, not over prior art.
2. Submit Comparative Experimental Data: Present quantitative tables showing individual component activity vs. combined formulation performance.
3. Decouple Active Ingredient Interdependency: Structure dependent claims to highlight functional co-action between active components.
4. Cite High Court IPD Precedents: Reference binding IPD rulings prohibiting improper administrative blending of Section 3(e) with Section 2(1)(ja).

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