



* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

% Judgment reserved on: 15.05.2026
Judgment delivered on: 22.06.2026

+ C.A.(COMM.IPD-PAT) 109/2022

SHAAFI NATURCURE LLP

.....Appellant

versus

ASSISTANT CONTROLLER OF PATENTS AND DESIGNS

.....Respondent

Advocates who appeared in this case:

For the Appellant : Mr. Kapil Kumar and Mr. Abhishek Jain,
Advocates.

For the Respondent : Mr. Sumit Nagpal, SPC with Mr. Tanmay Saini
and Mr. Kunal Khurana, Advocates.

CORAM:

HON'BLE MR. JUSTICE TUSHAR RAO GEDELA

J U D G M E N T

TUSHAR RAO GEDELA, J.

1. The present appeal has been filed under Section 117A of the Patents Act, 1970 (hereinafter referred to as "*the Act*") assailing the order dated 16.09.2020 (hereinafter referred to as "*impugned order*") passed by the Assistant Controller of Patents and Designs (hereinafter referred to as "*learned Controller*") whereby the respondent refused the Indian Patent Application bearing no. 201911048481 (hereinafter referred to as "*subject application*") on the grounds that the invention does not meet the requirements of Section 2(1)(j), Section 3(p) and Section 10(4)(a) and 10(4)(b) of the Act.

2. Briefly, the facts as stated in the appeal are as under:-

2.1 The appellant filed the present application titled "*A HERBAL*



POWDER COMPOSITION FOR THE TREATMENT OF ASTHMA” seeking grant of patent on 27.11.2019. It was numbered as Indian Patent Application no.201911048481. Thereafter, the First Examination Report (hereinafter referred to as “*FER*”) was issued on 01.01.2020. The appellant claims to have filed a detailed response to the said *FER* on 20.06.2020 alongwith amended claims.

2.2 The respondent issued a notice of hearing on 29.06.2020 scheduling the oral hearing on 29.07.2020. The appellant through its agent sought and was granted an adjournment, scheduling the hearing to 28.08.2020.

2.3 The agent of the appellant addressed arguments on 28.08.2020 and pursuant thereto, the appellant filed detailed written submissions on 11.09.2020. Consequent thereto, *vide* the impugned order dated 16.09.2020, the subject application was rejected.

2.4 Impugning the order dated 16.09.2020, the present appeal has been preferred.

CONTENTIONS OF THE APPELLANT:-

3. Appearing on behalf of the appellant, Mr. Kapil Kumar, learned counsel, at the outset assailed the impugned order on the ground that the five steps process directed to be followed by this Court in ***Hoffmann La Roche Ltd. vs. Cipla Ltd.: 2015 SCC OnLine Del 13619*** was not followed and as such, the impugned order needs to be set aside and the patent application be remanded back for reconsideration.

4. Learned counsel would contend that the refusal is erroneously premised on the ground that the composition of the present invention is obvious in view of the teachings contained in prior arts D1 to D10. He would contend that apart from the six ingredients which have been claimed in the present invention, there are several herbs which are also useful in the



treatment of asthma, for example *Adhatoda Vasica*, *Achyranthes Aspera*, *Zingiber Officinane*, *Curcuma Longa* and *Calotropis Procera*.

5. Learned counsel urged that the invention pertains to selection of herbs out of a pool of several available herbs which are traditionally known for treatment of asthma and thus, cannot be treated as a routine experimentation. According to learned counsel, the inventive step lies in the herbal composition in powdered form comprising six herbs for the treatment of all five types of asthma. It is claimed that the inventor has worked out and optimised the ratios of each of the ingredients which can be useful for treatment of asthma. Notwithstanding the aforesaid submission, learned counsel would contend that even if it is assumed, though without admitting, that the present invention is a routine experiment, there is no document much less any prior art document which discloses the combination of six herbs as contained in the present invention in specific ratios for the treatment of asthma.

6. Learned counsel emphasised that the subject matter of the prior art documents D1 to D10, whether read alone or in combination, do not teach a person skilled in the art to reach the present invention. He would contend that the prior documents D1, D3, D6 and D7 are citations from Traditional Knowledge Digital Library (hereinafter referred to as “TKDL”) and the information provided therein being too skeletal, cannot be considered as an enabling disclosure and thus, the same are not relevant prior art documents to determine inventive step.

7. Dilating further on the aforesaid prior art documents D1 to D10, learned counsel relied upon the detailed comparison of prior art documents *vis-a-vis* the present invention in support of his contentions. The submissions of the learned counsel regarding the prior art D1 to D10 are as



follows:-

“D1, D3, D6 and D7 are citations from TKDL and the information provided being too skeletal, that the same cannot be considered as an enabling disclosure and is much beyond the workshop experiments to arrive at the present composition and therefore, are not relevant prior art documents for the purposes of judging inventive step.

D1 relates to aqueous formulation of Tephrosia purpurea leaves having diuretic property and prepared as decoction for treating asthma. As well established, diuretic property can only reduce water retention in the body and will have limited ability when used as single compound formulation, for treating Asthma.

D2 is directed to "Evaluation of antihistamic activity of herbal drug isolated from Cuscuta reflexa Roxb." wherein the extract used was prepared in ethanol employing Soxhlet extractor. It only confirms mast cell stabilizing activity through pre-clinical trials and emphasizes further studies to understand its mechanism. Further, it makes a passing reference for the traditional use of ethanolic extract of whole plant of Cuscuta reflexa Roxb without any corroborations confirming safe use.

D3 relates to a composition comprising Cuscuta (aqueous extract of seeds), sweet fennel (aqueous extract of fruit) and sugar based semisolid preparation containing rose petals. The components of the said composition are totally different from the claimed composition comprising of specific parts of six herbs in specific proportion. It nowhere mentions, let alone teaches the use of stems of Cuscuta in the treatment of asthma.

D4 provides passing reference to use of single component of fruit and leaves of Morinda citrifolia for treating allergies, such as bronchitis, asthma and pruritus. Further, it also shows the effect of noni as potential anti-hypertensive, hypoglycemic and anti-dementia agent. Moreover, D4 also shows better effects of leaves of noni as compared to its fruits which it itself is a negative teaching. The conclusion of the article arrived at clearly indicates that further studies for detailed chemical analysis clinical trials and the ailments/conditions are necessary.

D5 is a review article on single component Terminalia arjuna and use of its fruit, leaves, seed and bark for various diseases including astringent, cooling, aphrodisiac, cardiogenic, tonic in fractures, ulcers, diabetes, cough, tumors, inflammation, skin disorders asthma, etc. Further, the article mainly focuses on the use of T. arjuna in cardiac disorders. Further, the study mentioned in respect of anti-inflammatory activity focusses on a formulation of five medicinal plants (Commiphora mukul, Terminalia arjuna, Boswellia serrata, Semecarpus anacardium and Strychnos nux vomica) and makes passing reference in respect of use of T.



arjuna as antiinflammatory agent.

D6 relates to a single compound formulation of Piper longum for various ailments like Cough with expectoration, cough / bronchitis, Bronchial asthma, Gastric tympanitis. Even the dose of Piper longum is not mentioned, let alone the particular composition of the present invention or any other component.

D7 relates to a single compound formulation of fruit of Piper nigrum for cough, bronchitis or pain of chest in form of syrup but which asthma is not specified.

D8 just mentions use of Leaf decoction, root powder of Tephrosia purpurea for asthma, but the disclosure is not an enabling one. Further, the mechanism of action as disclosed in D8 indicates use of Tephrosia purpurea primarily as blood purifier.

D9. relates to alcoholic extract of Terminalia arjuna for asthma, but the dose, asthma type is not disclosed, neither is there an indication to cure all types of asthma. Further, the said prior art is not an enabling one.

D10 relates to a patent application with multi-components, two of which are Piper nigrum and Piper longum. Further, the said application discloses the synergistic polyherbal composition and therefore, does not indicate standalone use of Piper nigrum and Piper longum in the treatment of asthma. Even otherwise, the said prior art has been mentioned in the complete specification.”

8. Learned counsel emphatically argued that the respondent has not correctly considered or appreciated the affidavit filed by the inventor to clarify the objections contained in the hearing notice as well as in the FER. He would contend that if any evidence is developed after the patent grant, the same is not excluded from consideration for understanding the full range of an invention which may not have been achieved at the time of filing the patent application. He also would contend that there is no requirement that the properties and advantages of an invention were fully known before the patent application was filed in order for that work to be introduced into evidence. He argued that the annexures submitted alongwith the affidavit of the inventor clearly demonstrated that the present



invention involved technical ingenuity. According to him, Annexure A which was filed alongwith the affidavit clearly showed the components, their ratio/ranges, particular plant used, the form in which it is to be provided/used, the types of asthma cured, clearly indicating that the claimed composition *per se* is not obvious in view of the prior art documents D1 to D10. Similarly, according to him, Annexure B appended to the affidavit of the inventor related to information of individual components, their efficacy and other aspects such as side effects etc., or the types of asthma these compositions could cure individually which demonstrated that individual herbs are not as effective as the specific composition which at times could even result in side effects if taken disproportionately.

9. Learned counsel also argued that the Guidelines For Processing of Patent Applications Relating To Traditional Knowledge and Biological Material, 2012 (hereinafter referred to as the “TK Guidelines”) have not been considered in its entirety and only certain portions have merely been cherry picked, for example guiding principles nos.2 and 4, which has caused prejudice to the appellant. Alternatively, learned counsel contended that the TK Guidelines are mere guidelines and not binding in nature. He would contend that the inventive step of an invention ought to be acknowledged if the surprising effect of the claimed composition *vis-a-vis* the already known prior art composition as provided in the form of an illustration in the TK Guidelines. According to the learned counsel, in the present case, the surprising effect has been demonstrated and proved which has been ignored and overlooked by the respondent.

10. So far as the objection under Section 3(p) of the Act is concerned, learned counsel would submit that none of the prior art teaching in D1 to



D10 provide conclusive evidence that the components of the present composition are useful for treatment of asthma only. In other words, he would contend that the documents D1 to D10 showed that other parts of the components of the present invention were traditionally used to treat various other ailments and treatment of asthma was only by way of a passing reference.

11. It was contended that the respondent failed to appreciate that the submitted affidavit of the inventor shows the negative effects of altering the ratio/ranges of the components. Based on this, the appellant submitted that the knowledge that components of the present invention are conclusively used for asthma is not motivating the inventors to refer to the cited prior art documents.

12. In continuation of the aforesaid submission, learned counsel would also submit that the efficacy of different permutations and combinations of these herbal components may result in altogether a different activity or side effects or may not be able to treat all five kinds of asthma. He would contend that there is an unpredictability of activity with respect to these herbal components as each of them have diverse 5-10 activities and thus, the present invention involves greater human ingenuity and efforts and therefore, cannot be simply construed or brushed aside as traditional knowledge.

13. Learned counsel for the appellant also placed great reliance on the agreement entered into between the appellant and the National Biodiversity Authority (hereinafter referred to as “NBA”) to submit that once such agreement has been entered into and executed with the authority, the objection under Section 3(p) of the Act must either be construed to have been met with or such objection is deemed to be unsustainable. According



to the learned counsel, Section 3(p) of the Act must be read harmoniously with the Biological Diversity Act, 2002 (hereinafter referred to as “BDA”). He disputed the contention of the respondent that the agreement executed between the appellant and NBA under Section 6 of the BDA is a mere regulatory clearance for access to biological resources and has no nexus with the patentability criteria under the Act. Thus, learned counsel would contend that once such agreement has been executed and entered into with the NBA, the objection under Section 3(p) of the Act would be rendered otiose.

14. On the objections raised in terms of Section 10(4)(a) and (b) of the Act, learned counsel would submit that the Complete Specifications (hereinafter referred to as “CS”) clearly discloses the exemplary herbal compositions and the method of preparing the same and thus, the basic requirements of the aforesaid provisions have been clearly met. That apart, he would contend that the affidavit of the inventor clearly demonstrated the working examples falling within the ranges as claimed in the present invention. In fact, the affidavit also discloses various compositions falling outside the scope of the claims of the present application thereby demonstrating negative effects of such compositions. Thus, according to the learned counsel, the CS read with the contents of the affidavit provide complete disclosure as required.

15. Additionally, learned counsel would emphasize that the affidavit of the inventor also demonstrated the verifiable data of the composition which was tried and tested on 300 individuals including children, women and men to represent all age groups and genders. He would submit that the said affidavit provides details of exceptional results captured on administration of the composition of the present invention upon the 300 individuals which



clearly demonstrated that the said composition showed enhanced efficacy over a broad spectrum group without apparent side effects. Thus, according to learned counsel, the objections raised under Section 10(4)(a) and 10(4)(b) of the Act have been fully met by the appellant.

CONTENTIONS OF THE RESPONDENT:-

16. Appearing for the respondent, Mr. Nagpal, learned CGSC strongly refuted the contentions raised on behalf of the appellant.

17. At the outset, Mr. Nagpal broadly touched upon the various relevant provisions of the Act, and the BDA, particularly Section 6. He would contend that the permission sought by an entity or an individual under the BDA is for the purpose of facilitating the entity or the individual to extract natural resources and sets out the regime for conservation of biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out of utilization of genetic resources. He also emphasized that the Act is a regulatory mechanism to ensure that no person shall undertake biodiversity related activities without approval of the NBA.

18. Learned CGSC would contend that Section 19 of the BDA provides the manner in which a person who intends to obtain any biological resource occurring in India is to apply to the NBA. He also stated that the provisions of Section 19 also stipulated that in case any person intends to apply for a patent or any other form of intellectual property rights, such person may also file an application to the NBA. According to him, provisions of Section 19 also provide that the NBA may make enquiries after consulting the Expert Committee and grant approval to the applicant which may include imposition of charges etc. However, he would forcefully contend that there is no provision in the entire BDA which would consider an application filed by an intended patentee as to the patentability of the



subject invention of the intended patentee. He would submit that the same is clear also from a bare perusal of the agreement dated 19.01.2021 placed on record by the appellant. Thus, in sum and substance, learned counsel would contend that other than providing a regulatory mechanism and revenue sharing, the BDA does not contemplate conducting enquiries in respect of patentability of a claimed invention.

19. From the aforesaid submission, learned CGSC would contend that patentability of a claimed invention has to be considered purely under the provisions of the Patent Act, 1970 and not the BDA. He further contends that in the present appeal, the appellant has failed to overcome the objections under Section 3(p) of the Act and has relied substantially on the agreement dated 19.01.2021 and the affidavit along with the annexures filed by the inventor, which is unsustainable in facts and law.

20. Having stated as above, learned CGSC referred to the additional written submissions dated 02.05.2026 filed on behalf of the respondent and read through the same. On merits, Mr. Nagpal would contend the claimed composition comprises six herbal ingredients each of which is independently known in the traditional systems of medicines for the treatment of asthma, Bronchitis and related respiratory ailments. This is clear from the teachings in the cited prior arts documents. Thus, according to learned CGSC, the claimed invention is nothing but an aggregation of properties of traditionally known components without any demonstrable technical advancement or unexpected effect.

21. Referring to Annexure B to the Biodiversity Agreement dated 19.01.2021, learned counsel would submit that the invention for which approval was granted describes the subject matter merely as “A HERBAL POWDER COMPOSITION FOR THE TREATMENT OF ASTHAMA”.



Other than that, the said Annexure makes no reference to classification of asthma into five distinct categories or that the claimed composition was capable of curing all such types of asthma. He emphasized that similarly, even the CS did not refer to any such sub-classification. He would contend that the differentiation into five types of asthma and the assertions made in Column 6 of the Chart at page 141 of the paper book and the accompanying affidavit are new technical features introduced for the first time at the hearing stage and cannot be considered. Therefore, he contended that the said chart constituting post-filing material does not form part of the original disclosure in the CS, thus attracting objection under Section 10(4)(a) and (b) of the Act.

22. Contrary to the contention of the appellant that the affidavit of the inventor was not considered by the respondent, learned CGSC argued in detail and referred to various paragraphs of the impugned order to contend that not only was the subject patent application considered in totality but the affidavit along with its annexures submitted by the inventor too was considered in great detail. To demonstrate and make good the above submission, learned CGSC invited attention to the following paragraphs of the impugned order:-

“With respect to effect of the composition of the present application in curing different types of asthma as mentioned in the hearing submission by the applicant's agent and also in the Annexure A of the affidavit by the inventor, it is pertinent to note that the complete specification as originally filed is silent regarding the different types of asthma. The specification, the claims of the instant application as well as the prior art documents disclose the use of herbs in the treatment of asthma. There is no basis for the statement that the asthma cured by the composition of the instant application is different from the one disclosed in the teachings of the prior art.

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An affidavit is submitted by the inventor providing data showing the



negative effects of altering the ratio/ranges of the components. With regard to the additional data, I would like to mention that the addition of any descriptive material has to be at least implicitly disclosed in the specification to be allowable.

Without prejudice to the matter discussed in the above paragraph, the data in the affidavit (see paragraph 8) lists various formulations consisting of a combination of specific ranges of each of the 6 herbs of the instant application and the side effects due to changes in the ratio of ingredients and also a preliminary survey on 300 patients showing the efficacy of the claimed formulation (see paragraph 15). Upon careful consideration, it is observed that the data provided in the affidavit is inconsistent with experimental data provided in the complete specification as originally filed.

a. As per the specification, composition with only 4 herbs is equally efficient in treating asthma in the same duration as composition with all 6 herbs. This is not the case of the formulations listed in the affidavit by the inventor.

b. Moreover, the specification discloses treating asthma with the composition of the invention in a minimum duration of 3 months (Example 1). However, as per the data in the affidavit, the minimum duration for curing asthma is 4-5 months.

c. Importantly, the formulation number IV listed in paragraph 8 of the affidavit consists of all the six herbs of the present application in the preferred ranges as claimed in claim I. Thus, as per the data provided in the affidavit, the composition as claimed in claim I is considered to cause side effects such as increase kaphaa and also tridosh.

Hence, the data provided in the affidavit by the inventor is not reliable and failed to show any unexpected effect of the claimed composition.

Therefore, in view of the above, the applicant's argument that the specific composition with specific ratio/ ranges of components is required for the enhanced efficacy is found not persuasive."

23. Learned CGSC also contended that Column 6 of the Chart at page 141 of the paper book makes a blanket assertion that the claimed composition is capable of curing all five types of asthma without any supporting experimental data or technical evidence. He contended that the Chart also did not disclose any specific formulation within the claimed



ranges nor does it provide any details regarding experimental methodology, comparative analysis or clinical validation. Thus, according to him, in the absence of such foundational data, the statements in Column 6 lack scientific substantiation.

24. Another relevant concern raised by the respondent is in respect of the contents of the affidavits of the inventor, particularly paragraph 8, wherein it was deposed that upon altering the ratios of the composition, the result was either less effective or exhibited serious side effects. According to Mr. Nagpal, learned CGSC, this clearly demonstrates that even the compositions which are covered within the claimed ranges may not be consistently effective and in fact, may produce undesirable effects. Thus, in that view too, learned counsel would contend that the blanket assertion made in Column 6 of curing five types of asthma with the given compositions is unreliable and lacks evidentiary value. In fact, as an example, the impugned order considered the Formulation IV which falls within the claimed ranges and itself leads to adverse effects, such as increase in kapha and tridosha thereby undermining the claim of technical advancement. On the basis of such observations, learned counsel contended that the conclusion reached by the respondent that the affidavit is not reliable, ought not to be disturbed.

25. So far as the contention of the appellant in respect of prior art documents D1 to D10 is concerned, learned CGSC submitted that contrary to the submission of the appellant that the said prior art documents attribute limited efficacy in relation to the specific types of asthma, however, none of the cited prior art documents disclose any such limitations and uniformly refer to treatment of asthma in general. Learned counsel would contend that in support of the aforesaid contention, the appellant had relied upon



Annexure A to the affidavit of the inventor, however, the same is based on an unfounded and unsupported classification of asthma into different types and thus, the contentions raised by the appellant *qua* the prior art documents is unfounded. He would also contend that the contentions of the appellant seem to be based on unilateral interpretation of the inventor without submitting supporting disclosure or evidence and as such, cannot be relied upon to establish inventive step.

ANALYSIS AND CONCLUSIONS:-

26. Heard learned counsel for the parties and perused the records of the case.

27. At the outset, it may be relevant to consider the argument of learned counsel for the appellant predicated on the provisions of the BDA. Learned counsel had relied upon the provisions of the BDA to primarily submit that once the NBA under the provisions of Section 19 grants approval to the application filed by any person in terms of Section 3 of the BDA for the purpose of obtaining any biological resource occurring in India, coupled with the agreement being executed between the person and the NBA, the objection under Section 3(p) of the Patents Act cannot be cited as an objection by the respondent while considering the patentability of the patent application of the appellant. Learned counsel had also contended that the BDA being an expression of the policy decision of the Government, has to be given primacy over the objections contained in Section 3 of the Act and once the NBA grants approval and executes an agreement as stipulated in the BDA, the objections under Section 3(p) of the Act would be rendered otiose.

28. In the opinion of this Court, the aforesaid arguments are fallacious and without any foundation. If one were to consider the Preamble of the



BDA, it is clear that the said Act has been promulgated for the purposes of (i) conservation of biological diversity, (ii) sustainable use of its components, (iii) fair and equitable sharing of the benefits arising out of the use of biological resources and knowledge, and (iv) for matters connected therewith. On the plain reading of the Preamble and the objects of the BDA, the main objective appears to be conservation of the biological diversity so as to ensure that the biological resources and the associated traditional knowledge is controlled under a regime and neither misused nor abused by entities. Upon a cursory consideration of various sections including Sections 3, 6, 7, 8, 18 and 19 of the BDA as also Rule 16 of the Biological Diversity Rules, 2024, (hereinafter referred to as “*the Rules*”), it is clear that the intention of the legislature was not only to protect and regulate the utilisation of biological resources or the knowledge associated thereto but also to ensure that the Government is able to gain financial benefit from the revenue sharing borne out of the commercial utilisation of such biological resources.

29. Sub-section 3 of Section 19 of BDA concerns itself with conducting an inquiry by the NBA after consulting an expert committee for the purposes of granting or refusing approval to an application filed by any person subject to regulations being made in that regard and further subject to terms and conditions as it may deem fit. A cumulative reading of Sections 6, 7, and 19 of BDA also makes it clear that the right to file an application for intellectual property rights to the appropriate authority is subject to mandatory registration with the NBA before grant of such intellectual property rights. The manner, mode and procedure for registration and obtaining prior approval from the NBA before seeking grant of intellectual property rights is prescribed in Rule 16 of the Rules.



Nowhere does the Act or the Rules provide ascertainment of patentability of the subject invention of a patent application. The approval that is granted by the NBA is statutorily reduced into writing in the form of an agreement on mutually agreed terms.

30. It appears to this Court that the basic framework of the regime contemplated under the BDA is only for the purposes of ensuring that no person or entity is able to utilise or extract biological resources without obtaining registration and approval from the NBA. It is also manifest from the provisions of the Act and the Rules framed thereunder that it is mandatory to obtain necessary approval from the NBA by an entity or an individual which is desirous of seeking a grant of intellectual property rights in a composition or invention which would involve extraction and utilisation of the biological resources for its invention etc. There is no provision in either the BDA or the Rules which confer any power or authority or even jurisdiction to the NBA to venture into or conduct any inquiry in any manner whatsoever with respect to the patentability or otherwise of any claimed invention. Thus, the mere grant of approval by the NBA has no rationale or remote nexus with the patentability of a claimed invention, which is the exclusive mandate of the Patents Act, 1970.

31. *A fortiori*, the aspect of patentability of a claimed invention being met with, once NBA grants approval under the provisions of BDA, is legally unfounded and is unsustainable. *Ergo*, the argument of the learned counsel for the appellant in this context is unmerited.

32. Resultantly, the objection under Section 3(p) of the Act has to be necessarily and satisfactorily overcome by the appellant. In view of the above, this Court now proceeds to examine the appeal on merits.

33. The claimed invention is titled as “*A HERBAL POWDER*”



COMPOSITION FOR THE TREATMENT OF ASTHMA” and relates to a herbal powder composition for the treatment of asthma. The said invention is directed to a novel herbal powder composition which comprises a mixture of six native Indian herbs useful for treating asthma. The field of invention of the present invention is as follows:-

“FIELD OF THE INVENTION: The present invention represents to a herbal powder composition for the treatment of asthma. More precisely, the invention is directed to a novel herbal powder composition comprising of a mixture of six native Indian herbs useful for treating asthma or similar airways conditions.”

34. The claimed herbal powder composition invention comprises of (a) Tephrosia Purpura (Sarphooka), (b) Cuscuta Reflexa (Aftimoon Kasoos), (c) Morinda Citrifolia (Noni), (d) Terminalia arjuna (Arjun Bark), (e) Piper Longum (Pipal Bari), and (f) Piper Nigrum (Kali Mirchi).

35. As per the CS of the subject application, drying is normally carried out in shade to prevent degeneration of the active ingredients due to UV light. Using a mechanised crusher is contemplated to make sure that no excessive heat is produced, as excessive heat could affect the properties of the raw materials.

36. To prepare the powders of the composition, Tephrosia Purpura (Sarphooka) is taken in an amount in the range of 25 to 60% by wt., (preferably 35 to 55% by wt., more preferably 40 to 50% by wt.), Cuscuta Reflexa is taken in the range of 1 to 30% by wt., (preferably 5 to 25% by wt., more preferably 8 to 20% by wt.), Morinda Citrifolia is taken in the range of 1 to 30% by wt., (preferably 5 to 25% by wt., more preferably 8 to 20% by wt.), Terminalia Arjuna is taken in the range of 1 to 30% by wt., (preferably 5 to 25% by wt., more preferably 8 to 20% by wt.); Piper Longum is taken in the range of 1 to 30% by wt., (preferably 3 to 25% by



wt., more preferably 5 to 20% by wt.) and Piper Nigrum is taken in the range of 1 to 30% by wt., (preferably 5 to 25% by wt., more preferably 8 to 20% by wt).

37. The claims submitted along with the reply to FER are as follows:-

“We Claim:

1. A herbal powder composition for the treatment of asthma comprising:

- (a) Tephrosia purpurea (Sarphooka), whole plant, 25 to 60% by wt;*
- (b) Cuscuta reflexa (Aftimoon Kasoos), stem and seeds, 1 to 30% by wt;*
- (c) Morindacitrifolia (Noni), fruits, 1 to 30% by wt;*
- (d) Terminallia arjuna (Arjun Bark), 1 to 30% by wt.;*
- (e) Piper longum (Pipal Bari) fruit, 1 to 30% by wt.; and*
- (f) Piper nigrum (Kali Mirch) fruit, 1 to 30% by wt.*

2. The composition as claimed in claim 1 wherein Tephrosia purpurea is in the range of 35 to 55% by wt.

3. The composition as claimed in claim 1 wherein Tephrosia purpurea is in the range of 40 to 50% by wt.

4. The composition as claimed in claim 1 wherein Cuscuta reflexa is in the range of 5 to 25% by wt.

5. The composition as claimed in claim 1 wherein Cuscuta reflexa is in the range of 8 to 20% by wt.

6. The composition as claimed in claim 1 wherein Morindacitrifolia is in the range of 5 to 25% by wt.

7. The composition as claimed in claim 1 wherein Morindacitrifolia is in the range of 8 to 20% by wt.

8. The composition as claimed in claim 1 wherein Terminallia arjuna is in the range of 5 to 25% by wt.

9. The composition as claimed in claim 1 wherein Terminallia arjuna is in the range of 8 to 20% by wt.

10. The composition as claimed in claim 1 wherein Piper longum is in the range of 3 to 25% by wt.

11. The composition as claimed in claim 1 wherein Piper longum is in



the range of 5 to 20% by wt.

12. The composition as claimed in claim 1 wherein Piper nigrum is in the range of 5 to 25% by wt.

13. The composition as claimed in claim 1 wherein Piper nigrum is in the range of 8 to 20% by wt.

14. The composition as claimed in claim 1 wherein honey, warm water or water at room temperature is applied as a carrier while administering to the subject in need.

15. A process for the preparation of the composition as claimed in claim 1 comprising the following steps:

(a) shade drying of Tephrosia purpurea, Cuscuta reflexa, Morindacitrifolia. Terminallia arjuna. Piper longum and Piper nigrum separately;

(b) crushing/grinding the dried parts of Tephrosia purpurea, Cuscuta reflexa, Morindacitrifolia, Terminallia arjuna. Piper longum and Piper nigrum, separately, maintaining the temperature in ambient conditions to a fine powder; and

(c) mixing the powders so obtained in step (b) of Tephrosia purpurea, Cuscuta reflexa, Morindacitrifolia, Terminallia arjuna. Piper longum and Piper nigrum in the ratio as recited in claims 1 to 13.”

38. As per the impugned order, the cited prior arts disclose the following:-

- **D1** discloses a single ingredient composition comprising Tephrosia purpurea, useful in the treatment of asthma.
- **D2** discloses that Cuscuta reflexa is traditionally used for cough, cold and asthma by the tribal Gujjar and Bakerwals of the Baramulla district of Kashmir valley. D2 teaches the anti histaminic activities of the ethanolic extract of Cuscuta reflexa.
- **D3** discloses a composition comprising Cuscuta reflexa along with another herb, useful in the treatment of asthma.
- **D4** discloses that Morinda citrifolia (noni) was traditionally used to relieve allergic symptoms such as bronchitis, asthma and pruritus.



- **D5** discloses that the bark of *Terminalia arjuna* is used in Indian Indigenous System of Medicine for the treatment of asthma, bronchitis and cough.
- **D6** discloses a single ingredient composition comprising *Piper longum*, useful in the treatment of asthma.
- **D7** discloses a single ingredient composition comprising *Piper nigrum*, useful in the treatment of bronchitis.
- **D8** teaches that roots, leaves, seeds and stem bark of *Tephrosia purpurea* are traditionally used as folk medicine.
- **D9** discloses the anti-asthmatic activity of the alcoholic extract of *T. arjuna* bark. The study suggests that the antiasthmatic activity of the bark may be due to the mast cell stabilising effect.

39. Learned counsel for the respondent, during the arguments, had submitted that there is a distinction in the description of “Asthma” in the affidavit of the inventor which is conspicuous by its absence in the CS. The learned counsel argued that as per the affidavit, the invention claimed under the subject application treats five different types of asthma, and such disclosure is not available in the CS. He had further contended that wherefrom the 5 types of asthma have been classified, has neither been evidenced nor documented by the inventor in the CS. In order to appreciate the said contention, it is appropriate to reproduce the relevant para of the affidavit. The same reads thus:-

“6. That asthma is of five types i.e. 1. Maha shwas 2. Urdhva shwas 3. China shwas 4. Tamak shwas and 5. Kshudra shwas.

i. Symptoms of Maha shwas include continuous breathing, blurred vision, facial swelling, constipation, difficulty in urination, stuttering, wheezing sound of breathing.

ii. Symptoms of Urdhva shwas include difficulty in taking deep breaths because of covering of channels of face and entire body by Kaphaa causes acute pain in entire body. Pupils tend to fixate upward, gazing around with wide open eyes, fainting, suffering



with pain, dry mouth, irritability, excessive inhaling than exhaling causing breathlessness.

iii. Symptoms of China shwas include excessive effort required in exhaling breath, entire body aches, difficulty in breathing, flatulence, excessive sweating, fainting, burning sensation around ureter, watery eyes, weakness, panting, redness in one eye, restlessness, dry mouth, change in skin color, mumbling.

iv. Symptoms of Tamak shwas include stiffness in head, by increasing more kaphaa it r causes influenza, abnormal noise in throat, heart pain, patient feels darkness all around and faints, fainting after continuous coughing, pain while discharging phlegm, feels temporary after expelling phlegm, throat pain, discomfort in speaking, reduced sleep, chest pain when lying down, sitting is more comfortable than lying down, sweating on face, frequent dry mouth.

v. Symptoms of Kshudra Shwas include reverse airflow towards upper respiratory tract, this type of asthma is not so painful, does not inflict much pain to the body, and doesn't cause digestive problems.

7. That the present composition, with specific ingredients in specific proportions is effective on all types of aforementioned Asthma. However, if the individual components are chosen or various combinations chosen from these components itself to make various compositions, they are not as effective as the composition being claimed in the present invention. To show that the present composition is more effective and synergistic (resulting in unexpected properties) as compared to any other combination or individual plants, some experiments were conducted and I found out some extraordinary results as elucidated in Annexure A and as below:

- Some less effective compositions found are mentioned as below;
 - a) Only beneficial for stomach, not breathing Sarphooka + Noni + Kali Mirch + Pipal Badi
 - b) Only beneficial for fever Aftimoon + Aijuna + Kali mirch
 - c) Only beneficial for gastric ulcer ' Sarphooka + Kali mirch + Noni
 - d) Only beneficial for Inflammation Saiphooka + Arjuna + Pipal badi

Apart from above compositions, some other compositions were also tested and it was found that such compositions were less effective on various patients as compared the compositions of tire present invention comprising all six components i.e. Sarphooka + Aftimoon + Noni + Arjuna + Kali Mirch + Pipal Badi, which gave best results.”

40. To the said extent, the respondent appears to be correct. Indeed the



appellant in its CS had not disclosed any information regarding 5 different variants of asthma. Besides, even in the affidavit of the inventor, no evidence or documentary proof of such different variants of asthma were submitted. Thus, there being no tangible material or evidence of existence of different types of asthma, the claim now brought forth in the affidavit rightly could not be considered by the learned Controller.

41. Further, the learned counsel for the respondent submitted that the applicant's agent mentioned in their submission that *"the components if used individually or in some other compositions or other forms could result in negative side effects."* However, such information is not disclosed under the CS of the subject application. This aspect was placed before the respondent for the first time by the appellant by way of the affidavit and annexures appended thereto. In this context, it is significant to note that the learned Controller had taken into consideration Formulation IV whereby the appellant disclosed that the said composition may result in adverse effects like enhanced kapha and tridosha. In such circumstances, it was not erroneous on the part of the learned Controller to have concluded that the claimed invention or the composition containing 6 herbs appear to be contrary to public health.

42. The data submitted through the affidavit, under paragraph 8, provides various formulations which consist of combinations of specific ranges of each of the 6 herbs of the subject application alongwith the side effects, if the ratio of ingredients is changed.

43. Paragraphs 8 and 15 of the said affidavit is reproduced as follows:-

"8. That when I tried to alter the ratio/ranges of the components, the compositions were either less effective or had serious side -effects as mentioned below:

"I. Cold:



1. Sarphooka - 70%
2. Noni - 5%
3. Kali mirch-5%
4. Arjuna - 5%
5. Pipal badi - 5%
6. Aftimoon-10%

II. Diarrhea:

1. Aftimoon - 40%
2. Arjuna-15%
3. Kali mirch - 10%
4. Noni-5%
5. Pipal badi - 10%
6. Sarphooka - 20%

III. Itching:

1. Kali mirch - 40%
2. Sarphooka - 25%
3. Aftimoon -10%
4. Aijuna-10%
5. Pipal badi-10%
6. Noni-5%

IV. Increase Kaphaa, increase tridosh

- 1. Sarphooka - 30%**
- 2. Aftimoon-10%**
- 3. Pipal badi - 30%**
- 4. Kali mirch-10%**
- 5. Noni-10%**
- 6. Aijuna-10%**

V. Hypoglycemic effects:

1. Sarphooka - 30%
2. Aftimoon - 5%
3. Pipal badi-10%
4. Kali mirch- 5%
5. Nom-10%
6. Arjuna-40%

VI. Damage of liver and kidney:

1. Sarphooka - 20%
2. Aftimoon-10%
3. Fipal badi - 15%
4. Kali mirch - 10%
5. Noni- 40%
6. Aijima-5%



Thus, it is clear that the compositions with specific ratio/ranges will be effective and if these are altered, there will be side effects and the purpose will be defeated.

15. That I say that the composition was (tied on around-300 individuals, which included children, women and men to represent all age groups and genders and exceptional results were found with the composition of the present invention in that the present composition could show enhanced efficacy over a broad spectrum of group and most importantly without any apparent side effects. In other words, a preliminary survey on 300 patients confirmed safety and efficacy of the claimed formulation.

I. Data of children - Total 37 patients

15 Children symptoms: light fever, dry cough, suffocation, imitation, shortness of breath, loss of appetite, weakness & headache.

Given treatment and cured in 4-5 months

22 Children symptoms: excessive thirst, indigestion, excessive cough, cold, some had constipation, some had diarrhea, difficulty breathing

Given treatment and cured in 5-6 months

II. Data of female - Total 115 patients "

40 patients - Hoarsness in voice, constipation, suffocation, shortness of breath in walking and climbing on stairs, High BP, sleeplessness, anger, excess fat, dry cough, lack of saliva, excess thirst, oedema, inflammation of any part of body, disorder of urination, frequent urination, urinary disorders.

Given treatment and cured in 6 months

75 patients — stress, palpitation when walking & during activity, gastric problem every time, diabetes, BP, cough, cold, congestion in throat, vertigo, discomfort in breathing, nausea, heat in the body not fever, pain in forehead, irritation in head, difficulty in exhale the cough.

Given treatment and cured in 5-6 months

III. Data of male - Total 147 patients

67 patients -symptoms: indigestion, common cold, diabetes, feeling fever all the time, headache and breathlessness, gastric problem, lack of sleep,



tightness in chest and throat, constipation, painful urination, oedema, fatty liver, distention in stomach after food, itching in body.

Given treatment and cured in 6 months

53 patients - symptoms: acidity, nausea, nervousness, liver dysfunction, swelling in feet, hoarseness, difficulty in breathing, shortness of breath after activity, lack of appetite, palpitation any time, frequent urination, excess thirst, sometimes diarrhea and constipation, high BP, pain in body, taking inhaler.

Given treatment and cured in 5-6 months

27 patients - symptoms: fatty liver, shortness of breath, cough, phlegm, headache while wheezing, constipation, excessive thirst, difficulty walking, irritation

Given treatment and cured within 5 months.

44. This Court notes that the only statement in the CS in this regard is in the background of the specifications, which is reproduced as follows:-

“Although a role of herbal treatment of asthma is uncertain because of lack of well controlled scientific studies, the use of traditional or herbal medicines in the whole world has grown substantially over the last few decades. Indian herbs and treatments mentioned in ancient Ayurveda, is one of the oldest medical practices in the world and have benefited patients for thousands of years. The combination of herbs is believed to produce synergistic effects and reduce possible side effects.”

45. Moreover, while the affidavit discloses all the above information, peculiarly, the CS of the present application is silent regarding the side effects/any negative effects of the various combinations of the herbs in the composition. From the above reproduced para, the submission of the respondent that is “in some other compositions or other forms” cannot be determined from the above disclosure from the CS. The formulation IV as reproduced above from the said affidavit have possible side effects as per the given information while falling within the claimed ranges under claim 1 of the subject application.

46. It is important to note that apart from the above reproduced para of



CS of the present application, no other disclosure is mentioned in the description regarding the side effects of changing the proportion or changing the various combinations of herbs. The data filed under affidavit submitted by the appellant clearly shows the negative effects of altering the ratio/ranges of the components.

47. It is important to note that if an applicant files additional data before the Patent Office, the addition of any descriptive material has to be at least implicitly disclosed in the specification.

48. In *AstraZeneca AB & Anr. vs Alkem Laboratories Limited*, CS (COMM) No.410/2020, decided on 02.11.2020, this Court emphasised that the evidence filed after priority date to show technical advance can only be taken into account to confirm the existence of technical effect which is found embedded in the specification in question and which is capable of being understood by a skilled person having common general knowledge and not to consider the same evidence to establish its effect for the first time. There relevant paras are reproduced hereunder:-

“103. The plaintiffs’ argument that post filing data relating to the invention is admissible is based on two grounds.

i. First and foremost, the applicant may not be fully aware of the advances and properties of the subject invention, in this case, the compound DAPA, on the priority date. In this behalf, it is stated that DAPA’s properties for treatment of heart failure came to be known only subsequently.

ii. Second, there is no requirement in law that all properties, advantages, and characteristics should be stated on the filing date of the patent application. In support of their plea, the plaintiffs relied upon Genetics institute, LLC, vs. Novartis vaccines, 655 F.3d 1291 (2011); and Knoll Pharm. Co. vs. Teva Pharms. USA, Inc., 367 F.3d 1381, 1385. It was argued that the plaintiffs had complied with the best code rule as engrafted in Section 10(4) of the Act which is qualified by the expression “known to the applicant”. It was also contended that they had satisfied the examiner on the aspect of inventive step and factually the examiner had raised no such



objection in his examination report of October 2007. The plaintiffs also sought to contend that they met the plausible unknown technical effect test as formulated in *Generics (UK) Limited vs. Yeda Research and Development Company Limited*, (2017) EWHC 2629 (Pat).

104. In this context, I may refer to the judgement in *Generics (UK) Limited vs. Yeda Research and Development Company Limited*, (2017) EWHC 2629 (Pat) cited on behalf of the defendants. In this case, Generics, which was the claimant, sought revocation of a European patent [entitled low-frequency glatiramer acetate therapy] of which the defendant i.e. Yeda was the registered proprietor and a third party [i.e. Teva] was the exclusive licensee. One of the issues which arose for consideration before the Court concerned the lack of inventive step for want of technical contribution and insufficiency.

105. On behalf of Generics, it was contended that the claimed inventions made no technical contribution to the art and, therefore, did not involve inventive steps as summarized in another judgement i.e. *Generics (UK) Ltd vs Yeda Research and Development Co Ltd*, [2013] EWCA Civ 925. Alternatively, it was argued that the technical contribution was insufficient as per principles summarised by Kitchin LJ in *Idenix Pharmaceuticals Inc vs. Gilead Sciences Inc*, [2016] EWCA Civ 1089. The Court after discussing the issue made the following crucial observations.

“197. In case this case goes further, I must briefly address the Defendants' reliance upon evidence which post-dates the priority date of the Patent. It is Signature Not I.A.Verified No. 8826/2020 in CS (COMM) No. 410/2020 & I.A. No. 8859/2020 in CS (COMM) No. Digitally Signed By:VIPIN KUMAR RAI Signing Date:02.11.2020 15:05:16 common ground that such evidence can only be relied upon to confirm the existence of a technical effect which is plausible in the light of the specification and the skilled person's common general knowledge, and not to establish the existence of a technical effect for the first time.”

[Emphasis is mine]

106. **Therefore, what emerges is this: that post priority date evidence which has been furnished in Dr. Washburn's affidavit to show technical advance can only be taken into account to confirm the existence of technical effect which is found embedded in the specification of IN 625 and is capable of being understood by a skilled person having common general knowledge and not to rely upon the same to establish its effect for the first time.**

107. The plaintiffs have not been able to demonstrate, at least at this



stage, the existence of such technical effect in the specifications. The plaintiffs' argument that the examiner should have been conscious of the inventive step objection or that evidence of technical advance could be placed before the Court even at this juncture fails to take into account the plain language of Section 64(1)(f) read with Section 2 (1)(ja) of the Act. The defendants are entitled, as noted above, to submit, in support of their challenge, that there is no demonstrable technical advance as on the date of priority of IN 625. ”

(Emphasis supplied)

49. Since the examples contained in the CS have various issues, considering the data/information submitted by way of the affidavit and annexures appended thereto would amount to establishment of the effect for the first time as the information disclosed in the affidavit has no reference at all in the CS.

50. In view of the above ratio and having regard to the fact that the CS is silent regarding the negative effects of the composition in case the ratio of ingredients in the composition is changed, the data provided under paragraph 8 of Annexure 1 of the affidavit submitted by the appellant cannot be permitted to be taken into consideration and has rightly been rejected by the respondent.

51. On the other hand, the appellant relied on ***Bayer Pharm Aktiengesellschaft vs. The Controller General of Patents and Designs***, C.A.(COMM.IPD-PAT) 255/2022, decided on 13.03.2024 by this Court to submit that working examples are required to demonstrate the feasibility and workability of an invention and they do not define the patent's scope.

52. However, it is important to note that the example provided by the appellant shows that the examples do not support the claimed invention, as the claims contain 6 ingredients to produce the synergistic effect, while the data contains examples of 4 ingredients and shows synergy. In effect, it would mean that the claimed invention, as claimed under claim 1



comprising 6 ingredients claimed to be therapeutic, is in conflict with the CS. The Examples 4, 5 and 6 are reproduced as follows:-

“Example 4

A person was administered 1 g of the composition (any of composition a., b. c. d. or e.) along with warm water, twice a day for a period of six months. The morning dose was administered half an hour before breakfast and the evening dose an hour after dinner. The person was found to get significant relief from asthma.

Example 5

A person was administered 1 g of the composition (composition e.) along with warm water, twice a day for a period of seven months. The morning dose was administered half an hour after breakfast and the evening dose an hour after dinner. The person was found to get significant relief from asthma.

Example 6

A person was administered 1 g of the composition (composition f.) along with warm water, twice a day for a period of seven months. The morning dose was administered half an hour after breakfast and the evening dose an hour after dinner. The person was found to get significant relief from asthma.”

53. The composition (f.) under Example 6, has 4 ingredients only and it still results in significant relief from asthma. In view of the above discussed reasoning of non-acceptance of data provided under the affidavit and issues discussed regarding the examples of the CS, we hold that the present invention lacks the inventive step under Section 2(1)(ja) of the Act. In the absence of synergy and motivation from the cited prior arts, specifically D6, D7 and D10, to add/combine 2 or more ingredients, the inventive step is not established. The subject application is also not an invention under Section 2(1)(j) of the Act as the invention is disclosed under the cited prior arts D1 to D10 and other combinations of 4-5 compounds also show the synergy like the claimed composition of 6 compounds.

54. Further, the examples under the CS do not support the claim of the present invention in terms of the duration of treatment. The CS of the



subject invention discloses 5 compositions consisting of all 6 herbs. The concentration of each herb in each composition is different. As per the clinical study data, the duration of treatment is in the range of 3 months to 8 months, irrespective of the type of composition. For instance, under Example 1, it is administered twice a day for a period of three months, where the morning dose is administered half an hour before breakfast and the evening dose an hour after dinner.

55. Therefore, from the said data in the CS of the subject application, it can be stated that different proportions of the herbs show the same efficiency within the same duration of treatment.

56. In the absence of the synergy of the compound under the claimed composition, the present invention lacks an inventive step as per the definition of Section 2(1)(ja) of the Act.

57. Therefore, the invention claimed under the subject application does not constitute an invention under Section 2(1)(j) of the Act.

OBJECTION ON THE GROUND OF SECTION 3(p) OF THE ACT:

58. As per the impugned order, the subject application is not allowed under Section 3(p) of the Act as well.

59. Section 3(p) of the Act is reproduced as follows:-

“(p) an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.”

60. The TK guidelines under principle 2 state that the combination of plants with already known therapeutic effects with further plants with the same known therapeutic agents is considered to be an obvious combination if all plants are previously known for treating the same disease. Similarly, the guiding principle 4 states that discovering the optimum/workable ranges of traditionally known ingredients by routine experimentation is not



inventive. The principles 2 and 4 of the TK Guidelines are reproduced as follows:-

“Guiding Principle 2: Combination of plants with known-therapeutic effect with further plants with the same known-therapeutic agents wherein all plants are previously known for treating the same disease is considered to be an obvious combination.

Guiding Principle 4: Discovering the Optimum or Workable Ranges of Traditionally known ingredients by Routine experimentation is not inventive.”

61. Since all 6 ingredients are previously known for treating the same disease, the present invention is an obvious combination as per the Guiding Principle 2. Additionally, as per guiding principle 4, discovering the optimum/workable ranges of traditionally known ingredients through Routine experimentation is also not inventive.

62. Thus, applying the scheme provided in the aforesaid Guiding Principle no.2 and 4 to the facts of the claimed invention and considering the absence of synergy as discussed earlier, it appears that the combination of the ingredients present therein are already known for their treatment of asthma and adding further ingredients with same known effects would fall foul of Section 3(p) of the Act. Therefore, the subject application is not patentable under Section 3(p) of the Act.

OBJECTION UNDER SECTION 10(4)(a) and (b) OF THE ACT:

63. To address the objection under Section 10(4)(a) and (b) of the Act, the appellant has relied on the data submitted by way of the affidavit. As discussed above, the data submitted by way of affidavit has been held to be unacceptable above and therefore, additional information/data provided by the appellant cannot be considered to overcome the objection under Section 10(4)(a) and (b) of the Act.



64. In view of the issues regarding the CS discussed above, the rejection of the data submitted through the affidavit and considering the abovementioned judgement in *AstraZeneca AB (supra)*, the CS is not fully and particularly disclosing the claimed invention as required under Section 10(4)(a) of the Act. Additionally, the present invention also fails to disclose the best method of performing the invention as required under Section 10(4)(b) of the Act.

65. Accordingly, as a result of the above analysis, the appeal fails and is dismissed alongwith pending applications, if any. No costs.

TUSHAR RAO GEDELA
(JUDGE)

JUNE 22, 2026/Sumit/rl