THE PATENTS ACT, 1970

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THE PATENTS RULES, 2003

(AS AMENDED)

SECTIONS 15

IN THE MATTER OF A PATENT FOR

PATENT APPLICATION NO: **201911038394**

DATED: **23/09/2019**

Hearing u/s 14 held on: 30rd December 2025

BY "Galgotias University, India.……Applicant

Having Address for service:…….....ENNOBLE IP,B-17, FIRST FLOOR, SECTOR 6, NOIDA-201301 (UP),INDIA.

Appeared:

Mr. Harshit Khandelwal (IN/PA: 5340)…….. Authorized Patent Agent for the Applicant

CORAM: Asst. Controller of Patents and Designs

D E C I S I O N

1. An application for patent bearing number 201911038394 was filed in Patent office, Delhi on 23/09/2019 by Mr. Kunal Setiya [IN/PA-2570]. Mentioned application having title "TOPICAL ANTI-INFLAMMATORY OINTMENT FORMULATION AND A METHOD OF PREPARATION THEREOF." The request for examination was filed on 25/09/2023 under Rule 24B of the Patents Rules, 2003 (as amended). The said application was published on 15/11/2019 having journal number 46/2019. The said application was examined under sections 12 and 13 of the Patents Act, 1970 (as amended) and First Examination report was issued on 03/01/2025. In response to the First Examination Report, applicant submitted its reply on 01/09/2025 with amended claims 1-7.

2. The examiner on re-examination of response to FER and other documents filed, raised further objection on invention u/s 2(1)(ja), non-patentability u/s 3, and Sufficiency of Disclosure u/s 10 (4) in view of arguments & documents filed in the response to FER, amendments made in claims and merits of such documents & arguments filed. Therefore, a hearing u/s 14 was offered to the applicant based on the set of objection (mentioned below) raised in hearing notice and the hearing was scheduled on 30/12/2025 and communicated to the applicant through hearing notice letter dated 28/11/2025 containing statement of objections as follows:

Objections

Invention u/s 2(1)(ja)

1. As stated in FER, Document D1 discloses a topical anti-inflammatory pharmaceutical and/or dermocosmetic composition comprising tamarind seed polysaccharide as active ingredient mixed with one or more acceptable excipients along with a further active ingredient selected from the group consisting of antimicrobial agents, anti-inflammatory agents, analgesic agents and wound-healing agents. The composition further comprising an extract of Aesculus hippocastanum. A composition, further comprising an extract of Helichrysum italicum, Ferula spp., Zanthoxylum bungeanum or mixtures thereof. Document D2 discloses a pharmaceutical composition comprising: (a) a COX-2 inhibitor selected from celecoxib; valdecoxib; paracoxb; and (b) a poorly aqueous soluble non-ionizable polymer selected from the group consisting of ethylcellulose and poly(ethylene oxide-co-ε-caprolactone). D2 discloses a process for forming nanoparticles, comprising: (a) forming an organic solution comprising a COX-2 inhibitor having a solubility in water of less than 1 mg/mL over the pH range of 6.5 to 7.5 at 25°C, and a poorly aqueous soluble nonionizable polymer dissolved in a solvent; (b) forming an aqueous solution, wherein said COX-2 inhibitor and said nonionizable polymer are poorly soluble in said aqueous solution; (c) mixing said organic solution with said aqueous solution to form a first mixture; (d) removing said solvent from said first mixture to

form a suspension comprising said nanoparticles and aqueous solution. Further, D3 also discloses Formulation and Evaluation of Cox-2 Inhibitor (Etoricoxib) Loaded Ethyl Cellulose Nanoparticles for Topical Drug Delivery. In addition D4 teaches nanoprecipitation technique for the synthesis of etoricoxib nanoparticles. Drug and polymer were dissolved in acetone and sonicated for 10-15 min. The drugpolymer solution was added drop by drop into 0.6% PVA solution under continuous mechanical stirring at 700 rpm. Spontaneous precipitate formation can be observed. After 4 h of continuous stirring, the solvent from the resultant precipitate was removed by rotary evaporation. Free flowing amorphous nanoparticles were obtained. The solution proposed by the instant invention is a topical anti-inflammatory ointment formulation comprising a tamarind seed polysaccharide, COX-2 inhibitor, basil leaf extract, aloe vera gel, hydroxypropylmethyl cellulose (HPMC) and glycerin. However, Documents D1-D3 discloses similar formulations. Therefore, from the teachings of D1-D3 the present topical anti-inflammatory ointment formulation and preparation method thereof would have been obvious to a person skilled in the art. Moreover, applicant doesn't provide any technical advancement for the claimed formulation and its preparation method. In the absence of technical advancement/synergistic effect/unexpected effect through comparative study with the closest prior art, the claimed formulation seems to be appears as a mere modification. To prove an inventive step, the applicant should relate the distinguishing features of the present application

over the cited prior art documents to a surprising technical effect or make plausible that this distinguishing feature is not obvious in light of the prior art teaching of D1-D3. Thus, the subject matter of claims 1-7 still lacks an inventive step u/s 2(1)(ja) of The Patents Act.

Non-Patentability u/s 3

1. (i) The subject matter of claims 1-6 still attracts section 3(d) of the Patents Act, as the claimed formulation seems to be appears as new form of known substance, combination of known substances and lack of enhanced therapeutic effect since COX-2 inhibitor is a well-known active pharmaceutical ingredient (API) widely used for its antiinflammatory and analgesic properties and Tamarind seed polysaccharide is a known excipient commonly used for stabilization purposes in drug formulations. (ii) The method claim 7 is the mere use of a known process in view of D2, unless such known process results in a new product or employs at least one new reactant such substance are not patentable under section 3(d) of The Patents Act. (iii) The claims 1-6 also attracts section 3(e) of the Patents Act, as the claimed formulation seems to be mere admixture and no synergistic effect has been shown in specification through comparative study.

Sufficiency of Disclosure u/s 10 (4)

1. (i) The specification doesn't provide any supporting data (comparative data) with closest prior art to prove the synergistic effect for the claimed formulation. Hence, said claims 1-6 are

not allowed u/s 10(4) of The Patents Act. (ii) The method claim 7 should be sufficiently define the process steps along with all the essential technical features with respect to molar ratio of compounds, reaction condition etc., as per section 10(4) of The Patents Act.

3. The hearing was held on 30/12/2025 and applicant authorized Patent agent Mr. Harshit Khandelwal (IN/PA: 5340), attended the said hearing and presented his arguments on behalf of the applicant. The applicant agent filed post-hearing written submissions with other relevant documents on 14/01/2026.

4. During the hearing as well as in written submission learned applicant agent in response to invention u/s 2(1)(ja) and section 3 and other raised objections presented her argument over cited prior art D1-D3 in detail.

Analysis

Claims at the time of filing of application	Claims post FER	Claim post first hearing
1-10	1-7	1-3

For objection on Invention u/s 2(1)(ja):

The present application relates to topical pain relief formulations and methods thereof. In particular, the present invention relates to a topical antiinflammatory ointment formulation

comprising etoricoxib and an herbal extract for providing relief from pain and inflammation, and a method of preparation thereof. .

Document Cited are:

D1: US2013136813A1;

D2: WO2008135829A2.

D3: Nano Biomed. Eng., 2018, Vol. 10, Iss. 1; DOI: 10.5101/nbe.v10i1.p1-9

As per the hearing notice, an objection is the lack of invention u/s 2(1)(ja) of the Patents Act, 1970. The hearing notice reiterates that the claimed topical anti-inflammatory ointment formulation and its preparation method lack inventive step in view of prior art Documents D1–D3. Document D1 discloses topical pharmaceutical or dermocosmetic compositions containing tamarind seed polysaccharide along with anti-inflammatory agents and other excipients, indicating that the use of tamarind seed polysaccharide in anti-inflammatory topical formulations is already known. Document D2 discloses pharmaceutical compositions comprising COX-2 inhibitors and polymers, including processes for forming nanoparticles through solvent mixing and solvent removal techniques. Document D3 further discloses etoricoxib-loaded polymeric nanoparticles specifically intended for topical drug delivery. Additionally, Document D3 further, teaches nanoprecipitation methods for preparing etoricoxib nanoparticles using acetone and polymer solutions followed by solvent evaporation, which is

similar to the preparation method claimed in the present application. In view of these disclosures, the it was observed that the claimed formulation comprising tamarind seed polysaccharide, COX-2 inhibitor, basil leaf extract, aloe vera gel, HPMC, and glycerin, as well as its preparation method, would have been obvious to a person skilled in the art based on the teachings of D1–D3 and the known nanoparticle preparation techniques disclosed in D3. Further, the applicant has not demonstrated any technical advancement, synergistic effect, or unexpected technical effect over the cited prior art through comparative data. In the absence of such evidence, the claimed invention appears to be a mere modification of known formulations. Therefore, Claims 1–7 are considered to lack inventive step u/s 2(1)(ja) of the Patents Act, and the applicant is required to establish inventive step by demonstrating a surprising technical effect or non-obvious technical advancement over the cited prior arts.

In response, the learned agent of the applicant submits that the Controller has already acknowledged the novelty of the claimed invention. The applicant amended the claims to specify the exact names and percentages of all ingredients and reagents, with support from the as-filed specification, and also amended the method claim to include precise quantities of all components.

The learned agent of the applicant provided experimental data demonstrating the anti-inflammatory activity of the claimed ointment formulation using the albumin denaturation assay,

with diclofenac sodium as the standard. The results show that formulation F9 exhibited the highest anti-inflammatory activity of 91.46±2.25%, which is significantly higher than etoricoxib alone (73.43±2.06%), diclofenac sodium (68.35±2.64%), and individual ingredients. The formulation also demonstrated good spreadability ranging from 58–68%, with the best formulation showing 67.07±0.098%, indicating suitability for topical application.

The learned agent of the applicant argues that the claimed invention is inventive over Documents D1–D3 because the prior art does not disclose the specific combination and precise low concentrations of ingredients, particularly the use of only 0.1% etoricoxib along with tamarind seed polysaccharide, basil leaf extract, aloe vera gel, HPMC, and glycerin. The prior art also does not disclose the use of basil leaf extract and glycerin in such formulations, nor does it provide comparable efficacy data, spreadability values, or evidence of superior anti-inflammatory activity.

The learned agent of the applicant further submits that Document D1 does not disclose etoricoxib, basil leaf extract, glycerin, or the preparation method or comparative efficacy data. Document D2 discloses nanoparticle formulations but uses significantly higher drug concentrations and does not disclose basil leaf extract, glycerin, or the claimed formulation characteristics or performance. Document D3 discloses etoricoxib nanoparticles but does not

specify the claimed low drug percentage, nor does it disclose the specific combination of herbal extract, glycerin, or the demonstrated superior anti-inflammatory activity and spreadability.

The learned agent of the applicant emphasizes that the present formulation achieves unexpectedly superior anti-inflammatory activity despite using a very low drug concentration and provides improved spreadability, which are not disclosed or suggested in the cited prior art.

The learned agent of the applicant also argues that the prior art does not provide any teaching or motivation for a person skilled in the art to combine the claimed features to arrive at the present invention.

Accordingly, the learned agent of the applicant submits that the claimed formulation and method involve an inventive step u/s 2(1)(ja) of the Patents Act 1970, and requests the Controller to withdraw the inventive step objection.

Upon examination, it is observed that applicant has submitted the final amended claims 1-3 on 14.01.2026. The closest prior art is represented by Document D3 in combination with Documents D1 and D2, as these documents disclose the same purpose, same class of drug, and same type of delivery system. Document D3 discloses topical delivery of etoricoxib-loaded polymeric nanoparticles specifically designed to enhance topical anti-inflammatory efficacy. Document D2 further discloses nanoparticle compositions comprising COX-2 inhibitors such as celecoxib, valdecoxib, and parecoxib with poorly water-soluble polymers, prepared using

organic solvent dissolution followed by mixing with aqueous phase and solvent removal to form nanoparticles.

Document D1 discloses topical anti-inflammatory formulations comprising tamarind seed polysaccharide and anti-inflammatory agents along with pharmaceutically acceptable excipients. These documents collectively establish that (i) etoricoxib and other COX-2 inhibitors are well known topical anti-inflammatory drugs, (ii) nanoparticle formulations using polymer and solvent evaporation techniques are standard methods to improve topical delivery of poorly soluble COX-2 inhibitors, and (iii) tamarind seed polysaccharide is a known anti-inflammatory excipient or active component in topical formulations. Thus, the prior art discloses the same therapeutic objective, same drug class, same delivery strategy (polymer-based nanoparticle formulation), and same type of topical dosage form.

The distinguishing features of the claimed formulation over the closest prior art are limited to the specific selection and quantitative optimization of formulation components, namely (i) use of tamarind seed polysaccharide at 0.0035%, (ii) use of basil leaf extract at 0.43%, (iii) use of aloe vera gel at about 20%, (iv) use of HPMC at 0.75%, (v) use of glycerin at 2%, and (vi) use of etoricoxib at 0.1%, along with a preparation method involving dissolution of polymer and drug in solvent followed by mixing and solvent evaporation to obtain nanoparticulate dry mixture and incorporation into gel base.

However, each of these features represents routine formulation measures that are well known to a person skilled in topical pharmaceutical formulation. Tamarind seed polysaccharide is already disclosed in D1 as an anti-inflammatory component and polymeric excipient. The use of polymeric excipients such as cellulose derivatives including HPMC as viscosity modifiers, stabilizers, and gel-forming agents is standard practice in topical formulations. The use of glycerin as a humectant and penetration enhancer is conventional and forms part of the common general knowledge of formulation scientists. Aloe vera gel is widely used as a topical vehicle due to its moisturizing, soothing, and wound-healing properties, and its incorporation into anti-inflammatory topical compositions represents an obvious excipient selection. Similarly, herbal extracts such as basil leaf extract are well known in the art for their anti-inflammatory and antioxidant properties and their use in combination with conventional anti-inflammatory drugs represents an obvious additive therapeutic strategy.

The selection of specific percentages of drug and excipients falls within routine optimization, as it is standard practice for formulation scientists to adjust concentrations of active ingredients, polymers, humectants, and excipients to achieve desired viscosity, spreadability, and drug release characteristics.

Document D2 explicitly discloses nanoparticle formulations of COX-2 inhibitors using organic solvent dissolution and solvent evaporation techniques, which is substantially identical to the

preparation method claimed. Document D3 also teaches nanoprecipitation of etoricoxib using acetone and polymer solution followed by solvent removal, which directly corresponds to the claimed preparation process. Therefore, the preparation method does not involve any technical deviation from established nanoparticle formulation methods.

Starting from D3 or D2 as the closest prior art, the objective technical problem can be defined as providing an alternative topical anti-inflammatory formulation of etoricoxib with suitable spreadability and anti-inflammatory efficacy. This problem does not involve overcoming any technical prejudice, nor does it require development of a new delivery principle, new material, or new mechanism of action. The claimed solution represents a predictable and routine combination of known anti-inflammatory agents, known polymers, known herbal extracts, and known topical excipients using known nanoparticle preparation methods. A person skilled in the art, faced with the objective problem, would be motivated to select commonly used topical excipients such as HPMC, glycerin, aloe vera gel, and known herbal anti-inflammatory agents such as basil extract, as these are widely disclosed in pharmaceutical literature and formulation handbooks as compatible and beneficial excipients for topical drug delivery. The selection of tamarind seed polysaccharide is directly suggested by D1, while the selection of etoricoxib nanoparticle delivery is explicitly taught by D3. The combination of these teachings does not require inventive skill but merely involves aggregation of known components performing their

expected and known functions. The observed anti-inflammatory activity and spreadability represent inherent and expected properties of topical formulations containing anti-inflammatory drugs and viscosity-modifying polymers. The reported improvement in activity cannot be considered unexpected, as enhancement of anti-inflammatory activity through improved drug delivery, polymer stabilization, and combination with herbal anti-inflammatory agents is a predictable outcome based on known pharmacological and formulation principles. No new synergistic mechanism, new structural feature, or unexpected physicochemical interaction has been demonstrated that would not be anticipated by a person skilled in the art.

Furthermore, the reduction in drug concentration to 0.1% represents routine dose optimization rather than an inventive technical advancement, since nanoparticle delivery systems are specifically designed to improve drug bioavailability and allow reduction in drug concentration. A person skilled in the art would reasonably expect that improved delivery efficiency through nanoparticle formulation and use of penetration enhancers such as glycerin would permit reduction in drug dose while maintaining therapeutic efficacy. The selection of specific quantitative ranges of excipients represents routine experimental optimization based on viscosity, stability, and spreadability requirements, which falls within ordinary skill and does not involve inventive ingenuity. The formulation components perform their conventional and expected roles: tamarind seed polysaccharide and HPMC act as polymeric stabilizers and

viscosity enhancers, glycerin acts as humectant, aloe vera gel acts as topical vehicle, basil extract acts as known anti-inflammatory herbal additive, and etoricoxib acts as COX-2 inhibitor. There is no functional interdependence between these components that produces a new or unexpected technical effect beyond additive effects of known components.

In view of the explicit teachings of D1, D2, and D3, and the common general knowledge of pharmaceutical formulation, the claimed formulation represents an obvious aggregation of known components combined using known methods to achieve a predictable result. A person skilled in the art would have had a reasonable expectation of success in arriving at the claimed formulation without exercising inventive ingenuity. Therefore, the claimed subject matter of claims 1-3 does not involve any technical advancement or non-obvious technical feature over the prior art and lacks inventive step u/s 2(1)(ja) of the Indian Patents Act 1970.

For objection on Non-Patentability u/s 3:

As per the hearing notice, an objection is the non-patentability u/s 3(d, e) of the Indian Patents Act 1970. The hearing notice raises objections under Sections 3(d) and 3(e) of the Indian Patents Act 1970 against the claimed formulation and method. It is stated that claims 1–6 fall u/s 3(d) because the claimed formulation appears to be a new form or combination of known substances without demonstrating any enhanced therapeutic efficacy. The COX-2 inhibitor is a well-known active pharmaceutical ingredient with established anti-inflammatory and analgesic

properties, and tamarind seed polysaccharide is a known excipient used for stabilization in drug formulations. Therefore, the claimed formulation is considered to lack evidence of enhanced therapeutic effect over known substances. Further, method claim 7 is objected to u/s 3(d) on the ground that it involves the use of a known process already disclosed in Document D2. Since the process does not result in a new product or involve any new reactant, it is considered non-patentable. Additionally, claims 1–6 are also objected to u/s 3(e), as the claimed formulation appears to be a mere admixture of known substances, and the specification does not provide sufficient comparative data to establish any synergistic effect arising from the combination. Therefore, the formulation is considered to lack patentable merit under these provisions of the Act.

In response, the learned agent of the applicant submits that the claimed invention relates to a novel topical anti-inflammatory ointment formulation comprising specific concentrations of etoricoxib, tamarind seed extract, basil leaf extract, aloe vera gel, cellulosic polymer, and glycerin. The learned agent of the applicant argues that the invention is not a new form of a known substance but a new product altogether, as the cited prior art documents D1–D3 do not disclose the combination including basil leaf extract, aloe vera gel, and glycerin. The learned agent of the applicant further submits that the claimed formulation demonstrates enhanced therapeutic efficacy, as evidenced by experimental data showing that formulation F9 exhibits

significantly higher anti-inflammatory activity (91.46±2.25%) compared to etoricoxib alone (73.43±2.06%). The learned agent of the applicant also argues that the method claim is dependent on the product claim and therefore does not fall within the scope of section 3(d). The learned agent of the applicant contends that section 3(d) applies only to new forms or derivatives of known substances, such as salts, esters, polymorphs, or similar derivatives, and not to entirely new compositions. Since the claimed formulation is not a derivative or new form of a known substance but a novel and inventive composition, section 3(d) is not applicable. The learned agent of the applicant also relies on prior Patent Office decisions, including the Pfizer Products Inc. vs. Natco Pharma Limited case and another Indian Patent Office order, to argue that once an invention is found to be novel and inventive, it cannot be rejected u/s 3(d). Accordingly, the learned agent of the applicant asserts that the claimed invention does not fall within the scope of section 3(d) and requests the Controller to waive the objection.

The learned agent of the applicant traverses the objection u/s 3(e) by submitting that the claimed invention is not a mere admixture but a synergistic topical anti-inflammatory ointment formulation comprising specific concentrations of etoricoxib (0.1%), tamarind seed extract (0.0035%), basil leaf extract (0.43%), aloe vera gel (20%), cellulosic polymer (0.75%), and glycerin (2%), along with a defined preparation method. The learned agent of the applicant states that nine formulations (F1–F9) were prepared and evaluated, with the best formulation

showing a spreadability of 67.07±0.098%, indicating good suitability for topical application. The therapeutic efficacy was evaluated using the albumin denaturation assay (Mizushima and Kobayashi method), comparing the formulations and individual ingredients against diclofenac sodium as the standard. The results show that formulation F9 exhibited the highest anti-inflammatory activity (91.46±2.25%), which is significantly higher than etoricoxib alone (73.43±2.06%), basil leaf extract (58.46±2.37%), tamarind seed extract (9.53±1.93%), aloe vera gel (11.68±1.85%), and even diclofenac sodium (68.35±2.64%). Based on this comparative data, the learned agent of the applicant argues that the claimed formulation demonstrates enhanced therapeutic efficacy beyond the individual components and the standard drug. Accordingly, the learned agent of the applicant contends that the composition produces a synergistic effect rather than a mere aggregation of known ingredients, and therefore does not fall within the scope of section 3(e) of the Indian Patents Act, 1970.

Upon examination, it is observed that the subject matter of amended claim 1 relates to a topical anti-inflammatory ointment formulation comprising etoricoxib (0.1%), tamarind seed polysaccharide (0.0035%), basil leaf extract (0.43%), aloe vera gel (about 20%), hydroxypropylmethyl cellulose (0.75%), and glycerin (2%). Etoricoxib is a well-established selective COX-2 inhibitor and is a known substance with well-documented anti-inflammatory and analgesic activity. Tamarind seed polysaccharide, HPMC, aloe vera gel, and glycerin are

also well-known pharmaceutical excipients commonly used as stabilizers, viscosity enhancers, gel-forming agents, penetration enhancers, and humectants in topical drug delivery systems. Basil leaf extract is likewise a known herbal ingredient with reported anti-inflammatory and antioxidant properties. Therefore, the claimed formulation represents a combination of known pharmacologically active substance (etoricoxib) with known excipients and known herbal additives that perform their expected and conventional functions in topical formulations.

Section 3(d) applies to new forms, derivatives, or formulations of known substances unless such modification results in enhanced therapeutic efficacy of the known substance. In the present case, etoricoxib remains the sole pharmacologically active API responsible for COX-2 inhibition. The formulation does not alter the chemical structure, pharmacodynamic mechanism, or intrinsic therapeutic activity of etoricoxib. The tamarind seed polysaccharide, HPMC, aloe vera gel, and glycerin function only as formulation excipients that improve viscosity, stability, spreadability, hydration, and topical acceptability. These excipients do not modify the molecular interaction between etoricoxib and its biological target (COX-2 enzyme), nor do they convert etoricoxib into a new chemical entity or therapeutically distinct derivative. The incorporation of excipients and herbal additives results in a conventional pharmaceutical formulation of a known drug, which constitutes a new form or new presentation of the known substance rather than a new substance itself.

The learned agent of the applicant's reliance on increased percentage inhibition of protein denaturation does not establish enhanced therapeutic efficacy within the meaning of section 3(d). The albumin denaturation assay is an in vitro biochemical model that provides an indirect indication of anti-inflammatory potential but does not establish enhanced therapeutic efficacy in terms of pharmacodynamic effect, bioavailability at the target site, or clinical efficacy in comparison to the known substance administered in conventional form. The observed increase in percentage inhibition is attributable to formulation-assisted delivery and additive contribution of other anti-inflammatory ingredients such as basil extract, rather than enhancement of the intrinsic therapeutic efficacy of etoricoxib itself. Section 3(d) requires demonstration of enhancement in the therapeutic efficacy of the known substance, not merely improvement in formulation performance, stability, spreadability, or additive pharmacological contribution of additional ingredients. Since etoricoxib retains its original pharmacological identity and mechanism, and the formulation does not demonstrate a significant enhancement in the intrinsic therapeutic efficacy of etoricoxib, the claimed subject matter constitutes a new form or formulation of a known substance without enhanced efficacy and is therefore non-patentable u/s 3(d).

Further, amended claim 3 relates to a method of preparation involving dissolution of tamarind seed polysaccharide in water, dissolution of etoricoxib and basil extract in acetone, mixing the

solutions, evaporating the solvent to obtain a nanoparticulate dry mixture, and incorporating aloe vera gel, HPMC, and glycerin. These steps represent conventional nanoprecipitation and solvent evaporation techniques widely used in pharmaceutical formulation for poorly water-soluble drugs. The process does not involve any new reactant, new chemical transformation, or new synthetic pathway that results in the formation of a new chemical entity. The process merely converts a known substance (etoricoxib) into a formulated dosage form using standard formulation techniques. Since the process yields only a formulation of a known substance without producing a new substance with enhanced therapeutic efficacy, the method also falls within the scope of section 3(d) and is therefore non-patentable.

Claims 1 and 2 are also non-patentable u/s 3(e), which excludes mere admixtures of known substances resulting only in aggregation of properties. In the present formulation, each component performs its known and expected function independently. Etoricoxib provides anti-inflammatory activity through COX-2 inhibition. Tamarind seed polysaccharide and HPMC function as polymeric stabilizers and viscosity modifiers. Glycerin acts as a humectant and penetration enhancer. Aloe vera gel serves as a topical base with moisturizing and soothing properties. Basil leaf extract contributes its known anti-inflammatory effect. There is no evidence of any new functional interaction between these components that produces a novel technical effect beyond the sum of their individual properties.

The anti-inflammatory activity data submitted by the applicant shows that basil leaf extract alone possesses significant anti-inflammatory activity (58.46%), and etoricoxib alone exhibits higher activity (73.43%). The increased activity of formulation F9 (91.46%) represents an additive or cumulative effect arising from the combined presence of multiple anti-inflammatory agents rather than a synergistic effect resulting from a new functional relationship between components. Synergism requires demonstration that the combined effect exceeds the expected additive effect based on individual contributions and involves a functional interaction that produces a qualitatively different technical outcome. The data provided does not establish such synergistic interaction, but rather reflects the predictable additive pharmacological contribution of multiple anti-inflammatory substances.

Moreover, the excipients such as HPMC, glycerin, and aloe vera gel do not possess independent anti-inflammatory activity sufficient to modify the pharmacological action of etoricoxib. Their role is limited to formulation stabilization, viscosity modification, and topical delivery enhancement. These excipients do not interact chemically or pharmacodynamically with etoricoxib in a manner that produces a new or unexpected therapeutic mechanism. The formulation therefore represents a physical mixture of known active and inactive ingredients, each contributing its expected and known property without any emergent or synergistic technical effect.

Claim 2, which specifies etoricoxib as the COX-2 inhibitor, further confirms that the formulation is based on a known API used in its conventional pharmacological role. The selection of etoricoxib does not introduce any new structural feature, new mechanism of action, or new functional interaction with excipients beyond routine formulation practice. Therefore, claims 1 and 2 represent a mere admixture of known substances resulting in aggregation of known properties and fall squarely within the exclusion u/s 3(e).

Accordingly, claims 1–3 are non-patentable u/s 3(d) as they relate to a formulation and preparation method of a known substance without enhancement of therapeutic efficacy, and claims 1–2 are additionally non-patentable u/s 3(e) as they represent a mere admixture of known substances without demonstration of synergistic technical effect.

For objection on Sufficiency of Disclosure u/s 10 (4):

As per the hearing notice, an objection is the lack of sufficiency of disclosure u/s 10 (4) of the Indian Patents Act, 1970. It was observed that the specification does not provide adequate supporting or comparative data with respect to the closest prior art to demonstrate any synergistic effect of the claimed formulation. In the absence of such comparative evidence, the specification fails to fully substantiate the technical advancement or synergy claimed, and therefore claims 1–6 are not allowable u/s 10(4).

Secondly, method claim 7 is objected to on the ground that it does not sufficiently and clearly define the process steps and essential technical parameters required to perform the invention. Specifically, the claim lacks details such as molar ratios, reaction conditions, and other critical technical features necessary for proper implementation. As a result, the method claim does not meet the requirements of complete and sufficient disclosure u/s 10(4) of the Patents Act.

In response, the learned agent of the applicant submits therapeutic efficacy data to address the objection regarding lack of supporting evidence. The anti-inflammatory activity of nine formulations (F1–F9) was evaluated using the albumin denaturation assay, with diclofenac sodium as the standard drug and individual ingredients tested separately. The results show that formulation F9 exhibited the highest anti-inflammatory activity (91.46±2.25%), which is significantly higher than etoricoxib alone (73.43±2.06%), basil leaf extract (58.46±2.37%), tamarind seed extract (9.53±1.93%), aloe vera gel (11.68±1.85%), and diclofenac sodium (68.35±2.64%). Based on these results, the applicant argues that the claimed formulation demonstrates superior therapeutic efficacy and requests reconsideration and withdrawal of the objection. With respect to the method claim, the learned agent of the applicant submits that claim 7 (now amended as Claim 3) has been revised to include the exact quantities of all ingredients and process details, with support from the as-filed specification, and marked-up and

clean copies of the amended claims have been provided. The the learned agent of the applicant therefore requests withdrawal of the insufficiency objection.

Upon examination, it is observed that the therapeutic efficacy data submitted by the the learned agent of the applicant does not adequately overcome the objection u/s 10(4). Although the applicant provides anti-protein denaturation results for formulations F1–F9 and compares them with individual ingredients and diclofenac sodium, the data does not include any comparative analysis with the closest prior art formulations cited during examination. The objection specifically required comparative data vis-à-vis the closest prior art to substantiate the alleged synergistic effect. The the learned agent of the applicant has only compared the formulation with individual components and a standard drug, which does not establish superiority over known etoricoxib topical nanoparticle formulations or tamarind seed polysaccharide-based compositions already disclosed in prior documents. Therefore, the specification still fails to provide sufficient technical evidence to demonstrate a synergistic or unexpected effect over the prior art. In the absence of such comparative data, the requirement of full and fair disclosure u/s 10(4) remains unmet.

Further, the anti-inflammatory assay employed (albumin denaturation method) is an in vitro screening model and does not directly establish enhanced therapeutic efficacy in a clinical or in vivo setting. The data reflects the cumulative activity of multiple known anti-inflammatory

ingredients rather than a demonstrated synergistic interaction arising from a specific technical feature of the claimed formulation. No statistical synergy analysis or mechanistic evidence has been provided to show that the combined effect exceeds the expected additive effect of etoricoxib and basil extract.

With respect to the amended method claim, although the applicant has incorporated specific quantities of ingredients, the process still lacks critical technical parameters necessary for reproducibility and clarity. Essential features such as mixing rate, temperature control, solvent evaporation conditions, particle size control parameters, duration of stirring, environmental conditions, and other operational variables that directly affect nanoparticle formation are not comprehensively defined. Merely specifying ingredient quantities does not sufficiently define the process in a manner that enables a person skilled in the art to reliably reproduce the claimed nanoparticulate system without undue experimentation. Section 10(4) requires complete specification to particularly describe the invention and the method by which it is to be performed. The present disclosure remains deficient in essential process parameters that govern nanoparticle formation and stability.

In view of the above, the present objection remains technically and legally sustainable. The submitted efficacy data does not establish synergistic effect over the closest prior art, the specification does not sufficiently support the claimed technical advancement, and the method

claim continues to lack full and precise definition of essential technical features as required u/s 10(4). Accordingly, the objections under present head are maintained.

For objection on NBA raised in the hearing:

Learned agent of the applicant has complied with NBA requirement. Thus, NBA objection has been waived off.

Conclusion:

5. In view of the above, the requirements of objections raised through the said hearing notice are not met and the subject matter of present claims 1-3 dated 14/01/2026 are found to be not-inventive u/s 2(1) (ja) as well as non-patentable u/s 3(d), 3(e) and further objected for lack of sufficiency of disclosure u/s 10(4) of the Indian Patents Act, 1970. There is no pre-grant opposition filed as seen from the "view uploaded documents" as of date and time.

6. In view of facts and findings, supra, the submissions of the agents during the hearing and subsequently through the written submission, including all the documents on record and also in view of my above findings, the instant application no. 201911038394 dated 23/09/2019 does not comply with the requirements of sections 2(1) (ja), 3(d), 3(e), and 10(4) of the Indian Patents Act, 1970 (as amended).

7. Having considered all the circumstances, as the objections communicated in the hearing notice relating to section 2(1) (ja), 3(d), 3(e), and 10(4) are not met, the undersigned hereby

refuse the instant application No. 201911038394 for the grant of patent u/s 15 of the Patents Act, 1970.

8. This is to be noted that the aforesaid observations, and decision thereof, are based solely on the electronically uploaded documents to date.

Dated, 13th day of Feb 2026

Sd/-

(DR. RAM KISHAN)

ASSISTANT CONTROLLER OF PATENTS & DESIGNS

PATENT OFFICE, DELHI.