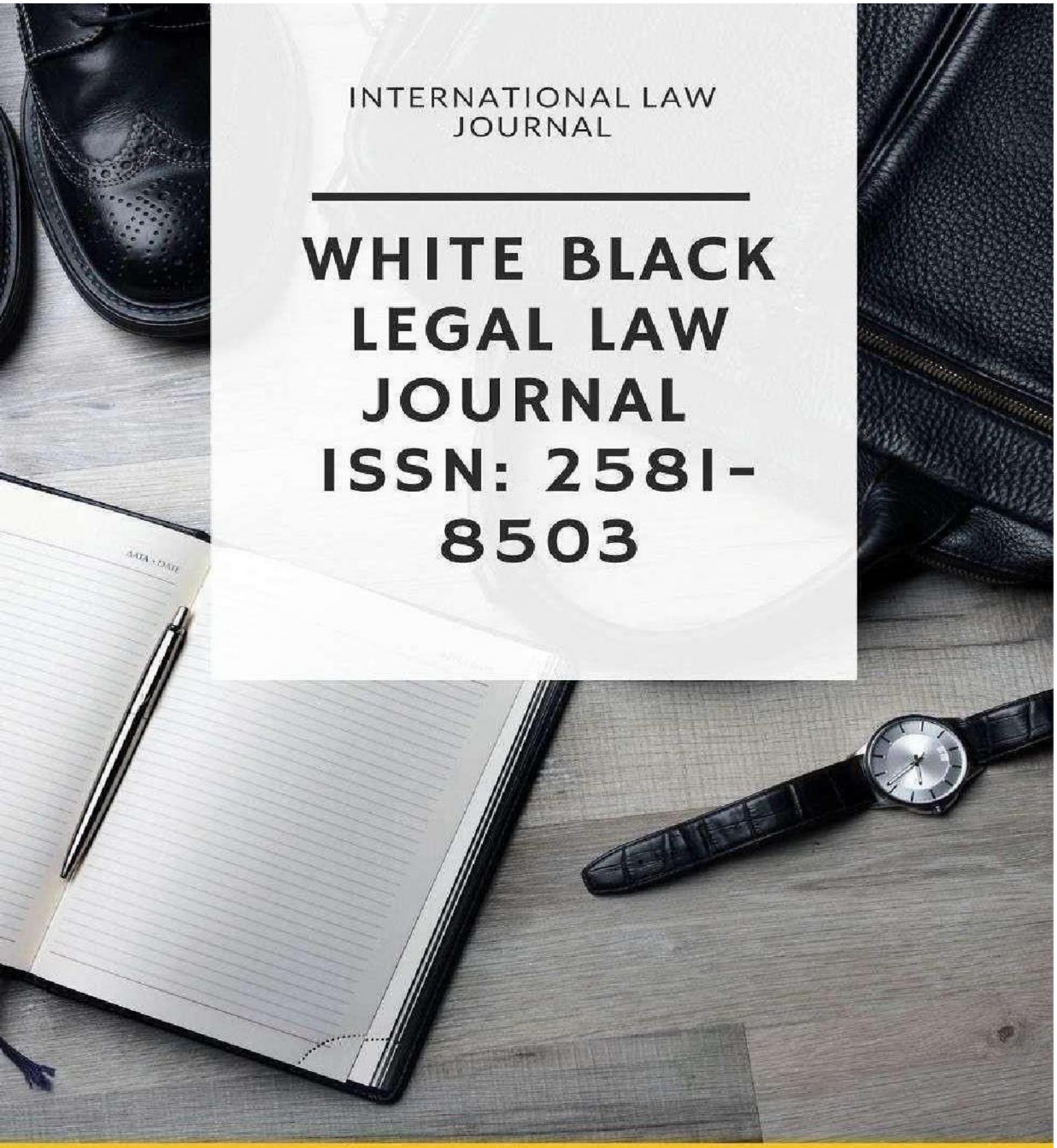

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INTELLECTUAL PROPERTY RIGHTS AND REGULATORY GAPS IN THE INDIAN COSMECEUTICAL INDUSTRY

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ABSTRACT

Cosmeceuticals occupy an increasingly important space between cosmetics and pharmaceuticals. Their formulations may contain bioactive ingredients and their marketing may make claims concerning skin structure, appearance or function, yet Indian law does not expressly recognise "cosmeceutical" as a separate regulatory category. This paper examines the resulting interaction between product classification, intellectual property protection and consumer protection. It analyses the Drugs and Cosmetics Act, 1940, the Patents Act, 1970 and the Consumer Protection Act, 2019, with particular attention to the cosmetic–drug boundary, patentability of formulations, misleading claims and the practical limitations of trade-secret protection. It also compares the Indian position with the claims-based approach of the United States and the more structured safety and substantiation model of the European Union. The analysis finds a regulatory mismatch: products with therapeutic-adjacent claims may enter the market through a cosmetics pathway while innovators may encounter demanding patentability standards, particularly where formulations combine known ingredients. The paper argues for a proportionate hybrid framework that distinguishes ordinary cosmetics, cosmeceuticals and drugs; requires evidence proportionate to the claim and risk; strengthens controls over misleading representations; and aligns intellectual-property incentives with regulatory expectations. The proposed reforms are intended to improve legal certainty, consumer information, innovation incentives and regulatory consistency without treating all cosmeceuticals as pharmaceutical products.[1]

Keywords: Cosmeceuticals; Intellectual Property; Patent Law; Trademark Law; Consumer Protection; Regulatory Classification; Section 3(d); Drugs and Cosmetics Act; Misleading Claims; Claim Substantiation.

[1] The Consumer Protection Act, 2019, s 2(47).

1. INTRODUCTION

1.1 Concept and Significance

The term "cosmeceutical" combines "cosmetic" and "pharmaceutical" and is generally used for products positioned between conventional personal-care products and therapeutic products. The category includes formulations containing bioactive ingredients such as peptides, retinoids,

hydroxy acids, botanical extracts and other actives that are marketed as providing benefits beyond cleansing or basic beautification. The supplied study notes the rapid growth of the global market and the increasing consumer demand for evidence-based skincare.[2] The legal significance of the category lies less in the label "cosmeceutical" than in the relationship between formulation, intended use and marketing claims. A product may look and be sold like a cosmetic while making representations about physiological effects. This creates a boundary problem because regulation, intellectual property and consumer protection may apply different thresholds to the same product. The result is uncertainty for manufacturers and consumers and a risk that regulatory treatment does not correspond to the strength of the claim being made.

1.2 The Cosmetic–Drug Boundary in India

The Drugs and Cosmetics Act, 1940 ("DCA") uses separate definitions for "cosmetic" and "drug". The definition of cosmetic is directed to preparations applied to the human body for cleansing, beautifying, promoting attractiveness or altering appearance, whereas the definition of drug covers products intended for the diagnosis, treatment, mitigation or prevention of disease and substances affecting bodily functions or conditions.[2] This binary structure does not expressly identify a middle category for products that make therapeutic-adjacent claims without claiming to diagnose or treat disease.[3]

The practical difficulty is illustrated by claims such as "reduces the appearance of wrinkles", "improves skin elasticity", "stimulates collagen" or "repairs sun-damaged skin". The legal character of such statements depends on how the claim is understood and applied. Claims limited to cleansing, moisturising or beautifying are more readily accommodated within the cosmetic category, while disease-treatment claims move towards drug regulation. Guidance and regulatory practice therefore become important in deciding where a particular claim falls.

[2] Grand View Research, Global Cosmeceuticals Market Report 2023–2030 (2023).
[3] The Drugs and Cosmetics Act, 1940

1.3 Intellectual Property and Consumer-Protection Implications

Regulatory ambiguity has direct intellectual-property consequences. A formulation made from known ingredients may encounter the exclusions relating to mere admixture and new properties or uses of known substances under the Patents Act, 1970.[4] At the same time, a brand may seek trademark protection for a distinctive product name while using the packaging and advertising surrounding that mark to communicate health or efficacy benefits. Trademark registration and advertising legality are therefore related but distinct questions. Consumer-protection law supplies an additional layer of control over false or misleading representations.[4]

The central proposition of this paper is that the problem is systemic rather than confined to one statute. A product may face relatively modest cosmetic requirements at market-entry stage, demanding patentability requirements when protection is sought, and a fragmented enforcement environment when claims are challenged. The resulting misalignment can reduce incentives for evidence-based innovation while increasing the possibility of consumer confusion.

2. RESEARCH PROBLEM, OBJECTIVES AND METHODOLOGY

2.1 Statement of the Problem

Indian law does not expressly define or classify cosmeceuticals as a distinct category. The existing binary cosmetic–drug structure is therefore required to accommodate products with hybrid characteristics. This produces four connected problems: first, uncertainty over classification and permissible claims; second, difficulty in securing appropriate patent protection for formulations that combine known actives; third, potential consumer deception through health-oriented branding and advertising; and fourth, a gap between the level of evidence suggested by a claim and the regulatory evidence expected of the product.

The problem is not simply that regulation is "strict" or "lenient". Rather, the thresholds operate unevenly. A manufacturer may be able to market a product with a cosmetic classification while an inventor seeking a patent may face a demanding showing concerning novelty, inventive step, or the effect of a claimed combination. This can encourage reliance on secrecy and branding rather than disclosure and formal protection, while leaving consumers without a consistent means of evaluating claims.

[4] The Patents Act, 1970, ss 2(1)(j), 2(ja), 3(d) and 3(e).

2.2 Objectives and Research Questions

The study has five principal objectives:

(i) to examine the Indian classification of cosmetics and drugs and its application to cosmeceuticals;

(ii) to analyse patentability barriers under the Patents Act, particularly sections 3(d), 3(e) and 2(ja);

(iii) to evaluate trademark and consumer-protection responses to misleading health and efficacy claims;

(iv) to compare the Indian position with the United States and European Union; and

(v) to propose reforms capable of aligning innovation incentives with safety and consumer protection.

The principal research questions are whether Indian law requires a distinct regulatory category for cosmeceuticals; whether existing patentability standards appropriately accommodate formulation innovation; whether current controls adequately address health and efficacy claims; and what features of foreign regulatory systems can be adapted to Indian conditions. The working hypothesis is that the absence of a dedicated category, combined with restrictive or uncertain intellectual-property pathways, produces a regulatory gap that weakens both innovation incentives and consumer protection.

2.3 Methodology and Scope

The research follows a doctrinal and comparative legal method. It examines the relevant Indian statutes and rules, regulatory guidance, judicial authority identified in the supplied material, patent-office guidance and selected international frameworks. The comparative component focuses on the United States and European Union because they demonstrate two different methods of dealing with the cosmetic–drug boundary: claims-based classification and enhanced regulation within the cosmetics framework. The study is limited to legal and regulatory analysis and does not attempt an economic or epidemiological assessment of the market.

3. INDIAN REGULATORY FRAMEWORK FOR COSMECEUTICALS

3.1 Statutory Definitions and Classification

The DCA is the starting point for determining whether a product is regulated as a cosmetic or drug. Its definitions were designed around a distinction between products concerned with

cleansing or appearance and products concerned with disease, treatment or bodily function. For cosmeceuticals, however, the intended use may be communicated through claims that fall between these poles. The absence of an express statutory definition means that the legal status of the product must be inferred from the existing categories rather than determined under a dedicated framework.[5]

Regulatory guidance consequently assumes importance. The supplied material describes a claims-oriented approach in which structure-function or aesthetic statements are more compatible with cosmetic treatment, whereas disease-related or therapeutic claims can bring the product within drug regulation. The distinction is difficult where the wording is subtle. "Reduces the appearance of fine lines" communicates an aesthetic outcome, while "reduces wrinkles" may suggest a direct physiological effect. Such linguistic distinctions can have regulatory consequences without necessarily corresponding to a meaningful difference in the consumer's perception of the product.

3.2 Safety, Efficacy and Enforcement Gaps

The paper identifies a further gap between the evidentiary expectations applicable to drugs and those applicable to cosmetics. Cosmetics do not generally enter the market through the same clinical-development pathway as pharmaceutical products. Consequently, a product marketed with strong efficacy language may be supported by a different level of evidence from that expected of a drug making a comparable physiological claim. The issue is not that every cosmetic claim requires a pharmaceutical clinical trial; rather, the evidence should be proportionate to the nature and risk of the claim.[6] The enforcement structure also contributes to uncertainty. The DCA operates through central and state regulatory institutions, and differences in interpretation or enforcement can create practical compliance variation. A manufacturer seeking nationwide consistency may therefore modify claims, labels or supporting material to manage different regulatory expectations. Such fragmentation increases compliance costs and can produce inconsistent outcomes for products that are substantively similar.

[5] The Drugs and Cosmetics Act, 1940
[6] The Drugs and Cosmetics Rules, 1945, as amended.

4. PATENTABILITY OF COSMECEUTICAL INNOVATIONS

4.1 General Patentability Standards

Cosmeceutical inventions are assessed under the general patent framework unless a statutory exclusion applies. The Patents Act, 1970 requires an invention to satisfy the statutory requirements of invention, novelty and inventive step and to be capable of industrial application. Section 2(ja) defines inventive step in terms of technical advancement or economic significance, or both, together with non-obviousness to a person skilled in the art. Thus, the fact that a formulation is commercially successful or cosmetically attractive does not by itself establish patentability.

4.2 Section 3(e): Mere Admixture

Section 3(e) excludes a substance obtained by mere admixture where the resulting substance does not exhibit properties fundamentally different from those of the constituents. This provision is particularly relevant to cosmeceuticals because many formulations combine known ingredients such as vitamins, botanical extracts, peptides, antioxidants or retinoids in different concentrations. A claim that merely places familiar ingredients together, without demonstrating a meaningful technical result, may therefore encounter an exclusion even where the final product is commercially new.[7]

For formulation applicants, the important question is consequently not whether every ingredient is individually known, but whether the combination produces a legally relevant result that distinguishes it from a simple aggregation of known properties. Evidence of unexpected stability, compatibility, delivery characteristics or another demonstrable technical effect may strengthen the case for patentability. The supplied paper refers to Indian Patent Office guidance as relevant to the examination of cosmetic and pharmaceutical formulations.[8]

4.3 Section 3(d) and the Significantly Enhanced Effect

Section 3(d) addresses, among other things, the discovery of a new property or new use of a known substance unless the statutory requirement concerning a significantly enhanced effect is satisfied. The provision has particular importance where an applicant relies on a known active ingredient but claims a new formulation, combination or result. The Supreme Court's decision in Novartis AG v Union of India provides the leading authority on the operation of

[7] The Patents Act, 1970, s 3(e).
[8] Indian Patent Office, Patent Prosecution Guidelines: Cosmetic and Pharmaceutical Formulations (2020).

section 3(d) and emphasises the need for evidence directed to the statutory standard rather than a merely formal change to a known substance.[9]

The difficulty for cosmeceuticals is one of proportionality. Pharmaceutical patent cases may involve therapeutic efficacy as the relevant outcome, whereas cosmetic innovation may concern measurable changes in skin appearance, texture, elasticity, stability or delivery. Treating every cosmeceutical innovation as if it must demonstrate pharmaceutical therapeutic efficacy risks making the patent threshold disconnected from the technical contribution actually claimed. At the same time, lowering the standard so far that any new combination of known ingredients becomes patentable would weaken the inventive-step and anti-evergreening functions of patent law.

4.4 Illustrative Formulation Analysis

Consider an anti-ageing serum containing encapsulated retinol, a peptide complex, green-tea extract, vitamin C and hyaluronic acid, supported by stability studies, in-vitro evidence and consumer testing. The existence of separate prior art for each component would not automatically answer the patent question. The analysis should consider the claimed formulation as a whole, the prior art, the technical problem addressed, the skilled person's expectations and whether the claimed combination produces an unexpected or otherwise patent-relevant result.

If the evidence demonstrates only that each known ingredient performs its established function, an objection based on obviousness or mere admixture may be persuasive. If, however, the particular combination or delivery system produces an unexpected technical effect such as a demonstrable improvement in stability or controlled delivery the applicant may have a stronger basis for patent protection. The key reform need is therefore not a cosmetic-specific monopoly, but clearer and proportionate examination criteria for cosmetic formulation technologies.

5. TRADEMARKS, ADVERTISING AND CONSUMER PROTECTION

5.1 Trademark Protection and Health-Suggestive Branding

Trademark protection serves a different function from patent protection. It protects source-identifying signs rather than the underlying formulation. The Trade Marks Act, 1999 contains absolute grounds of refusal, including circumstances involving lack of distinctiveness, descriptiveness and certain misleading indications. A mark suggesting efficacy may therefore raise issues of distinctiveness and deception, but registration of a mark does not amount to

[9] Novartis AG v Union of India & Others, (2013) 6 SCC 1.

scientific certification of the claims communicated by the product as a whole.[10]

The distinction is important for cosmeceuticals because brand names, taglines, packaging and promotional material frequently work together. Terms such as "clinically proven", "dermatologist approved", "pharmaceutical grade" or "collagen boosting" may communicate a level of efficacy, testing or regulatory oversight that the product does not actually possess. The legal analysis should therefore separate the registrability of the mark from the truthfulness and substantiation of the associated representation.

5.2 Misleading Claims and the Consumer Protection Act

The Consumer Protection Act, 2019 treats false or misleading representations as an unfair trade practice. This provides an important consumer-facing remedy, but enforcement can be difficult where technical evidence is required to establish whether a claim is scientifically justified. A consumer may understand "clinically proven" to mean that a robust clinical study exists, while the manufacturer may rely on a small consumer-perception survey or laboratory testing. The resulting information asymmetry makes substantiation standards particularly important.[11]

The case law identified in the supplied paper, including Colgate-Palmolive Co v Hindustan Lever Ltd, illustrates the broader judicial concern with advertising representations and consumer perception. For cosmeceuticals, the principle supports a stronger requirement that claims be proportionate to the evidence behind them. An aesthetic claim supported by an appropriate consumer study should not be presented as though it were proof of a therapeutic effect.[12]

5.3 The Advertising Standards Gap

The principal weakness is fragmentation. Drug regulation, cosmetic regulation, trademark law and consumer protection may address different parts of the same representation, but they do not necessarily operate through a single claim-substantiation system. A manufacturer can therefore face uncertainty about what evidence must be generated before a claim is placed on packaging or in advertising. A dedicated cosmeceutical framework should close this gap by linking categories of claims to minimum evidentiary requirements.

[10] The Trade Marks Act, 1999, s 9.
[11] The Consumer Protection Act, 2019
[12] Colgate-Palmolive Co v Hindustan Lever Ltd, 2008 (12) SCC 305.

6. TRADE SECRETS AND INNOVATION STRATEGY

Where patent protection is uncertain, manufacturers may prefer confidentiality. Formulations, manufacturing parameters, stability data and process know-how can have commercial value if they are kept secret. The supplied research identifies secrecy as a practical alternative to patent disclosure, but also highlights a central weakness: a formulation contained in a marketable consumer product may be capable of analytical examination and reverse engineering.[13]

Trade-secret protection is therefore not a substitute for a patent in every circumstance. A patent can provide an enforceable exclusionary right for a defined term in return for disclosure. A trade secret may last longer, but only while secrecy is maintained and does not necessarily prevent independent discovery or legitimate reverse engineering. For cosmeceutical companies, the appropriate strategy may therefore be to patent aspects that are difficult to keep secret while protecting manufacturing know-how, supplier information and process parameters through confidentiality measures.

The Indian framework should strengthen contractual and procedural protection for confidential information rather than create an automatic monopoly over undisclosed formulations. The reform objective should be to reduce misappropriation while preserving legitimate competition and independent discovery.

7.1 United States

The United States provides a useful contrast because the Food and Drug Administration uses intended use and claims as central elements in distinguishing cosmetics from drugs. Products making disease-treatment or comparable therapeutic claims can fall within drug regulation even when they are presented in a cosmetic form. Products confined to cosmetic purposes remain within the cosmetics framework. This approach places substantial responsibility on the wording and context of the claim and can provide stronger protection against the use of cosmetic presentation to avoid drug regulation.

From an intellectual-property perspective, United States patent law does not create a separate "cosmeceutical patent" category. Formulations must satisfy the ordinary requirements of patentability, including novelty, non-obviousness and utility. The comparative lesson is therefore not that the United States grants special patents, but that regulatory classification and patentability operate as separate legal inquiries. The regulatory status of a product does not

[13] Indian Society of Cosmetic Chemists, Cosmeceutical Industry Survey: Patent, Trademark and Trade Secret Protection Practices (2019).

itself determine whether the underlying technical invention is patentable.

7.2 European Union

The European Union regulates cosmetic products principally under Regulation (EC) No 1223/2009. The framework combines ingredient controls, safety assessment, responsible-person obligations and rules concerning claims. The European Commission's guidance emphasises that cosmetic claims should be supported by adequate and verifiable evidence and should not create an impression inconsistent with the available proof. This provides a useful model for India because it shows that enhanced consumer protection need not require every cosmeceutical to be treated as a pharmaceutical drug.[14]

The EU model therefore supports a proportionate approach: cosmetics can remain cosmetics, but the safety and evidentiary obligations become more demanding as the risk and strength of the claim increase. The key lesson for India is regulatory alignment rather than transplantation of foreign law. Ingredient restrictions, safety assessment and claim substantiation can be adapted to Indian conditions while retaining the basic distinction between cosmetic and medicinal products.

7.3 Comparative Lessons for India

The comparison reveals three broad models. The United States places strong weight on claims and intended use; the European Union maintains a cosmetics framework with structured safety and claim requirements; India relies on an older binary statutory architecture without an express cosmeceutical category. India need not reproduce either foreign model in full. Instead, it can combine their most useful features: claims-based classification, proportionate substantiation, risk-based ingredient controls and clearer institutional responsibility.

8. CRITICAL LEGAL ISSUES

8.1 Regulatory Classification Ambiguity

The central problem is the appearance-versus-function distinction. Small differences in wording can change the perceived legal character of a product, while consumers may understand the claims in substantially the same way. This creates uncertainty for manufacturers and regulators and can produce inconsistent enforcement. The absence of a dedicated category also makes it difficult to prescribe intermediate safety and evidence requirements.

[14] European Commission, Cosmetics Regulation Guidance: Claim Substantiation and Safety Assessment (2019).

8.2 Regulatory–IP Misalignment

The most significant structural problem is the mismatch between market regulation and patent protection. If a product can be marketed as a cosmetic without generating evidence comparable to that required for a drug, an inventor may have little commercial incentive to incur the cost of pharmaceutical-level evidence merely to satisfy a patent objection. Yet a formulation patent may be challenged under sections 3(d), 3(e) or 2(ja) when the claimed contribution is a new combination of known actives. This can encourage secrecy, rapid imitation and brand-based competition rather than investment in disclosed technical innovation.

8.3 Consumer Information and Safety

Cosmeceuticals create an information asymmetry because consumers may not know whether a statement is supported by a laboratory test, a consumer study or a clinical investigation. The stronger the implied physiological benefit, the greater the need for transparent substantiation. A regulatory framework should also provide a mechanism for collecting complaints and adverse-event information so that emerging safety signals are not left entirely to general consumer remedies.

8.4 Misleading Terminology and Ingredient Representation

Terms that imply pharmaceutical quality or clinical validation can be particularly problematic. The same is true of ingredient-centred representations that mention sophisticated technologies or biological materials without explaining concentration, function or the limits of the evidence. The problem is not merely technical accuracy; a statement may be literally true yet materially misleading in context. Consumer law should therefore assess the overall impression created by the claim.

8.5 Regulatory Arbitrage

Differences between jurisdictions can also encourage regulatory arbitrage. A manufacturer operating across markets may encounter different ingredient restrictions, claim requirements and evidence thresholds. If Indian regulation is substantially less demanding than major export markets, products or claims may be tailored differently for India. Clear and internationally compatible standards would reduce this divergence while preserving regulatory space for domestic conditions.

9. PROPOSED REFORMS

9.1 Statutory Recognition and Three-Tier Classification

The DCA should recognise cosmeceuticals expressly and establish a three-tier structure: (A) ordinary cosmetics making basic cleansing, grooming or appearance claims; (B) cosmeceuticals making therapeutic-adjacent or biologically active claims without claiming to diagnose, cure or prevent disease; and (C) drugs making disease-related therapeutic claims. The category should be determined primarily by intended use and claims, supported where necessary by formulation and risk information.

A statutory definition should be deliberately narrow. A possible formulation is: "Cosmeceutical" means a topical preparation containing a biologically active ingredient and marketed for a specified aesthetic or skin-function benefit beyond basic cleansing or grooming, but not represented as diagnosing, curing, treating, mitigating or preventing disease. The purpose is classification, not the creation of a new unregulated class.

9.2 Proportionate Safety and Claim Substantiation

Cosmeceuticals should be subject to a proportionate evidence framework. Low-risk aesthetic claims may be supported by appropriately designed consumer or laboratory studies; stronger biological claims should require stronger evidence, including controlled clinical evidence where the nature of the claim warrants it. The manufacturer should retain substantiation material and make an evidence summary available to regulators and, where appropriate, consumers.

Labels should distinguish between appearance claims and physiological or therapeutic claims. Where a percentage improvement is stated, the basis of measurement should be identified. Terms such as "clinically proven", "pharmaceutical grade" or "dermatologist approved" should not be used unless the manufacturer can demonstrate what the statement means and possesses evidence commensurate with the representation.

9.3 Patent Examination Reform

Patent law should not create a special monopoly for cosmeceuticals, but examination guidance should explain how ordinary patent standards apply to formulation inventions. Under section 3(e), the focus should remain on whether the combination is a mere admixture or produces a materially different property. Under section 3(d), the inquiry should be tied to the claimed technical contribution rather than assuming that every cosmetic innovation must establish a

pharmaceutical therapeutic outcome. Evidence of unexpected stability, compatibility, controlled delivery or measurable cosmetic performance may be relevant where it genuinely demonstrates the claimed technical effect.

The Indian Patent Office could publish clearer examination examples dealing with combinations of known actives, encapsulation technologies, delivery systems and formulation stability. Such guidance would improve predictability without diluting the requirements of novelty and inventive step.

9.4 Trademark and Advertising Controls

Trademark examination and advertising enforcement should remain conceptually distinct, but they should communicate with each other where a mark or associated representation implies a regulated health benefit. Health-suggestive branding should not be treated as scientific proof. Advertising rules should require manufacturers to possess substantiation before making quantified efficacy, clinical or professional-endorsement claims.

9.5 Institutional Coordination and Adverse-Event Reporting

A dedicated expert mechanism within the existing regulatory structure could issue classification guidance, maintain claim-substantiation standards, coordinate with state authorities and review safety signals. Rather than creating a wholly separate regulator, India could use a specialised expert committee supported by CDSCO and coordinated with state drug authorities. A simplified reporting mechanism for adverse reactions and serious consumer complaints would improve post-market surveillance.

9.6 Ingredient and Concentration Transparency

For ingredients capable of producing significant biological effects, greater concentration transparency should be considered, subject to legitimate confidential-information concerns. Consumers should be able to compare meaningful information about active ingredients and understand the intended use and limitations of the product. Transparency should be balanced against the need to protect genuinely confidential manufacturing know-how.

9.7 International Harmonisation

India should draw on the EU and US approaches while avoiding direct transplantation. Internationally compatible ingredient restrictions, claim-substantiation principles and safety assessment terminology would reduce compliance costs for exporters and limit regulatory

arbitrage. The ASEAN experience also demonstrates the value of regional harmonisation while allowing domestic regulatory choices.[15]

9.8 Institutional Fragmentation and Regulatory Predictability

The classification problem is closely connected with institutional fragmentation. The central regulator and state authorities may perform different functions, while consumer-protection institutions address misleading representations from a different statutory perspective. For a hybrid product, this can produce overlapping but incomplete forms of supervision. A manufacturer may understand a product to be compliant because it satisfies the requirements associated with cosmetics, while a claim may nevertheless attract scrutiny under consumer-protection principles. Conversely, a consumer may challenge an advertisement without possessing the technical information needed to determine whether the underlying efficacy representation is justified.

Predictability is therefore a substantive regulatory value. Businesses require sufficiently clear rules to determine the evidence that must be generated before launch, and consumers require sufficiently clear information to distinguish a cosmetic benefit from a therapeutic claim. The answer is not necessarily a single regulator for every aspect of the product. A more realistic approach is coordinated administration: a central technical mechanism can establish classification and substantiation guidance, while state authorities continue ordinary enforcement and consumer institutions retain their statutory jurisdiction. Clear referral and information-sharing procedures would reduce duplication and inconsistent outcomes.

The proposed approach should also recognise the diversity of cosmeceutical products. A low-risk moisturising product containing a biologically active botanical should not automatically face the same evidentiary burden as a formulation claiming to modify inflammatory pathways or deliver a high-potency active. Regulation should therefore be risk-based. Classification should consider the nature of the active ingredient, concentration, route of application, intended user population and the seriousness of the claim. This would permit regulatory resources to be concentrated on products presenting greater potential risk while avoiding unnecessary burdens on ordinary personal-care innovation.

9.9 The Need for Regulatory–IP Alignment

Intellectual-property policy and product regulation should be designed as complementary

[15] ASEAN Secretariat, ASEAN Harmonized Cosmetics Regulatory Framework (2018).

rather than isolated systems. Patent law rewards disclosure of technical innovation by granting time-limited exclusivity, whereas product regulation protects consumers by controlling safety and representations. If regulatory requirements are minimal but patent standards are perceived as disproportionately demanding, the system may encourage firms to compete through branding, secrecy and marketing rather than through disclosed technical research. That outcome is undesirable where the underlying objective is to promote safe and evidence-based innovation.

Alignment does not mean that regulatory approval should guarantee a patent, or that patentability should determine whether a product can be sold. The two inquiries serve different purposes. Alignment means that the evidence demanded by each system should be intelligible and proportionate to the claimed contribution. For example, where a cosmeceutical applicant demonstrates a new delivery system producing an objectively measurable improvement in stability or controlled release, patent examination should consider that technical evidence under the ordinary statutory tests. The regulatory system can separately determine whether the associated consumer claim is sufficiently substantiated. This separation preserves the integrity of both regimes while avoiding contradictory incentives.

A clearer framework would also improve investment decisions. Companies deciding whether to patent a formulation must assess disclosure costs, prosecution risk and the likelihood of imitation. If examination practice is predictable and the evidentiary pathway is transparent, innovators can make that decision on commercial and technical grounds rather than regulatory uncertainty. The same predictability benefits smaller Indian enterprises, which may lack the resources of multinational companies to maintain multiple formulations, labels and evidence packages for different markets.

9.10 Implementation Roadmap

Reform can be implemented incrementally rather than through an entirely new regulatory statute. The first stage should be definitional. The DCA and subordinate rules should identify the characteristics of a cosmeceutical and establish the boundary between cosmetic, cosmeceutical and drug claims. The second stage should establish claim categories and minimum substantiation requirements. This could begin with guidance and model claim language, followed by binding rules after consultation with industry, regulators, dermatologists, toxicologists and consumer organisations.

The third stage should address intellectual property. The Indian Patent Office should publish examination examples dealing specifically with formulation combinations, encapsulation,

delivery technologies and evidence of unexpected technical effects. These examples should clarify how sections 2(ja), 3(d) and 3(e) interact without creating a separate lower patentability standard. The objective is greater consistency and transparency, not automatic grant of patents to products labelled as cosmeceuticals.

The fourth stage should strengthen post-market oversight. Manufacturers should maintain records of substantiation and complaints, and a proportionate reporting system should identify serious or recurring adverse events. Regulators should periodically review claims and ingredient restrictions as scientific knowledge develops. Finally, India should use international regulatory experience as a reference point for periodic review, particularly in relation to prohibited or restricted ingredients, safety assessment and claims.

Implementation should be accompanied by transitional arrangements. Existing products should receive a reasonable period in which to review classification, labels and substantiation. New products should comply from the commencement date. Regulatory guidance should be publicly accessible and written in sufficiently clear terms to reduce dependence on informal advice. An effective framework should also include an appeal or review mechanism for disputed classification decisions, thereby improving procedural fairness and reducing unnecessary litigation.

The overall objective is a proportionate regulatory architecture rather than maximal regulation. The Indian market requires room for formulation innovation, small and medium enterprises and consumer choice, but those interests should operate within a framework that prevents unsupported therapeutic impressions. The most sustainable model is consequently one in which regulatory obligations increase with the strength of the claim and the potential risk of the product, while intellectual-property rights remain governed by ordinary patent and trademark principles supported by clearer sector-specific guidance.

10. CONCLUSION

Cosmeceuticals expose a structural weakness in Indian regulatory design: a product category that is commercially and technologically significant is being accommodated within a binary legal framework that was not drafted specifically for hybrid products. The absence of an express category affects classification, safety requirements, advertising, intellectual-property strategy and enforcement. The resulting uncertainty is not adequately solved by treating all cosmeceuticals as drugs or all of them as ordinary cosmetics.

The patent dimension reinforces the problem. Sections 2(ja), 3(d) and 3(e) provide legitimate

safeguards against obvious, repetitive or weakly differentiated inventions, but their application to modern formulation technologies should remain connected to the actual technical contribution claimed. The objective should be neither automatic patentability nor pharmaceutical-level evidence for every cosmetic innovation. It should be a predictable application of ordinary patent principles to the particular technical problem and result demonstrated by the applicant.

Consumer protection requires a similar principle of proportionality. Claims should be matched to evidence. The stronger the implied therapeutic or physiological benefit, the stronger the substantiation should be. Trademark registration should not be confused with scientific validation, and advertising should be assessed according to the overall impression conveyed to consumers. Coordinated enforcement is essential because a single product may simultaneously implicate cosmetics regulation, intellectual property and consumer law.

The most appropriate reform is therefore an integrated framework recognising three levels cosmetics, cosmeceuticals and drugs while applying proportionate safety and evidence requirements. A dedicated statutory definition, clearer patent examination guidance, stronger claim-substantiation rules, coordinated enforcement and improved post-market reporting would provide greater certainty without imposing the full burden of pharmaceutical regulation on every advanced skincare product. Such a framework would better balance innovation, competition, consumer choice and public health in India's growing cosmeceutical sector.

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