



IPAB Intellectual Property Appellate Board

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OA/16/2016/PT/KOL

MONDAY, THIS THE 11TH DAY OF JANUARY, 2021

**HON'BLE SHRI JUSTICE MANMOHAN SINGH
HON'BLE DR. B.P. SINGH**

**CHAIRMAN
TECHNICAL MEMBER (PATENTS)**

ASTHRISTIS RELIED PLUS LTD.
AN AUSTRALIAN COMPANY, OF SUITE 2A,
GROUND FLOOR, 15 LAKE STREET VARSITY
LAKES QUEENSLAND 4227 AUSTRALIA

...APPLICANT/APELLANT

(Represented by: Mr.HariSubramaniam, Ms.Aditi Subramaniam and
Mr.Sanuj Das)

Versus

CONTROLLER OF PATENTS AND DESIGNS
THE PATENT OFFICE BRANCH BAUDHIK
SAMPADA BHAVAN CP-2, SECTOR V, SALT LAKE
KOLKATA – 700 091

...RESPONDENT

(Represented by - None)

ORDER

Hon'ble Shri Justice Manmohan Singh, Chairman

Hon'ble Dr. B.P. Singh, Technical Member (Patents)

1. The present appeal is filed under Section 117A of the Indian Patents Act, 1970, against the order dated 11/12/2015, passed by the Respondent, being the then Assistant Controller of Patents & Designs, under Section 15 of the Indian Patents Act, refusing to grant the Appellant's Indian patent application no. 1904/KOLNP/2009.

2. It is the case of the appellant that the impugned Order is bad in law inasmuch as the impugned Order:
- 2.1 is based upon prior art documents which were cited for the first time in the notice of hearing dated 15 September 2015, thereby depriving the Appellant any opportunity to the Respondent to differentiate the said citations with the present invention;
 - 2.2 has been passed without application of mind, simply on the basis of a mosaic of prior art documents cited in various jurisdictions and does not provide any reasoning as to how the cited documents are relevant for determining the inventive step of the present invention;
 - 2.3 fails to consider that the cited document D5 was published in the year 2009 i.e., D5 was published after the priority date (15 November 2007) of the present invention and thus, cannot be considered for examining the inventive step of the present invention in view of Section 13(1)(a) of the Act;
 - 2.4 is an unreasoned order and does not take into consideration even a single submission of the Appellant filed on 14 October 2015 differentiating the cited art or explaining how the present invention is outside the ambit of Section 3 of the Act;
 - 2.5 fails to appreciate that every single prior art except D5 was found to be irrelevant for the purposes of novelty and inventive step in all other jurisdictions;
 - 2.6 errs in the interpretation and application of Section 3(e) and Section 3(j) of the Act and completely disregards scientific data substantiating efficacy / synergy of the present invention, in refusing the subject application;

2.7 the unreasoned nature of the impugned Order and the prosecution history of the subject application reveal that every time the Appellant filed submissions to overcome the objections raised by the Respondent, a new objection was raised and a new document was cited. It appears that the Respondent had, from the very beginning, made up its mind to refuse the subject application; and,

2.8 fails to appreciate that an invention may be simple but as long as the invention is novel, inventive, industrially applicable and patentable, protection ought to be granted in accordance with the spirit of the Act.

3. The learned counsel for the appellant has brought to our notice that:

3.1 Cited documents D6 and D12 to D19 in the FER were identical to and quoted verbatim from the Written Opinion of ISA;

3.2 Cited documents D1 to D5 in the FER were identical to and quoted verbatim from the search report dated 30 August 2012 in the corresponding US Application No. 12/515,254;

3.3 Cited documents D7 to D11 in the FER were cited from the search report dated 13 April 2010 on the corresponding EP application.

3.4 Thus, it is evident that the Respondent had merely mosaiced citations from different jurisdictions / corresponding applications and cited them in the present application. Yet, the Respondent conveniently ignored that fact that despite the citations above, the corresponding foreign applications were held to be novel, inventive and patentable in various jurisdictions as well.

- 3.5 The FER also raised objections of disunity of invention and non-patentability of the present invention under Section 3(c), Section (e), Section 3(i) and Section 3(j).
- 3.6 The lackadaisical manner in which the present application was examined is evident from the fact that while citing Section 3(c) and Section 3(j), the Respondent thought it fit to simply state that 'the formulation of the alleged invention includes extract and parts of many plants, thus it attracts the provisions of 3(c) and 3(j) of the Act', without giving any reasoning thereto.
- 3.7 A Notice of Hearing was issued wherein the Respondent:
- 3.7.1 maintained the objections in respect of cited documents D7 to D13 of the FER;
 - 3.7.2 maintained the objection on disunity of invention;
 - 3.7.3 cited eight (08) documents (D1, D8 to D14 of the hearing notice) for the first time.
- 3.8 Surprisingly, the Respondent issued another communication on 16 September 2015 (page 157 of appeal brief) citing Section 3(p) for the first time, basing reliance on two (02) TKDL citations.
- 3.9 Further, the hearing notice dated 15 September 2015 did not cite the objections of Section 3(c), Section (e), Section 3(i) and Section 3(j). Thus, these objections were deemed to have been met.
- 3.10 Pursuant to a request for adjournment, the Respondent issued a second hearing notice.
- 3.11 To the Appellant's surprise, the hearing notice dated 30 September 2015 reintroduced the objections of Section 3(c) and Section (e).
4. The invention as explained by the learned counsel of the appellant is as under:

- 4.1 The present invention provides a topical formulation of herbal extracts for prophylactic management and / or treatment of arthritis;
- 4.2 More specifically, the present invention provides a topical formulation of the compounds obtained from the plant 'Comfrey' i.e., comfrey or comfrey-derived compound such as allantoin, and tannic acid, and may optionally comprise a penetration enhancer (to promote absorption of drug through the skin);
5. We have noted that first hearing notice was issued on 15/09/2015 and pursuant to an adjournment request by the appellant, a second hearing notice was issued on 30/09/2015 and the hearing was held on 12/10/2015. We also noticed that hearing notice included fresh citations, hence adequate time should have been given to the appellant to prepare their counter arguments properly.
6. The learned counsel of the appellant has argued that no proper opportunity was given to them to address the newly cited documents in hearing notice by the Respondent.
7. They have drawn our attention to a previous order of this Board as follows:
- 7.1 Reliance is also placed on the order of the **Hon'ble IPAB in *Tibotec Pharmaceuticals Ltd. vs. The Controller of Patents and Designs - Order No. 82 of 2015 in OA/24/2011/PT/DEL [being filed herewith as Annexure F]*** which held:
- "...9. The reading of the impugned order passed by the Assistant Controller of Patents & Designs reveals **that the Controller relied on the objection raised for lack of inventive step and the insufficiency of disclosure during examination by citing prior arts namely US 6248775 and CA 2472133. But the fact remains on the basis of***

the perusal of the FER dated 11.06.2008 there is not a whisper made about the above said so called prior arts.

It is pertinent to note at this stage in respect of US 6248775 there is no mention about the said prior art even in the hearing notice or the same was revealed on the date of exact hearing and the same is mentioned for the first time only in the impugned order.

10. *It is seen that in the hearing notice, the prior art cited was entirely different as the same reveals that they have sought to rely the prior art mentioned is US 6428775 which is nothing to do with the present patent of the appellant and the same is related to "Makeup remover composition". **The yet another infirmity found on the face of the impugned order is that the other two prior arts CA 2472133 and WO 99/67417 have been mentioned only in the hearing notice and no adequate and reasonable opportunity was given to the appellant to give their reply or explanation. Therefore, it is crystal clear that the Assistant Controller has placed reliance on a wrong prior art and also over looked the fact of not furnishing the specific objections relating to the prior arts relied by the Controller for arriving at the conclusion to the effect of rejecting the application on the ground of lack of obviousness and inventive step. Therefore, we have no hesitation to hold that the impugned order was passed in flagrant violation of principles of natural justice and the entire impugned order is vitiated on that ground....***

7.2 The appellant further submitted that the Respondent, thus, passed the impugned Order in violation of the Principles of

Natural Justice, in view of the well-settled judicial precedents, and the same ought to be set aside.

8. Now, we look at the order of the Respondent. The operating portion of the order is quoted herein below:

8.1 *Upon consideration of the objection vis a vis the arguments placed by the agent of the applicant followed by written submission under the provision of section of the Patent Act, I shall turn my eyes one by one to the objection raised in hearing letter dtd.30/09/2015 and submission thereby.*

8.2 *First of all I need to mention that the present application deals with a topical formulation including comfrey or comfrey derived compounds and tannic acid (as per proposed amended claims during hearing) which is used for the treatment of arthritis.*

8.3 *Though there is definite mention of comfrey derived compounds whereas no individual specific compounds has been disclosed in the specification all along, but only comfrey extract has been mentioned. The term **comfrey derived compounds** as proposed in amended claims still lack clarity without having clear definition. This unclear term as used in the proposed claim also lead to more than one formulation and eventually failed to overcome objection 6 of the hearing letter. Another pertinent point is that composition is depended on parts of plant used which should be dependent on specific extraction process , but surprisingly the whole specification is silent regarding the same. **The formulation includes the compounds as extracted from comfrey root extract , comfrey leaf extract or a combination thereof as mentioned in even in proposed claims attracts the provision of section 3(j) of the Act as objected vide hearing objection 5 of the hearing letter.** There is a disclaimer that the biological material used in the present*

application are neither obtained from India nor it is based on any research or information on such material obtained from India which addresses National Biodiversity issue and hence it was not objected in the hearing.

8.4 *With these remarks I am switching to the next **issue of inventive step** with regard to prior art D1 (and D6-D8) which disclose the use of a cream comprising comfrey root extract (Kytta) for the treatment of arthritis. D1 discloses that comfrey root extract contains tannins, and tannic acid derivatives and D2 discloses the use of tannic acid in the treatment of arthritis. Moreover D3 discloses a gel comprising arnica extract which contains tannic acid and D4 discloses the anti-pain and anti-inflammatory effect of tannic acid. So it can be concluded from prior art that comfrey and its comfrey derived compounds and tannic acid are widely known including its topical formulation. Hence I am in the opinion that with these teachings the skilled person may arrive to the final result by routine experimentation to the subject application. Further, I am in the opinion that the mere trial of already described method and compounds in prior art are considered as a matter of mere judicious selection and routine optimization of the same by the skilled person to arrive at the desired result.*

8.5 *In this juncture I need to mention in the section 2(1)(j) of the Act which states that*

invention means a new product or process involving an inventive step and capable of industrial application and as per section 2(1) (ja) inventive step means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art.

- 8.6 *In proposed amended claim there is a mention of eucalyptus oil but it is inferred that without unexpected effect and support of the same in the specification, it does not contribute the subject application to overcome the objection related to inventive step issue. Another constituent Wthania Somnifera is also useful in the treatment of osteoarthritis as evident from the search report of traditional knowledge.*
- 8.7 *In the light of above definition of the Act it can be summarized that inventive step of the subject composition is not at all substantiated with regard to prior arts. **It can be stated that the subject invention is unable to qualify for waiving the objection against inventive step ground over the cited documents.***
- 8.8 *And also considering the **section 3(e) of the Act** which states that a substance obtained by mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance.*
- 8.9 *In the context of above mentioned section I am still in opinion that the subject of the application is an aggregation or duplication of known properties of prior art compounds having known components and known uses. Besides the application lacks to substantiate the synergism as provided in example 17 of the specification where remarkable activity is not observed with regard to commercial topical drug formulation having unknown composition. The composition G2(10% comfrey extract) is less active in pain reduction and activities than the same composition without comfrey(G3).As a result of sufficient data in support of synergism the subject application failed to overcome the objection u/s 3(e) of the Act.*
- 8.10 *In the present context **I am skipping the discussion related to rest objections raised in the hearing letter dtd.***

30/09/2015 as the said discussion does not have meaningful and significant contribution to the same over the above mentioned paragraphs.

8.11 So in view of the facts and circumstances of the application as above and outstanding objections of this hearing notice 1904/KOLNP/2009 dtd. 30/09/2015 which are still outstanding in the opinion of undersigned I hereby refuse the application no. 1904/KOLNP/2009 dtd. 21/05/2009 against the hearing notice dtd.30/09/2015 under section 15 of the Patents Act, 1970 (as amended).

9. Primarily The respondent has refused the instant application basically on three grounds: (i) under section 3(j), (ii) section 2(1)(ja) and (iii) section 3(e) leaving other objection of hearing notice unaddressed.

10. The learned counsel of the appellant has submitted their argument on all the three aspect as follows:

10.1 Further, the Respondent has erred in observing in the impugned Order that: *the formulation includes the compounds as extracted from comfrey root extract, comfrey leaf extract or a combination thereof as mentioned in even in proposed claims attracts the provision of Section 3(j) of the Act;*

10.2 Section 3(j) of the Act bars from patentability plants in whole or any part thereof;

10.3 It is submitted that the present invention is related to a topical formulation of the compounds obtained from the plant 'Comfrey' i.e., comfrey or comfrey-derived compound such as allantoin, and tannic acid. The present invention, thus, is a formulation utilizing extracts from plants in a specific concentration and not the plant or part thereof itself. The objection of the Respondent under Section 3(j) is absurd,

arbitrary, misconceived and the impugned Order ought to be set aside on this ground.

10.4 The Respondent has erred in failing to appreciate that the present invention is inventive over the cited art, the same art having been cited in countries with a more advanced and stringent examination process such as United States of America, Japan and China, amongst others. A copy of the latest Form 3 on record dated 27 August 2019 is filed herewith as Annexure I.

10.5 As stated above, cited documents D1 to D5 in the FER were cited during the prosecution of the corresponding US Application No. 12/515,254 which has since proceeded to grant under patent no. US 10322155.

10.6 The combination of two compounds as explained earlier, has been arrived at after a series of experimentation and trials. Millions of combinations of plant extracts are possible. In spite of the fact that, individually, many such plant extracts may possess medicinal properties, any arbitrary selection or combination will not result in the efficacy in the treatment of osteo-arthritis as disclosed in the present application. None of the cited prior art, either individually or in any combination, even remotely suggest, teach or disclose the invention claimed in the present invention. The Appellant relies on the following table distinguishing the cited art-

CITED DOCUMENT	INDIAN PATENT APPLICATION NO. 1904/KOLNP/2009
<p data-bbox="662 2131 703 2163">D1</p> <p data-bbox="479 2198 886 2454">Discloses a topical formulation of Kytta-Balsam, comprising an extract of comfrey. D1 is completely silent as to a composition comprising tannic acid in an amount 2% or more of the</p>	<p data-bbox="909 2198 1336 2454">As opposed to the present invention, there is nothing in D1 to suggest that the composition disclosed therein comprises tannic acid in an amount 2% or more of the weight of the formulation. Moreover, any trace</p>

total weight of the formulation.	amount of tannic acid that may be present in a comfrey root or leaf extract will be significantly lower than the claimed amount of 2% or more.
<p style="text-align: center;">D2</p> <p>D2 discloses a method for treating a disease associated with hyperproliferation of endothelial cells and/or neovascularization by administering to a subject an effective amount of tannins, or a pharmaceutically acceptable salt, metabolite, derivative or pro-drug thereof. In fact, D2 teaches that tannic acid has anti-angiogenic activity <u>and not</u> anti-inflammatory activity (page 17, lines 9 to 16 and claim 15).</p>	<p>D2, thus, teaches away from the present invention. Neither is there any disclosure nor any teaching in D2 for a combination of comfrey and tannic acid. Further, since D2 does not teach anti-inflammatory activity of tannic acid, there will be no motivation for a person skilled in the art to arrive at the present invention on the basis of D2 or combine D2 with any other document.</p>
<p style="text-align: center;">D3</p> <p>D3 discloses a gel for treatment of arthritis comprising arnica extract of about 10% by weight and <i>Symphytum officinale</i> (comfrey) extract of about 10% (paragraph 40 of D3). D3 does not disclose or teach the specific amounts of tannic acid in the arnica extract nor the final concentration of tannic acid.</p>	<p>As opposed to the present invention, there is nothing in D3 to suggest a composition comprising comfrey and tannic acid, wherein tannic acid is in an amount of 2% or more of the weight of the formulation. Based on the disclosure of D3, it would not be evident to a person skilled in the art as to how much tannic acid (if any) is present in the arnica extract of D3. In view thereof, there will be no motivation for a person skilled in the art to arrive at the present invention on the basis of D3 or combine D3 with any other document.</p>
<p style="text-align: center;">D4</p> <p>D4 discloses an extraction process of tannic acid from <i>Geranium wilfordii</i> tuber root as raw material using ethanol (Abstract).</p>	<p>As opposed to the present invention, D4 does not disclose a composition / formulation of tannic acid in combination with comfrey extract.</p>
<p>D5</p> <p>D5 is a post-published document and is, thus, irrelevant for examining the inventive step of the present invention.</p>	
<p style="text-align: center;">D6 and D7</p> <p>D6 and D7 teach use of comfrey extract to treat unilateral ankle pain. These documents do not teach or suggest the use of tannic acid (in any concentration) alone</p>	<p>D6 and D7 do not disclose a composition / formulation of tannic acid in combination with comfrey extract as in the present invention.</p>

or in combination with comfrey extract.	
D8 D8 is a monograph of a marketed formulation comprising comfrey root extract that is prepared by ethanol extraction. There is no disclosure or teaching of tannic acid (in any concentration) alone or in combination with comfrey extract in the said monograph.	As opposed to the present invention, there is nothing in D8 to suggest that the composition disclosed therein comprises tannic acid in an amount 2% or more of the weight of the formulation and a person skilled in the art will not consider D8 to arrive at the present invention.
D9 and D12 D9 and D12 disclose compositions comprising comfrey.	D9 and D12 do not disclose a composition / formulation of tannic acid in combination with comfrey extract <u>or</u> suggest that the composition disclosed therein comprises tannic acid in an amount 2% or more of the weight of the formulation as in the present invention.
D10, D11 and D13 D10, D11 and D13 disclose compositions comprising tannic acid or extracts containing tannins.	D10, D11 and D13 do not disclose a composition / formulation of tannic acid in combination with comfrey extract <u>or</u> suggest that the composition disclosed therein comprises tannic acid in an amount 2% or more of the weight of the formulation as in the present invention.

10.7 It is further submitted that the fact that the Respondent has cited thirteen (13) prior art documents against the present invention goes on to show the inventive merit of the present invention as opposed to the fact that it is obvious. In fact, the Respondent has used the disclosure of the present invention as a blueprint for piecing together the prior art to defeat patentability. The same amounts to hindsight and ought not to be allowed by this Hon'ble Board. It is submitted that the invention must be viewed not with the blueprint drawn by the inventor, but in light of the state of the art on the priority date of the present invention. The Appellant relies on the decisions of the United States Court of Appeals, Federal Circuit in Anita

Dembiczak and Benson Zinbarg, 175 F. 3d 994 (1999) being filed herewith as Annexure M and Interconnect Planning Corp. v. Feil, 774 F.2d 1132 (Fed. Cir. 1985) being filed herewith as Annexure N.

10.8 In the case of Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries AIR 1989 SC 1444, the Hon'ble Supreme Court had observed:

"...4. "In order to be patentable, an improvement on something known before or a combination of different matters already known, should be something more than a mere workshop 'improvement', and must independently satisfy the test of invention or an inventive step.

27. Another test of whether a document is a publication which would negative existence of novelty or an "inventive step" is suggested, as under:

balancing ip-protection

"Had the document been placed in the hands of a competent craftsman (or engineer as distinguished from a mere artisan), endowed with the common general knowledge at the 'priority date', who was faced with the problem solved by the patentee but without knowledge of the patented invention, would he have said, "this gives me what I want?" (Encyclopedia Britannica; ibid). To put it in another form: "Was it for practical purposes obvious to a skilled worker, in the field concerned, in the state of knowledge existing at the date of the patent to be found in the literature then available to him, that he would or should make the invention the subject of the claim concerned ?..."

10.9 In view of the precedent set forth by the Hon'ble Supreme Court, it is evident that a person skilled in the art would not consider the cited art in arriving at the present invention;

10.10 Therefore, it is amply clear that the present invention cannot be arrived at from the teachings of the cited art. The present invention, thus, is inventive, not obvious in view of the teachings of the cited art and the impugned Order ought to be set aside.

10.11 The Respondent has erred in refusing the present application by holding that the same is barred under Section 3(e);

10.12 It is submitted that synergy is understood to mean the interaction of substances that provides an overall enhanced effect that is greater than the sum of the individual substances alone. The Applicant asserts that the synergistic effect on an improvement in joint stiffness in patients is evident from the data on pages 54-55 of the specification. The data set out on page 54 were derived from a comparison of 4 formulations comprising varying amounts of comfrey extract and tannic acid, but are otherwise identical in terms of the other constituents in the topical formulations (as set out on pages 52 and 53). Importantly, formulations G1 and G2 represent contain both comfrey extract and tannic acid within the scope of the presently claimed invention; in contrast, formulations G3 and G4 contain only either one of tannic acid or comfrey extract;

10.13 The table below provides a summary of the effect of the G1-G4 formulations on the percentage of change seen in joint stiffness in patients with osteoarthritis of the knee, as assessed by the WOMAC index, noting that a higher WOMAC

Index score denotes greater stiffness. For ease of reference, the results of G1 and G2 are emphasized in bold:

Formulation	Comfrey extract and tannic acid values	Reduction in WOMAC index	% reduction in stiffness
G1	20% comfrey extract and 10% tannic acid	59.88	57.48
G2	10% comfrey extract and 10% tannic acid	75.42	62.37
G3	0% comfrey extract and 10% tannic acid	22.37	21.33
G4	20% comfrey extract and 0% tannic acid	29.29	31.26

10.14 The abovementioned data is shown in the middle panel of the table on page 54 of the application as filed as part of Example 17. It is apparent from the said data that formulations comprising the combination of comfrey extract and tannic acid (G1 and G2) gave greater improvement in joint stiffness, as seen by a reduction in the WOMAC index, as compared to G3 and G4 which lacked either comfrey extract or tannic acid. This effect was greater than the improvement that would otherwise have been expected if the effect of comfrey extract and tannic acid were merely additive. That is, G1 and G2 each provided a greater reduction in the WOMAC index of 59.88% and 75.42%, respectively, indicating a synergistic effect of the combination on joint stiffness.

10.15 Thus, it is respectfully submitted that Respondent has failed to consider that the topical formulation of the present invention comprising comfrey extract and tannic acid exhibits improved anti-inflammatory activity in vivo compared to the application of comfrey alone or tannic acid alone, as has been exemplified by way of Example 17 of the complete specification;

10.16 The arbitrary nature of the impugned Order is evident from the fact that, despite Example 17 clearly establishing synergy of the components of the present invention, the Respondent has stated in the impugned order that: besides the application lacks to substantiate the synergism as provided in example 17 of the specification where remarkable activity is not observed with regard to commercial topical drug formulation having unknown composition. The composition G2 (10% comfrey extract) is less active in pain reduction and activities than the same composition without comfrey(G3);

10.17 The Respondent has completely disregarded the conclusive portion of Example 17 which states how the various compositions exemplified in the complete specification have showed efficacy / synergy. The same is reproduced below: (lines 4 to 13, page 54 (page 111 of the appeal brief) and lines 1 to 4, page 55 (page 112 of the appeal brief) –

10.18 *“...Based on the analysis of the Womac Osteoarthritis Index findings after 8 weeks of treatment, the results show that formula G1 (20% comfrey with tannic acid) was the most effective for pain, formula G2 (10% comfrey with tannic acid) was the most effective for stiffness, and formula G1 (20% comfrey with tannic acid) was the most effective in alleviating difficulty in performing daily activities. Furthermore, formula G2 (10% comfrey with tannic acid) was found to be the second most effective formulation for pain, while formula G5 (the topical drug formulation) was found to be the second most effective formulation for stiffness and for alleviating difficulty in performing daily activities. The three formulations that included a combination of comfrey and tannic acid showed superiority over formulations with only comfrey or tannic acid alone.*

These results demonstrate a synergistic effect between comfrey and tannic acid in comparison to individual compounds in the treatment of conditions such as arthritis. This is based on 8 weeks of using the formula (The study test period) ...”

10.19 In the case of New Age Laminators Pvt. Ltd. vs. SPL's Sidhartha Limited, 2012 (51) PTC 392 (IPAB) [filed herewith as Annexure L] the Hon'ble IPAB while deciding the question of whether the invention was barred under Section 3(e) observed:

“...58. We agree with the contention of the respondent that invention is not a mere admixture. We therefore uphold the decision of the Controller where he stated that while preparing rodent repellent composition the applicant has not merely admixed the ingredient of the composition such as LDPE, EVA and rodent repellent together. Rather they are mixed in a proper and definite proportion, amounts at particular temperature and in a particular sequence. Even the affidavit of Vijay Kumar Guptadoes not reveal about these steps and proportions and amount of these ingredients. Therefore, the alleged process cannotbe considered as mere admixture. In view of this, this ground of opposition also fails....”

10.20 It is therefore respectfully submitted that the Respondent failed to appreciate that the claimed 'stable topical pharmaceutical nanogel composition of clobetasol propionate and salicylic acid' composition is not a mere admixture and is patentable under Section 3(e). The impugned Order ought to be set aside on this ground.

11. Let us first address the issue of lack of inventive step. As submitted by the appellant we have observed the prosecution history of various other jurisdictions and found that even after relying on similar prior arts, the invention has been granted there. We again hold that the grant of patent in some other jurisdiction has no binding effect on to the Indian Patent Office; but if the novelty and /or inventive step is questioned on the same prior arts, then it amounts to injustice and is against the principles of equity and fair play¹.

12. Further, the argument and tabular analysis submitted by the appellant is satisfactory enough to prove inventiveness as the determination of inventive step by the respondent is based on her subjective statement. The method of determination of inventive step has been elaborately addressed by this Board, in its order in PHARMACYCLICS, LLC² and for sake of brevity we are not inclined to repeat it here. Thus, keeping in view the submissions and facts as reviewed by us the objection under section 2(1) (ja); as lacking inventive step, does not sustain.

13. We look at the relevant provisions of section 3(e) and 3 (j) of the Patents Act, 1970 as under:

CHAPTER II³

INVENTIONS NOT PATENTABLE

Section 3

What are not inventions

The following are not inventions within the meaning of this Act,—

¹ IPAB OA/3/2017/PT/CHN

² IPAB OA/46/2000/PT/DEL

³ Available at <https://ipindia.gov.in/writereaddata/Portal/ev/sections/ps3.html>

(e) a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;

(j) plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals;

14. The provisions relating to Section 3(e) in GUIDELINES FOR EXAMINATION OF BIOTECHNOLOGY APPLICATIONS FOR PATENT⁴

SECTION 3 (e): MERE ADMIXTURE RESULTING ONLY IN AGGREGATION OF THE PROPERTIES OR A METHOD OF MAKING SUCH MERE ADMIXTURE

It is a well-accepted principle of Patent Law that mere placing side by side of old integers so that each performs its own proper function independently of any of the others is not a patentable combination, but that where the old integers when placed together has some working interrelation producing a new or improved result, then there is patentable subject matter in the idea of the working inter relations brought about by the collocation of the integers.

In Ram Pratap v Bhaba Atomic Research Centre (1976) IPLR 28 at 35, it was held that a mere juxtaposition of features already known before the priority date which have been arbitrarily chosen from among a number of

⁴ Available at https://www.ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_38_1_4-biotech-guidelines.pdf

different combinations which could be chosen was not a patentable invention.

Section 3(e) of the Act reflects the legislative intent on the law of patenting of combination inventions in the field of chemical as well as biotechnological sciences.

15. Plain reading of the section of the 3(e) and by going through the relevant provisions of Guidelines quoted above that the instant invention does not attract the provisions of section 3(e) as the relevant data shown in the specification proves the existence of synergistic effect. The holding of the respondent that “*Besides the application lacks to substantiate the synergism as provided in example 17 of the specification where **remarkable activity** is not observed with regard to commercial topical drug formulation having unknown composition*” does not hold water as first *remarkable activity* is not the requirement of law and secondly the data shown in the table above shows G1 and G2 each provided a greater reduction in the WOMAC index of 59.88% and 75.42%, respectively, indicating a synergistic effect of the combination on joint stiffness.

16. Now moving on to applicability of section 3(j), it is clear from plain reading of the above quoted legal provisions, that the invention is neither claiming *plants and animals in whole or any part thereof* nor relating to *seeds, varieties and species and essentially biological processes for production or propagation of plants and animals*; rather it relates a ‘topical formulation’ prepared of a combination of (i) comfrey and (ii) tannic acid in a particular proportion. There could be a debate on the proportion mentioned therein. But nevertheless the provisions of section 3(j) of the Patents Act, 1970 won’t be attracted for the reasons mentioned above, in the instant case.

17. Since learned counsel of the appellant has drawn our attention to granted case in foreign jurisdiction. We found the US granted

claims clearly mentions the upper and lower weight percentage of both comfrey and tannic acid in the formulation. But in contrast herein, they have shown lower limit of 4% and 2% for comfrey and tannic acid respectively but left upper limit open ended, when they say “*present in 4% or more of the weight of the formulation*” in case of comfrey and “*2% or more of the total weight of the topical formulation*” in case of tannic acid.

18. We are, therefore, of the opinion that while we accept the auxiliary claims, filed by the appellant deleting the feature(s) of *Comfrey derived compounds*; they should further amend the claims sufficiently defining the invention particularly incorporating the upper limit of the % *by weight* of ‘comfrey’ and ‘tannic acid’ both, with respect of *the weight of the formulation*.

19. We further observe that the respondent has left certain objections of hearing notice unaddressed. This practice is very unfair and against the set legal norms. The Controller is first *quasi-judicial* body who adjudicates the matter and he/she has no option to issue half-cock orders. The unaddressed objections may have never ending effect on a case. This Board cautions the respondent to refrain from such practices in future. We have considered the submissions of the appellant at various stages of prosecution as well as those made in front of us and are convinced to accept their arguments and proposed amended set of claims 1-7. Keeping in view the submissions of the learned counsel of the appellant, we are inclined to waive off all the other unaddressed issues by the respondent.

20. We, therefore, direct to appellant to submit the auxiliary set of claims deleting the features of *comfrey-derived compound* from the existing set of claims, clearly defining the upper limit of % *by weight* of *the formulation* for both ‘comfrey’ and ‘tannic acid’ based on the

description; within 3 weeks from the date of issuance of this order to the respondent.

21. We set aside the impugned order dated 11/12/2015 issued by the respondent, and direct the respondents to grant patent to the appellant on the amended set of claims 1-7, within 3 weeks from the date of submission of the amended set of claims by the appellant.

22. Keeping in view the above facts and circumstances, the instant appeal is allowed. No cost.

-Sd/-

(Dr. B.P. Singh)
Technical Member (Patents)

-Sd/-

(Justice Manmohan Singh)
Chairman

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