



2026:DHC:147



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

% Judgment delivered on: 09.01.2026

+ **C.A.(COMM.IPD-PAT) 423/2022**

STEIGERWALD ARZNEIMITTLEWERK GMBH Appellant

versus

**ASSISTANT CONTROLLER OF PATENTS AND
DESIGNS**

.....Respondent

Advocates who appeared in this case

For the Appellant : Ms. Vaishali Joshi, Mr. Ankush Verma and
Mr. Debashish Banerjee, Advocates.

For the Respondent : Mr. Arnav Kumar, Mr. Adit Garg and Ms.
Manya Gupta, Advocates.

**CORAM:
HON'BLE MR. JUSTICE TEJAS KARIA**

JUDGMENT

TEJAS KARIA, J

INTRODUCTION

1. The present Appeal is filed under Section 117A of the Patents Act, 1907 (“**Act**”) read with Section 151 of the Code of Civil Procedure, 1908 against the order dated 25.07.2017 (“**Impugned Order**”) whereby the Assistant Controller of Patents and Designs (“**Respondent / Controller**”) refused to grant the patent on the ground of lack of novelty and inventive step as required under Section 2(1)(j) of the Act.



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FACTUAL MATRIX

2. The Indian Patent Application No. 1285/DEL/2009 titled as *“METHOD FOR THE PRODUCTION OF A PLANT-BASED MEDICAMENT”* was filed on 23.06.2009 (**“Subject Application”**).
3. The Subject Application relates to a method for the production of a plant-based medicament which contains *Iberis amara*, *Menthae piperitae folium*, *Matricariae flos*, *Carvi fructus*, *Melissae folium*, *Angelicae radix*, *Liquiritiae radix*, *Cardui mariae fructus* and *Chelidonii herba* in the form of alcoholic extracts and a medicament produced according to this method, and its use (**“Suit Patent”**).
4. The Respondent issued a First Examination Report dated 27.07.2015 (**“FER”**) in the Subject Application. The main objection raised in the FER was that the claims do not have an inventive step in view of cited prior art including Kroll et al. *Phytomedicine*, 2006, 13, 12-19 (**“D1”**), WO1993002688A1 US7985433B2 (**“D2”**), Khardmaanaj (**“D3”**), Nuskha-e-sharbat (**“D4”**), Rasabandhana (**“D5”**) and Madhuyasti Guna (**“D6”**).
5. The Appellant submitted a detailed response to the FER on 11.07.2016 (**“Reply”**) wherein how the present invention was completely different from that disclosed by the cited prior arts. Despite a detailed Reply, the Respondent maintained their objections of lack of inventive step under Section 2(1)(j) of the Act and invention being contrary to the provisions under Sections 3(d), 3(e) and 3(p) of the Act.
6. The Respondent issued a hearing notice dated 02.03.2017 (**“Hearing Notice”**) scheduling a hearing on 07.04.2017 (**“Hearing”**) under Section 15 of the Act to resolve the objections raised in the Hearing Notice. During the Hearing, the Appellant advanced their submissions in response to all the



objections raised by the Respondent and submitted the post-hearing written submissions on 24.04.2017. During the Hearing, the Appellant was directed to take the approval of the National Biodiversity Authority for filing the Subject Application for the present invention. Accordingly, the Appellant filed the application for approval of the National Biodiversity Authority for filing the Subject Application for the present invention on 21.04.2017.

7. Thereafter, the Respondent *vide* the Impugned Order refused the grant of the Suit Patent under the Subject Application on the grounds of lack of novelty and inventive step, as required under Section 2(1)(j) of the Act.

SUBMISSIONS ON BEHALF OF THE APPELLANT

8. The learned Counsel for the Appellant submitted that:

8.1. Iberogast is a plant-based medicament (herbal combination preparation, phytopharmaceutical product), which is used for the treatment of functional dyspepsia and in gastrointestinal multi-target therapy. It has proved to be problematic to obtain a constant effective substance content in the finished medicament Iberogast and to obtain a consistent, reproducible quality. Corresponding investigations with regard to the pharmaceutical development indicated precipitations / crystal formation in the extract of angelica root, which led to inhomogeneities in the production batch and consequently led to unacceptable fluctuations of the osthol content (“**Lead Substance**”). On one hand, the recovery rate of the osthol content increased in the first weeks after the first analysis in clear-filtered solutions, and on the other hand, the total content decreased in production batches in accordance with the sediment formation. It was, therefore, an object of the present



invention to make possible a constant effective substance content in the finished medicament with a consistent, reproducible quality in the final package over a longer period. This problem was solved by a method to produce a plant-based medicament according to Claim 1 of the Subject Application.

- 8.2. The Respondent has failed to appreciate that the novel and inventive technical features of the claimed method have been characterized over the prior art. It is totally unclear as to how and / or why the characterizing feature of Claim 1 is obvious in view of the cited prior art documents. This clearly demonstrates that the Impugned Order is a non-speaking order, which has been passed without an understanding of the gist of the present invention.
- 8.3. The present invention is inventive over D1 since D1 does not indicate a defined specific mixing sequence. Furthermore, it is only briefly mentioned that the right mixing sequence would be essential but no further indications regarding the mixing sequence are disclosed. D1 mentions several potentially relevant factors such as duration of mixing, time of storage, and filtration. D2 also does not disclose the exact composition of the present invention and the pre-mixture *Liquiritiae radix* extract stabilizes *Angelicae radix* extract as well as the complete extract mixture is a unique, novel composition leading to high stable recovery of the Lead Substance. D3 to D6 disclose individual components that are known for their medicinal properties. However, the present invention's composition is completely unique and possesses superior properties in comparison to the disclosed prior arts.



Cited documents	Present invention
D1 and D2 do not indicate a defined specific mixing sequence. Only an arbitrary sequence of the individual components is mentioned.	Sequence of mixing is crucial. When considering liquid extracts of nine (9) plants, there is already, from a statistical viewpoint, a huge plurality of mixing options. Thus, unpredictable and incalculable interaction options are possible. The present invention is based on extensive research related to liquid plant extracts, especially to highly complex mixtures from different plants having different active ingredients. This results in a suitable mixing sequence, which enables a recovery of the lead substances of the individual extracts and which ensures the required stability and guarantees the efficacy as well as the harmlessness for later use as a medicament.
D1 and D2 do not disclose or make obvious a special mixing sequence or a pre-mixture. It only briefly mentions that right mixing sequence would be essential but no further indications regarding the mixing sequence are disclosed.	The accurate compliance with the right mixing order is essential to get a stable product with defined recovery rates of the lead substance. Especially, the premixture of Liquiritiae radix extract and Angelicae radix extract as mentioned in claim 1 is of high importance.
	Simple testing in order to find a suitable mixing sequence of nine extracts would result in 9! combinations, i.e., 362880 different combinations. When additionally considering pre mixing – still more options would be available. This is very extensive and does not lie within what an expert would routinely test. Accordingly, claim 1 is novel and inventive when compared to cited prior art D1 and



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	D2.
D3 - Carum Carvi Linn - Known for Medical use; D4 - Melissa Officinalis Linn- Used for Black Bile Treatment; D5 - Angelica Gluca - Formulated as Unstable solidified compound of Mercury - Used in different formulations of Mica/Biotite; and D6 - Glycyrrhiza glabra Linn - Used in treatment of Polydipsia/Excessive thirst - Vomitting/Emesis.	1) Present invention claims a method to make a plant based medicament, which is used for the treatment of functional dyspepsia and gastrointestinal multi-target therapy. It is a combination of 9 plants and herbal drugs – including Carvi Fructus, Melissa Folium, Angelica radix (root). No cited art is claiming a method to produce Iberogast or its mixing sequence. It is pertinent to mention here that the present invention is neither claiming a product or its use for any specific treatment. What is claimed is highly inventive and novel method to produce the medicament. 2) Present invention claims a novel method to produce a medicament – Iberogast, which 5 makes possible a constant effective substance content in the finished medicament with a consistent, reproducible quality in final package over a longer period. The superior effect of the claimed method for combining the plant extracts lies in certain ratios and sequencing. Surprisingly, only the use of production method according to claim 1 emerges as being effective. None of the traditional knowledge teaches or claims in isolation or in combination such sequencing of mixing. 3) The innovative and novel mixing sequence prevents formation of crystal of the ingredients of the herb extracts. Crystal formation affects the batch homogeneity. Therefore, the addition sequence according to the invention ensures a reproducible



	production of the product. 4) The initial mixing of Angelicae radix extract and Liquiritiae radix extract in step a) of claim 1 has surprisingly proved to be suitable. None of the cited traditional knowledge has any such effect or method of producing. D5 (Angelica Gluca) results in unstable solidified compound, thereby demonstrating that the present invention clearly provides a superior and novel effect.
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8.4. The Impugned Order is contrary to the principles laid down in Chapter 9, Paragraph 09.03.03.02 of the **Manual of Patent Office Practice and Procedure**, Version 3.0 dated 29.11.2019 which describes determination of an inventive step. The relevant paragraph is as reproduced hereunder:

“2. Invention as a whole shall be considered. In other words, it is not sufficient to draw the conclusion that a claimed invention is obvious merely because individual parts of the claim taken separately are known or might be found to be obvious.”

8.5. The Respondent has not provided proper reasoning to justify its refusal on the ground of lack of inventive step in the Impugned Order. Thus, the Impugned Order is contrary to the principles laid down in **F. Hoffmann-La Roche Ltd. & Anr v. Cipla Ltd.**, 2015 SCC OnLine Del 13619 and **Agriboard International LLC v. Deputy Controller of Patents and Designs**, 2022 SCC Online Del 940. In **Agriboard International LLC (supra)**, wherein it was held that the Controller has to analyse as to what is the existing knowledge and how the person skilled in the art (“**PSITA**”) would



move from the existing knowledge to the subject invention, captured in the application under consideration. Without such an analysis, the rejection of the patent application under Section 2(1)(ja) of the Act would be contrary to the provision itself. In the present case, the Impugned Order lacks reasoning as to how and / or why the PSITA would be motivated to modify the teachings of the cited prior art documents in order to arrive at the Suit Patent of the present invention.

- 8.6. The Respondent has failed to support its conclusion on lack of inventiveness by showing that a PSITA would have clear motivation to arrive at the present invention based on the cited prior art documents. Thus, the question is not, if the skilled artisan ‘could’ read the invention from the prior art (this constitutes hindsight), the question is ‘would’ the prior art direct him to the invention. In other words, the Respondent has failed to apply the ‘could-would’ approach. Reliance was placed upon the decisions in *F. Hoffmann-La Roche Ltd. & Anr.*, (*supra*) and *Enercon (India) Limited v. Aloys Wobben*, 2013 SCC OnLine IPAB 91 while making the above submission.
- 8.7. The present invention claims a novel method of sequencing and combing extracts which makes possible a constant effective substance content in the finished medicament with a consistent, reproducible quality in a final package over a longer period. When considering liquid extracts of nine plants, there is already, from a statistical viewpoint, a huge plurality of mixing options.



- 8.8. The present invention is based on a suitable mixing sequence, which enables a recovery of the Lead Substance of the individual extracts and which ensures the required stability and guarantees the efficacy as well as the harmlessness for later use as a medicament. Reliance was placed upon Page No. 11 of the Complete Specification. The relevant extract of the Complete Specification is reproduced hereunder:

“the crystal formation is significantly inhibited when the mixture sequence according to the invention is adhered to. Without adhering to this sequence, the content values for osthol lie far outside the permissible tolerance both in the angelica drug extract and also in the finished product, i.e., the recovery of the lead substance osthol did not lie in the range of 95 to 105% of the target value. The batches produced with adherence to the mixture sequence according to the invention no longer had any deviations. Likewise, it can be seen that when the sequence is adhered to, scarcely any crystal formation is to be observed. For example, Fig. 1 and 2 show the batch homogeneity with regard to the examined plant ingredient (osthol) with an arbitrary sequence (Fig. 1) and with the mixture sequence according to the invention of the individual herb extracts in accordance with Examples 1, 2 and 3 (Fig. 2). The examples 1, 2 and 3 according to the invention did not show any appreciable differences, so that a separate representation was dispensed with.”

Thus, the Respondent has failed to comprehend that the claimed method is the one that leads to a constant, reliable level of the Lead Substance in the finished product, while the others do not as shown by the Examples in the Subject Application.

- 8.9. Figure 1 shows the recovery rate of the Lead Substance indicated in % of the target value in the finished product. A recovery rate of 100% means that all osthol, which had been present in the initial



Angelicae radix drug extract, is also present in the finished product. A recovery rate between 95 and 105% is mandatory. Test batches A, B, C and D were all prepared using arbitrary mixing sequences. Only test batch D meets the criteria of having a recovery rate between 95 and 105%. Test batches A, B and C, which were also prepared according to other arbitrary mixing sequences fail. Figure 1 is reproduced hereunder:

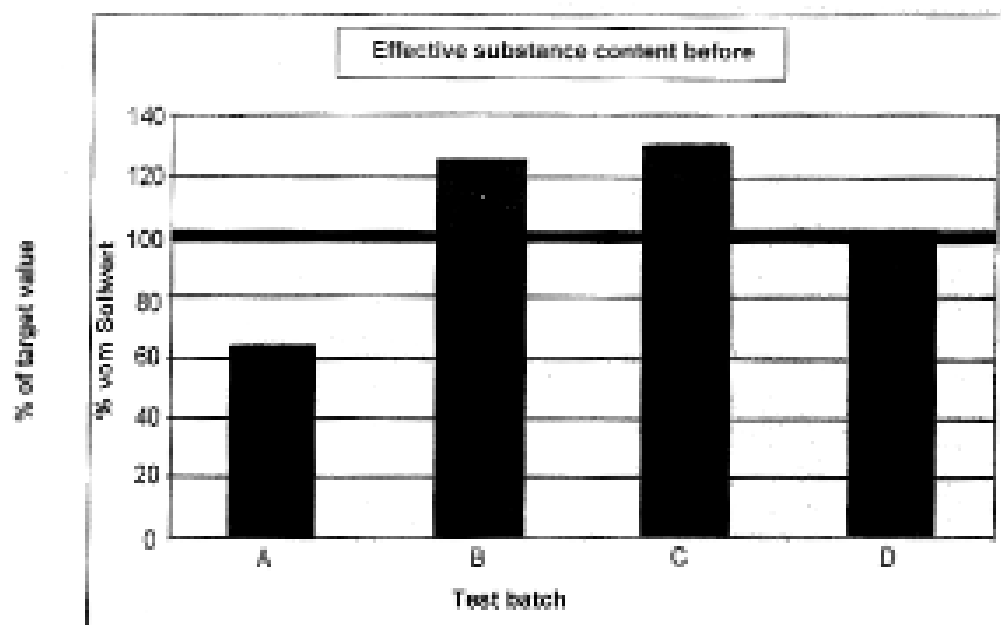


Fig. 1

8.10. In Figure 2, all six batches, which are graphically represented were prepared according to Example 1, i.e., according to the mixing sequence A. All batches meet the criteria of having a recovery rate between 95 and 105%. The same results were obtained using a mixing sequence according to Example 2



(sequence B) and according to Example 3 (sequence C). Thus, the results of Examples 2 and 3 were not represented separately. It bears mentioning that in respect of a method / process, Section 3(d) of the Act precludes patentability of “...*the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.*” Figure 2 is reproduced hereunder:

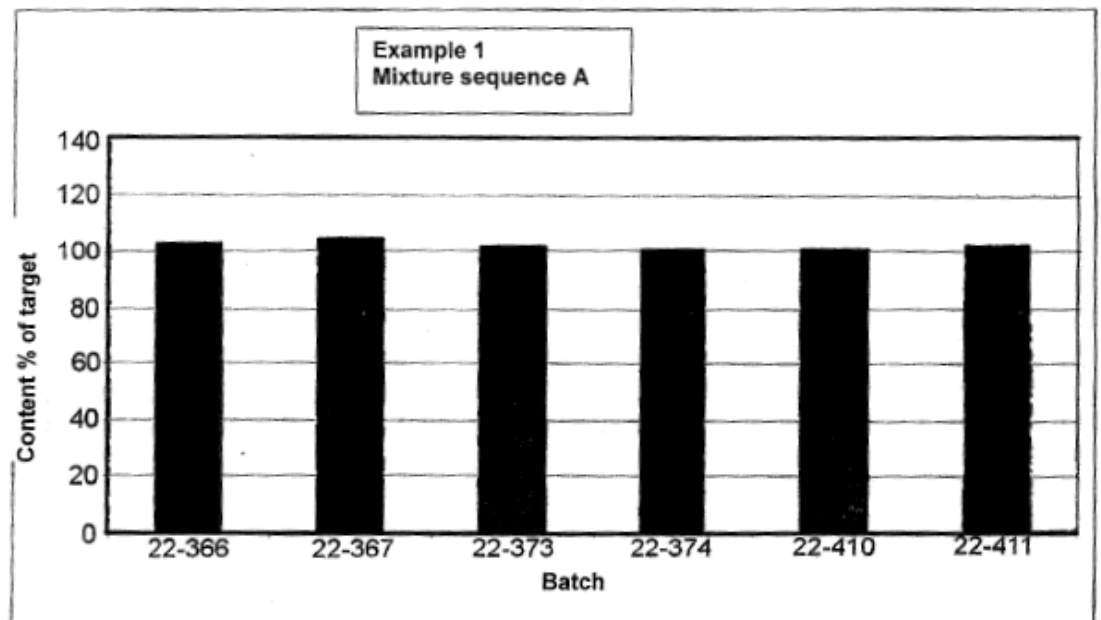


Fig. 2

Therefore, the process ought to be ‘known’ and the Respondent has failed to identify even a single reference that would render the claimed method as ‘known’ under Section 3(d) of the Act. In this regard, reliance was placed upon the decision in ***D.S. Biopharma Limited v. The Controller of Patents & Designs***, 2022 SCC OnLine Del 3211. Moreover, the Respondent acknowledged the novelty of the claimed method during the prosecution stage and



therefore, the provisions of Section 3(d) of the Act are not applicable in the present case.

- 8.11. The present invention does not relate to merely an admixture of nine plant extracts / drugs resulting in aggregation of properties. The superior effect of the claimed method for combining the plant extracts lies in certain ratios and sequencing. The claimed mixing sequence is not a mere admixture but is critical in achieving a stable and predictable recovery rate of the Lead Substance of between 95 to 105%. The accurate compliance with the right mixing order is essential in order to get a stable product with defined recovery rates of the Lead Substance. Especially, the pre-mixture of *Liquiritiae radix* extract and *Angelicae radix* extract as mentioned in Claim 1 is of high importance. The Respondent's findings are perverse inasmuch as the claimed method can neither be considered to be a mere admixture nor a process for producing an admixture, as envisaged in Section 3(e) of the Act.
- 8.12. Corresponding applications in major jurisdictions / groups of countries, *inter alia*, USA, Europe, Japan, South Korea, Australia etc. have proceeded to be granted further affirming the patentability of the amended set of claims as mentioned in the Subject Application.
- 8.13. Accordingly, the Impugned Order is liable to be set aside and the Suit Patent under the Subject Application shall be granted.



SUBMISSIONS ON BEHALF OF THE RESPONDENT

9. The learned Counsel for the Respondent submitted that:

- 9.1. The ingredients in the prior art, especially, D1 and D2 were identical and that the Suit Patent is primarily claimed in respect of the sequence of mixing of ingredients.
- 9.2. The present invention discloses a mixture of herbs in exactly the same proportions as is disclosed in D1. The compositions as stated in both the documents are set out hereunder:

<i>Composition as per the present invention</i>	<i>Composition as per the prior art document D1</i>
15 to 40 vol. % <i>Iberis amara</i>	Ethanollic extract (extracting agent: ethanol 50% (v/v)) of fresh plants of Bitter candytuft (<i>Iberis amara</i>) (1:1.5-2.5) – 15.0 ml
5 to 30 vol. % <i>Angelicae radix</i>	Ethanollic extract (extracting agent: ethanol 30% (v/v)) of Angelica root (<i>Angelicae radix</i>) (1:2.5-3.5) – 10.0 ml
20 to 40 vol. % <i>Matricariae flos</i>	Chamomile flower (<i>Matricariae flos</i>) (1:2-4) – 20.0 ml
10 to 30 vol. % <i>Carvi fructus</i>	Caraway fruit (<i>Carvi fructus</i>) (1:2.5-3.5) – 10.0 ml
5 to 30 vol. % <i>Cardui mariani fructus</i>	Milk thistle fruit (<i>Silybi mariani fructus</i>) (1:2.5-3.5) – 10.0 ml
10 to 30 vol. % <i>Melissae folium</i>	Balm leaf (<i>Melissae folium</i>) (1:2.5-3.5) – 10.0 ml
5 to 30 vol. % <i>Menthae piperitae folium</i>	Peppermint leaf (<i>Menthae piperitae folium</i>) (1:2.5-3.5) – 5.0 ml
5 to 10 vol. % <i>Chelidonii herba</i>	Celandine herb (<i>Chelidonii herba</i>) (1:2.5-3.5) – 10.0 ml
10 to 30 vol. % <i>Liquiritiae radix</i>	Liquorice root (<i>Liquiritiae radix</i>) (1:2.5-3.5) – 10.0 ml

In view of the above comparison, it is clear that the proportion of herbs used in the present invention is similar to that of D1, hence,



it would make the present invention obvious to a PSITA. In view of the same, the present invention is non-patentable as per Section 2(1)(j) of the Act.

- 9.3. As far as the need of a right sequence of mixing is concerned, D1 already teaches that the right sequence of mixing is necessary for better quality of finished product. This is enough motivation for a PSITA to come up with the right sequence of mixing. The present invention fails to disclose any data to show that it is technically advanced over D1. The Appellant is applying a problem-solving approach to claim inventiveness; however, it fails to produce any comparative data to establish technical advancement over D1.
- 9.4. D2 specifically discloses all the ingredients and various other parameters leading to a highly purified product and use of the same for the treatment of exactly similar disease or illness. D2 discloses medicament comprising, in the form of the ethanolic plant extract, about 15 to 40% by volume of *Iberis amara*, 10 to 30% by volume of *Menthae piperitae*, 20 to 40% by volume of *Matricariae*, 10 to 30% by volume of *Carvi fructus*, 10 to 30% by volume of *Melissae folium*, 10 to 30% by volume of *Liquiritiae radix*. The sequence of mixing as claimed by the Appellant has already been disclosed by D2. On a mere comparison of claims of D2 and the present invention, it becomes clear that the present invention is almost identical to D2.
- 9.5. D3 to D6 define the herbs separately, but these prior arts clearly teach that the use of these herbs and their extracts in medicine were traditionally known since ages. The medicament produced



by way of the process / method disclosed in the present invention is also used in treating similar type of disorders like functional dyspepsia and gastrointestinal multi-target therapy. Therefore, as far as the therapeutic use of the medicament is concerned, the present invention discloses no new or inventive use in view of the prior art cited documents.

- 9.6. The problem statement before the present invention is, *“precipitations/crystal formation in the extract of Angelica root, which lead to inhomogeneities in the production batch and consequently led to unacceptable fluctuations of the osthol content (lead substance)”*. In order to solve this problem, the present invention proposes a sequence of mixing wherein a pre-mixture of two herbs i.e., Angelicae radix extract and Liquiritiae radix extract (1:1 or 1:2) is mixed with the extracts of other herbs. Reliance was placed upon Table Nos. 1 and 2, forming part of both the documents i.e., present invention and D2, reveal that the crystals upto the size of 2 μ m is still forming. As far as the Lead Substance is concerned, the mixture in Example 1 is simply compared with some random mixtures as shown in Figures 1 and 2. The present invention merely discloses the problem without showing any significant comparative result for crystal formation or osthol content when compared with D1 and D2. The present invention fails to disclose the problem in the D1 and D2 and how the present invention is an advancement over D1 and D2. In view of the above, the present invention lacks inventiveness as per Section 2(1)(j) of the Act. Reliance was placed upon the decision in *Avery*



Dennison Corporation v. Controller of Patents and Designs, 2022 SCC Online Del 3659 while making the above submission wherein the Court had laid down tests for inventive step / lack of obviousness.

9.7. The Appellant does not claim the medicament itself, what is claimed is the process or method of producing this medicament. The medicament i.e., Iberogast, neither in its ingredients nor in its use, is new or inventive in any manner. The Appellant has to show how the claimed process or method yields better results in comparison with D1 and D2. Mere change in ways of mixing few ingredients cannot be inventive if it does not solve the problem of the prior arts or makes the product more efficacious in comparison. Even the sequence of mixing the ingredients is not inventive as it has been disclosed in D1 and D2 and any PSITA has the motivation to come up with the method or process of the present invention with a reasonable chance of success. To determine the obviousness, there must be a clear coherent thread from the prior arts to the invention. The coherent thread should lead from the prior art to the invention, suggesting a logical and foreseeable progression of technology or methodology. Reliance was placed upon the following decisions while making the above submission:

- a. *Bishwanath Prasad v. Hindustan Metal Industries*, (1979) 2 SCC 511
- b. *Novartis AG v. Union of India & Ors.*, (2013) 6 SCC 1



- c. *F. Hoffmann-LA Roche Ltd. & Anr. v. Cipla Limited*, 2012 SCC OnLine Del 4704
- d. *Enercon (India) Limited* (*supra*)
- e. *Alimentary Health Limited v. Controller of Patents and Designs*, 2024 SCC OnLine Del 3473
- f. *3M Innovation Properties Lid. & Anr. v. Venus Safety & Health Pvt. Ltd.*, 2016 SCC OnLine Del 5232

9.8. It is claimed by the Appellant that the novelty and inventiveness of present invention lie in the method to produce the medicament i.e., the novel mixing sequence which prevents formation of crystal of the ingredients of herb extracts. It was submitted by the Appellant that the crystal formation affects the batch homogeneity and that a suitable mixing sequence enables a recovery of the Lead Substance of the individual extracts, which ensures the required stability which makes the medicament harmless and effective for later use. However, the Appellant has failed to demonstrate that the present invention is in any manner superior than D1 or D2, in terms of reduced crystal formation or recovery of the Lead Substance.

9.9. The Appellant submitted that Section 3(d) of the Act is not applicable to the present invention as it is a method or process of mixing and it does not amount to 'new form of a known substance'. The scope of Section 3(d) of the Act cannot be restricted to product patents only. The proposition submitted by the Appellant that a new substance which lacks efficacy is not patentable under Section 3(d) of the Act but the method of



producing such substance is not hit by Section 3(d) of the Act. A new method is also required to pass the test of efficacy laid down in Section 3(d) of the Act. Reliance was placed upon the decisions in *Novartis AG (supra)*, *Zeria Pharmaceutical Co. Ltd. v. Controller of Patents and Designs*, 2025 SCC OnLine Del 4015 and *Chugai Seiyaku Kabushiki Kaisha v. Controller of Patents*, Neutral Citation: 2022:DHC:1337 while making the above submission.

9.10. The present invention is a mixture of nine plant extracts. The individual components of the mixture and its medicinal value is well known in the art even the volume or composition of each component has already been disclosed in D1 and D2. The alleged novel sequence of mixing is neither new nor inventive. The Appellant has failed to demonstrate any synergistic effect of the present invention, which is more than the mere aggregation of the properties of its components. The superior effect rendered by the method of combining the plant extracts in certain sequence, as claimed by the Appellant, lacks support from the disclosure in the Complete Specification of the Subject Application as no significant data is provided to explain how the method or process is not merely an admixture.

9.11. The contention of the Appellant that the present invention is a method or a process and hence, beyond the scope of Section 3(e) of the Act is also not sustainable. Section 3(e) of the Act clearly stated that a '*process of producing such substance*' which is merely an admixture is also not patentable. The Complete



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Specification does not provide any data to substantiate that the process or method renders any synergistic effect. In the absence of such data, the present invention is a merely a process of producing an admixture that only results in the aggregation of the properties of the known substances. In absence of data showing enhanced technical effect over the technical effect of individual components, the present invention is nothing but a mere admixture and therefore, cannot be patented under Section 3(e) of the Act. Reliance was placed upon the decision in *Stempeutics Research Pvt. Ltd. v. Assistant Controller of Patent & Designs*, 2020 SCC OnLine IPAB 16 and the Chapter 9, Paragraph 09.03.05.05, *Manual of Patent Office* (*supra*).

9.12. The Appellant submitted that the Subject Application has been granted in major jurisdictions / group of countries but once the patent application enters the domestic phase, various national patent offices examine the application in terms of the substantive and procedural laws of the respective country. Patent rights are territorial in nature, and are limited to the country of grant. Broadly speaking, in order for grant of a patent, the three tests of novelty, inventive step and industrial applicability have to be satisfied. However, there are several nuanced and intricate dimensions to these three tests, in each and every jurisdiction. Apart from the substantive law of a country, the patent prosecution practices of various patent offices are also different. Finally, the subjective satisfaction of each patent examiner in a jurisdiction would also be different. Reliance was placed upon the decision in



Communication Components Antenna v. ACE Technologies Corp. & Ors., 2019 SCC OnLine Del 9123 while making the above submission.

9.13. In view of the above, the Impugned Order shall be upheld and the Appeal is liable to be dismissed.

ANALYSIS AND FINDINGS

10. The present invention relates to a method for the production of a plant-based medicament containing *Iberis amara*, *Menthae piperitae folium*, *Matricariae flos*, *Carvi fructus*, *Mellissae folium*, *Angelicae radix*, *Liquiritiae radix*, *Cardui mariae fructus* and *Chelidonii herba* in alcoholic extracts form and a medicament produced by this method. Iberogast is a plant-based medicament that is used for the treatment of functional dyspepsia and in gastrointestinal multi-target therapy. Iberogast has both a tonus increasing effect in relaxed smooth musculature and also has a spasmolytic effect in paroxysmal states of the smooth musculature.

11. In the prior art documents, it was problematic to obtain a constant effective substance content in the finished medicament, Iberogast and to obtain a consistent, reproducible quality.

12. As per the summary of the Complete Specification, the object of the present invention is to make possible a constant effective substance content in the finished medicament with a consistent, reproducible quality in the final package over a longer period of time.

13. The present invention solves this problem by a method for the production of a plant-based medicament according to Claim 1. The present invention claims a method for the production of a plant-based medicament containing *Iberis amara*, *Menthae piperitae folium*, *Matricariae flos*, *Carvi*



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fructus, Mellissae folium, Angelicae radix, Liquiritiae radix, Cardui mariae fructus and Chelidonii herba in the form of alcoholic extracts.

14. Claims 1 and 2 of the present invention claims the method through the three following steps:

- a. Step (A) mixes Angelicae radix and Liquiritiae radix extracts in a defined volume ratio of 1:6-3:1.
- b. Step (B), this mixture is combined with another mixture containing Iberis amara, Matricariae flos and Carvi fructus.
- c. Step (C), the additional extracts of Cardui mariae fructus, Menthae piperitae folium, Melissa folium and Chelidonii herba are added.

15. In Step (A), Liquiritiae radix extract and Angelicae radix extract are mixed together in a volume ratio of 1:6 to 3:1 and then in at least one further step the mixture of Step (A) is added together with the extracts of the other ingredients or mixtures containing them, that are produced separately and if applicable once again contain Liquiritiae radix.

16. As per the Complete Specification of the Subject Application, crucial factor that solves the problem of prior art here is the sequence of additions of the individual drug extracts. A preferred variant of the method for the production of a plant-based medicament is characterized in that in Step (B), a mixture is produced which contain extracts of Matricariae flos, Iberis amara and Carvi fructus. Thereafter, the mixture of Step (A) is added to this and in Step (C), extracts of Cardui mariae fructus, Menthae piperitae folium, Melissa folium and Chelidonii herba are added. The abovementioned mixing sequence prevents the formation of crystals of the ingredients of the herb extracts. The crystal formation affects the batch homogeneity and



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therefore, according to the present invention the addition sequence ensures a reproducible production of the product. The mixing sequence (addition sequence) prevents the formation of crystals of the ingredients (secondary plant substances) of the herb extracts. The detailed description of the Complete Specification further states that the crystal formation is significantly inhibited when the mixture sequence according to the invention is adhered to.

17. The Impugned Order mainly focuses on cited documents D1 and D2 and states that if the process disclosed in D2 is studied along with D1, it would render the present invention obvious for a PSITA. The following reasoning was given by the learned Controller for the rejection of the Subject Application:

“While considering D1, which clearly states the use of a herbal multi-component preparation used in multi-target therapy. The pharmaceutical prerequisites of D1 has all components and for their combination, as is exemplified by Iberogast® (STW 5) a fixed combination of hydroethanolic extracts of bitter candytuft (Iberis amara), angelica root (Angelicae radix), milk thistle fruit (Silybi mariani fructus), celandine herb (Chelidonii herba), caraway fruit (Carvi fructus), liquorice root (Liquiritiae radix), peppermint herb (Menthae piperitae folium), balm leaf (Melissae folium) and chamomile flower (Matricariae flos) for use in the therapy of gastrointestinal complaints. All of these are Ethanolic extract (extracting agent: ethanol 50% (v/v)) of fresh plants and special measures were taken so that only drugs of a high quality level are used, which is a precondition for the production of standardized drug preparations complying with the quality requirements.

Here, in D1 all the components except one Cardui mariae fructus are disclosed that in too in highly purified form and also maintaining the high standards of purity in the form of ethanolic extracts which are similar to the present invention, makes the present invention obvious for the person skilled in the art as the purpose of using /application of this medicament is also similar.

In D1, Page 15 Para 2 of ‘Manufacturing and quality of the finished



Product' For the better quality of the finished product, the right sequence of mixture, the mixing time (30 min), the interim storage (2 weeks) and the filtration (sterile filter) are essential for avoiding unwanted reactions between the different extracts (for example major precipitations) and for ensuring stability.

Thus, in this invention by merely stating process steps of mixing different extracts, which are already clearly stated in prior art, without any significant data to show enhanced efficacy of the medicament when given to a patient/any other data showing higher stability lacks inventive step.

Similarly in case of D2 (which is a prior publication of same applicant), all the ingredients and various other parameters and factors leading to highly purified product and use of the same for the treatment of exactly similar disease makes the whole process if studied along with the D1 disclosure obvious for the person skilled in the art.

Whereas in case of D3-D6, Carum carvi, Melissa officinalis, Angelica glauca and Glycyrrhiza glabra are disclosed ,although these are defined separately ,therefore , are not much relevance to that of process claimed, but the use of these plants and their extracts in medicine is traditionally known since ages, specifically of Glycyrrhiza glabra in Strength promoting, Pittadosa alleviating and Melissa Officinalis as used for Black Bile Treatment(Ref-present invention being used for the treatment of functional dyspepsia and gastrointestinal multi-target therapy, similar types of disorders)

The applicant states that the present invention is neither claiming a product or its use for any specific treatment. What is claimed is highly inventive and novel method to produce the medicament. Also, constant effective substance content in the finished medicament with a consistent, reproducible quality in final package over a longer period. It is surprising and superior effect of claimed method for combining the plant extracts in certain rations and sequencing. Surprisingly only the use of production method according to Claim 1 emerges as being effective. None of the traditional knowledge teaches or claims in isolation or in combination such sequencing of mixing. The innovative and novel mixing sequence prevents formation of crystal of the ingredients of the herb extracts. Crystal formation affects the batch homogeneity. The present invention is



based on extensive research related to liquid plant extracts, especially to highly complex mixtures from different plants having different active ingredients. This results in a suitable mixing sequence, which enables a recovery of the lead substances of the individual extracts and which ensures the required stability and guarantees the effectiveness as well as the harmlessness for use as medicament.

But D1 clearly states at Page 15 Para 2 'Manufacturing and quality of the finished Product'

For the better quality of the finished product, the right sequence of mixture, the mixing time (30 min), the interim storage (2 weeks) and the filtration (sterile filter) are essential for avoiding unwanted reactions between the different extracts (for example major precipitations) and for ensuring stability.

Therefore, if such disclosure is there then a person skilled in the art has enough motivation to try and test various steps of mixing the known ingredients for better results in terms of stability and effectiveness. Hence, when all the ingredients are well documented in the prior art (D2) to the level of specific ratios and percentages of all the ingredients being exactly similar as documented in D1 and D2, and also the clear motivation in D1 to use a process step where mixing different ingredients in specific manner for better stability, present invention is not patentable u/s 3(d) of the act.

Applicant's submission stating that efficacy of method of production through the present invention has been further demonstrated through examples 1, 2, 3 provided in detailed specifications (Page 12-15).

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Here, one important point is to be noted that the in Ex-1 and Ex-2 the pre-mixtures is exactly the same in terms of ingredients and ratios and in Ex-3 only ratio differs, hence where are the process steps/manner which are affecting the production and stability of the final product?



If we study Table-1 and 2 for the results then also, size of crystal formation after 2 weeks and after 6 weeks is more or less similar in all the three cases, Approx. 2 μ m.

Thus, the amended claims 1-26 fall under scope of Section 3 (e) of the Patent Act, 1970 as claimed invention and relate to merely admixture of 9 plant extracts/drugs resulting in aggregation of properties.

Also, as claimed that surprising and superior effect of method for combining the plant extracts in certain ratios and sequencing is done, lacks support from the disclosure in complete specification where no significant data is provided to explain how the stated process steps are inventive and non- patentable u/s 3(d & e) of the act.

Since no reference has been cited showing that the claimed process is pre-known as exact teachings of traditional knowledge, therefore the objection raised u/s 3(p) is waived.”

18. The document D1 pertains to the quality of a phytomedicine depends on the quality of its herbs used as raw materials, their manufacturing process, and the characteristics of the final product. The abstract of D1 is reproduced hereunder:

“Abstract

The quality of a phytomedicine is defined by the quality of the herbal drug. the manufacturing of the drug preparations and the properties of the finished product, taking into account the special requirements of the individual herbal species in accordance with Good Manufacturing Practice (GMP) standards [2003. Medicinal Products for Human and Veterinary Use. Eudralex, vol. 4 (2003/94/EC)]. The quality control of the complete process is based on pharmacognostic methods, characteristic fingerprint chromatograms, defined amounts of marker substances, physicochemical characteristics and microbiological monitoring. For a herbal multi-component preparation used in multi-target therapy, these pharmaceutical prerequisites have to be ensured for all components and for their combination, as is exemplified by Iberogastlll (STW 5) a fixed combination of hydroethanolic extracts of bitter candytuft (Iberi3 amara), angelica. root (Angelicae radix),



thistle fruit (Silybi marianifructus), celandine herb (Chelidonii herba), caraway fruit (Carvi fructus), liquorice root (Liquiritiae radix), peppermint herb (Menthae piperitae folium), balm leaf (Melissae folium) and chamomile flower (Matricariae flos) using in the therapy of gastrointestinal compliants (Rosch et al., 2006)."

19. The learned Counsel for the Respondent cited D1 and submitted that the sequence of the mixture and mixing time are already disclosed. Therefore, the Respondent argued that it is obvious for PSITA to reach the sequence and abovementioned three stages claimed in the present invention. The relevant paragraph at Page No. 15 of D1 is reproduced hereunder:

" For the better quality of the finished product, the right sequence of mixture, the mixing time (30 min), the interim storage (2 weeks) and the filtration (sterile filter) are essential for avoiding unwanted reactions between the different extracts (for example major precipitations) and for ensuring stability.

*The identity and quality is secured by tests covering all components of the combination. Tests parameters include TLC fingerprint chromatograms covering all of the polarity range, the appearance (color, clearness), the density, the content of ethanol, the microbiological purity and the content of all nine components by the assay of characteristic marker substances. **The proportion of each component in the final product has to be within a range of 95---105% of the specified content.** The measurement is carried out by validated HPLC or GLC methods. In Fig. 2 the complete manufacturing and quality control scheme is shown."*

20. The learned Counsel for the Respondent referring to the conclusions of D1 argued that it is exactly what the Subject Application claims. The conclusion is reproduced hereunder:

".....Taking together the specified cultivation and processing of the plant parent material, the optimized production process, and the development and use of highly sensitive methods of analysis have led to an unprecedentedly high degree of standardization for the multi-drug product Iberogast® allowing a modern multi-target therapy."



21. Citing the Table No. 1 on Page No. 13 of D1, the learned Counsel for the Appellant submitted that the ratio given in the bracket is not same as the claimed ratio of the Subject Application. The ratio given in Table No. 1 is Ethanolic extract (extracting agent) ethanol 50% of the fresh plant of Bitter candytuft and 30% of ethanol with other ingredients. While in Claim 1 of the Subject Application, the ratio is of Angelicae radix extract and Liquiritiae radix extract which are mixed together in a volume ratio of 1:6 to 3:1. The Table No. 1 of D1 is reproduced hereunder:

Table 1. Composition of Iberogast®

Iberogast® contains in 100 ml

Ethanolic extract (extracting agent: ethanol 50% (v/v)) of fresh plants of

Bitter candytuft (1: 1.5-2.5) 15.0ml

Ethanolic extract (extracting agent: ethanol 30% (v/v)) of

Angelica root (1: 2.5-3.5) 10.0ml

Chamomile flower (1: 2-4) 20.0 ml

Caraway fruit (1: 2.5-3.5) 10.0 ml

Milk thistle fruit (1: 2.5-3.5) 10.0 ml

Balm leaf (1: 2.5-3.5) 10.0 ml

Peppermint leaf (1: 2.5-3.5) 5.0 ml

Celandine herb (1: 2.5-3.5) 10.0 ml

Liquorice root (1: 2.5-3.5) 10.0 ml

22. The cited document D2 pertains to the plant-based medicament having tonicising action on smooth muscular organs which are atonic or have decreased tone.

23. This Court notes that the two prior arts, D1 and D2 does not disclose the exact three step sequence using the specified ration of the ingredients. D1 and D2 also failed to disclose the exact ratio of the Liquiritiae radix extract and Angelicae radix extract that are mixed together in Step (A) of the mixing process.



24. As per the Respondent, the present invention of the Subject Application simply claims the increased stability without presenting any comparative result of crystal formation or osthol content. The sequence of the ingredients is crucial for the achievement of a desirable result. The Respondent relied on the Examples 1 to 3 of the Complete Specification of the Subject Application and submitted that there still is crystallization. The relevant paragraphs of the Complete Specification are reproduced hereunder:

“The osthol content was determined with regard to samples which were produced according to the mixture sequences of Examples 1, 2 and 3. A comparison was made with samples which were based on an arbitrary mixture sequence of the individual herb extracts. The results of the measurements are displayed in Figures 1 (arbitrary mixture sequence, without pre-mixture) and 2 (mixture sequences according to the invention). As can be seen from Fig. 2, the mixture sequence prevents the formation of crystals of the ingredients (secondary plant substances) of the herb extracts. The crystal formation was examined microscopically, wherein the measurements took place after 2 and respectively 6 weeks’ storage. The results are displayed in Tables 1 and 2.

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Table 1: 2 weeks’ storage at room temperature

Example 1	Example 2	Example 3
<i>Sediment light, dark, powdery; supernatant colloidal, very turbid; uniform particles of approx. 2 μm; isolated small crystals up to 2 μm</i>	<i>Sediment thin, dark powdery; supernatant colloidal, very turbid; uniform particles of approx. 2 μm; partly agglomerated; isolated small crystals approx. 1 μm</i>	<i>Sediment thin, dark, powdery; supernatant colloidal, very turbid; uniform particles of approx. 2 μm; a few agglomerates; small crystals</i>



Table 2: 6 weeks' storage at room temperature

<i>Example 1</i>	<i>Example 2</i>	<i>Example 3</i>
<i>Sediment light, dark, powdery; supernatant colloidal, slightly turbid; sediment of uniform particles, connected in a gel-like manner of approx. 2 μm; several small crystals up to 2 μm</i>	<i>Sediment light, dark powdery; supernatant colloidal, slightly turbid; uniform particles of approx. 2 μm; partly agglomerated in a mucous-like manner; isolated small crystals approx. 1 μm; a few up to 2 μm</i>	<i>Sediment light, dark powdery; supernatant weakly colloidal, scarcely turbid; uniform particles of approx. 2 μm; a few agglomerated; several quite small crystals 1 μm; a few needles up to 2 μm</i>

Per contra, the learned Counsel for the Appellant argued that the crystallization that was shown by the Respondent in the abovementioned table is too small, and the present invention is reducing is significantly as compared to the cite prior art documents.

25. According to the Complete Specification, as discussed earlier, the mixing sequence (three steps) prevents the formation of crystals of the ingredients of the herb extracts, and the crystal formation is significantly inhibited when the said mixture sequence according to the present invention is adhered to.

26. Further, the learned Counsel for the Respondent argued that the table given on the Page No. 12 of the Complete Specification of the Subject Application is same as the Table No. 1 on the Page No. 13 of D1. The said table of the Complete Specification is reproduced hereunder:



The invention is further explained below with the aid of examples.

EXAMPLES

Production formula

Ingredients	Amount in g	Amount in ml
Drug extract of chamomile flowers (1 : 2 – 4)	1980	2000
Fresh plant extract of bitter candytuft (1 : 1.5 – 2.5)	1455	1500
Drug extract of caraway (1 : 2.5 – 3.5)	975	1000
Mixture of drug extract of liquorice root (1 : 2.5 – 3.5)	990	1000
Drug extract of angelica root (1 : 2.5 – 3.5)	990	1000
Drug extract of milk thistle fruit (1 : 2.5 – 3.5)	970	1000
Drug extract of peppermint leaves (1 : 2.5 – 3.5)	495	500
Drug extract of lemon balm leaves (1 : 2.5 – 3.5)	990	1000
Drug extract of celandine (1 : 2.5 – 3.5)	990	1000

Extractant for *Iberis amara*: ethanol 50% (V/V)

Extractant for all other drug extracts: ethanol 30% (V/V)

The individual ingredients must be mixed homogeneously before weighing. The ingredients are weighed in and mixed

The Table No. 1 of D1 is reproduced hereunder:

Table 1. Composition of Iberogast®

Iberogast® contains in 100 ml

Ethanol extract (extracting agent: ethanol 50% (v/v)) of fresh plants of

Bitter candytuft (1: 1.5-2.5) 15.0ml

Ethanol extract (extracting agent: ethanol 30% (v/v)) of

Angelica root (1: 2.5–3.5) 10.0ml



<i>Chamomile flower (1: 2–4)</i>	<i>20.0 ml</i>
<i>Caraway fruit (1: 2.5–3.5)</i>	<i>10.0 ml</i>
<i>Milk thistle fruit (1: 2.5–3.5)</i>	<i>10.0 ml</i>
<i>Balm leaf (1: 2.5–3.5)</i>	<i>10.0 ml</i>
<i>Peppermint leaf (1: 2.5–3.5)</i>	<i>5.0 ml</i>
<i>Celandine herb (1: 2.5–3.5)</i>	<i>10.0 ml</i>
<i>Liquorice root (1: 2.5–3.5)</i>	<i>10.0 ml</i>

27. Before discussing these tables, it is important to examine what exactly the independent Claim 1 of the present invention of Subject Application is. The independent Claim 1 is reproduced hereunder:

“A method for the production of a plant-based medicament which consists of Librium amara, Mentha piperita folium, Matricaria flos, Carvi fructus, Melissa folium and Calendula herba in the form of alcoholic extracts, liquorice radix, Curcuma in a first step A) angelic radix extract and liquorice radix one or more mixed wherein in a volume ratio of 1 to 3:1 with the extracts of the other ingredients or mixtures containing them, which are produced separately and contain additional liquorice radix. 1. A method for the production of a plant-based medicament which consists of Librium amara, Mentha piperita folium, Matricaria flos, Carvi fructus, Melissa folium and Calendula herba in the form of alcoholic extracts, liquorice radix, Curcuma in a first step A) angelic radix extract and liquorice radix one or more mixed wherein in a volume ratio of 1 to 3:1 with the extracts of the other ingredients or mixtures containing them, which are produced separately and contain additional liquorice radix.”

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“Calim2. The method for the production of a plant-based medicament as claimed in Claim 1 characterized in that in a step B) a mixture containing step A is added thereto in a step C) extracts of Curcuma rhizoma fructus, Mentha piperita folium, Melissa folium and Calendula herba are added. Liquorice radix extract mixed together first volume angelic radix 1 to 3:1 Curcuma is used the mixture step A is added thereto in step extracts.”



28. From Table No. 1 of D1, the adjusting total quantities, changing solvent concentration may be considered as routine experiments, however, to render the claim obvious. The learned Controller has to discuss that how the cited prior arts documents teach to arrive at the claimed three step method, mixing Angelicae radix and Liquiritiae radix extracts in a defined volume ratio of 1:6-3:1. The learned Controller in the Impugned Order has failed to show such motivation. However, this Court notes that D1 mentioned that the right mixing sequence would be essential for desirable results.

29. As discussed earlier, the Complete Specification states that the three step sequence along with the specified ratio of mixing Angelicae radix and Liquiritiae radix extracts is crucial for a desired result of the present invention. Therefore, in order to establish the obviousness to PSITA, it is required to be explained as to how the teachings of D2 either alone or with D1 would reach to the claimed sequence along with specified ratio of mixing Angelicae radix and Liquiritiae radix extracts in a defined volume ratio of 1:6-3:1 in Step (A). Therefore, the reasoning of the learned Controller that the similarity of the ingredients in the present invention and in the D1 would lead to the similar sized crystals cannot be accepted without explaining that the claimed sequence is not disclosed in the D1, which, if used, prevent / inhibit the crystal formation.

30. The Impugned Order states that reading D1 and D2 together, renders the present invention obvious. However, it does not give reason as to how both the documents together would render the present invention obvious. The Impugned Order is devoid of such reasoning. Similarly, there is not reason provided the other cited documents D3 to D6 as well.



31. The reasoning of the Impugned Order under the heading “[B] Submissions and observations w.r.t the objections raised in the hearing notice” is reproduced hereunder:

“Similarly in case of D2 (which is a prior publication of same applicant), all the ingredients and various other parameters and factors leading to highly purified product and use of the same for the treatment of exactly similar disease makes the whole process if studied along with the D1 disclosure obvious for the person skilled in the art.

*** *** ***

Therefore, if such disclosure is there then a person skilled in the art has enough motivation to try and test various steps of mixing the known ingredients for better results in terms of stability and effectiveness. Hence, when all the ingredients are well documented in the prior art (D2) to the level of specific ratios and percentages of all the ingredients being exactly similar as documented in D1 and D2, and also the clear motivation in D1 to use a process step where mixing different ingredients in specific manner for better stability, present invention is not patentable u/s 3(d) of the act.”

32. In **Agriboard International LLC** (*supra*), this Court held that the Controller while raising the objection under Section 2(1)(ja) of the Act, has to analyse as to what is the existing knowledge in the cited prior arts and how the PSITA would move from the existing knowledge to the subject invention claimed in the patent application under consideration. The Court further held that without such an analysis, the rejection of the patent application on this ground would be contrary to the provision itself.

33. Therefore, the Impugned Order with respect to D1 and D2 is devoid of the reasoning as to how and / or why the PSITA would be motivated to modify the teachings of the cited prior art documents to arrive at the present invention of the Subject Application.



34. The Impugned Order also rejected the Subject Application on the ground of the Sections 3(d) and 3(e) of the Act. The reasoning provided in the Impugned Order is reproduced hereunder:

“Thus, the amended claims 1-26 fall under scope of Section 3 (e) of the Patent Act, 1970 as claimed invention and relate to merely admixture of 9 plant extracts/drugs resulting in aggregation of properties.

Also, as claimed that surprising and superior effect of method for combining the plant extracts in certain ratios and sequencing is done, lacks support from the disclosure in complete specification where no significant data is provided to explain how the stated process steps are inventive and non- patentable u/s 3(d & e) of the act.”

35. It is important to note that the in ***Nippon Steel Corporation v. Controller General of Patents, Designs***, Neutral Citation: 2024:DHC:6514, it was held that while raising the objection under Section 3(d) of the Act, the “known process, machine, or apparatus” need to be specified. Therefore, for raising an objection under Section 3(d) of the Act, the learned Controller must provide reasoning as to how the claimed method including the three steps with the specified ratio is “known” in the light of prior arts.

36. Therefore, if Section 3(d) of the Act is applicable, the learned Controller must provide a reasoning regarding the applicability of the said provision. The reasoning provided regarding the objection under Section 3(e) of the Act is also not sufficient as the Complete Specification of the Subject Application discusses that the specific ratio mentioned in Claim 1 and the three steps are resulting in a desirable result.

37. The desirable effect, as per the Complete Specification of the Subject Application is because of combining the plant extracts in certain ratios and



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sequencing. The accurate compliance with the right mixing order is essential to get a stable product with defined recovery rates of the Lead Substance.

38. Accordingly, in view of the abovementioned infirmities in the Impugned Order passed by the learned Controller, the Impugned Order is set aside, and the matter is remanded back for fresh consideration and passing a detailed order with adequate reasoning.

39. It is clarified that the merits of the case have not been examined, and the learned Controller shall decide the Subject Application in accordance with law without being influenced by any observations made by this Court in this Judgment within a period of six months from the date. The Appellant shall be granted a fresh opportunity of hearing before deciding the Subject Application.

40. Accordingly, the Appeal is disposed of with the aforesaid direction.

41. A copy of the Order shall be sent to the learned Controller General of Patents, Designs and Trademarks at llc-ipo@gov.in for the necessary administrative action.

TEJAS KARIA, J

JANUARY 9, 2026

KC/N