



IPAB Intellectual Property Appellate Board

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OA/8/2015/PT/MUM

MONDAY, THIS THE 9TH DAY OF NOVEMBER, 2020

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

**CHAIRMAN
TECHNICAL MEMBER (PATENTS)**

STIEFEL RESEARCH AUSTRALIA PTY LTD.

A CORPORATION ORGANIZED AND EXISTING UNDER THE LAWS OF AUSTRALIA
OF 8 MARCO COURT, ROWVILLE,
VIC 3178, AUSTRALIA

...APPELLANT

(Represented by -Mr Shukadev Khuraijam)

V.

THE CONTROLLER OF PATENTS
THE PATENT OFFICE,
BOUDHIK SAMPADA BHAWAN,
S.M. ROAD, NEAR ANTOP HILL POST OFFICE,
ANTOP HILL, MUMBAI - 400 037

.....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 23/09/2014, passed by the Respondent, being the Deputy Controller of Patents & Designs, under Section 15 of the Indian Patents Act, refusing to grant the Appellants' Indian patent application no. 441/MUMNP/2007.
2. It is the case of appellant that:

2.1 The Respondent has erred in refusing the application on the ground of lacking in inventive step under Section 2(l)(ja) of the Act on the wrong premise that the main claim does not have reference to 'disrupting substances like propylene glycol or petrolatum' which in the Respondent's opinion are essential to the invention. The learned counsel of the appellant has drawn the attention of this Board on the relevant portion of the specification reproduced below for reference:

"Propylene glycol, which is desirably included in dermatological compositions for its capacity as a penetration enhancer, is an additive that has been reported as undesirable in microemulsion technology because of its potential to disrupt or destabilise the formulation. WO 94/08603 (SMTTHKLINE BEECHAM CORPORATION) teaches the avoidance of propylene glycol and other polyhydroxyl alcohol cosurfactants because of and stability issues they introduce.

Another ingredient which is desirable in dermatological applications is petrolatum used for its occlusive and emollient properties. However because of its viscosity it is considered too difficult to incorporate in microemulsion formulations."

2.2 From the above, it is clear that such disrupting substances are not envisaged as 'essential' features of the invention. Since, the Respondent's decision on inventive step is directly based on the said finding; such decision ought to be set aside.

2.3 The impugned order has failed to appreciate that the present invention meets the requirements of inventive step in as much as the present invention has significant

technical advance explained in the Appellant's detailed oral submissions at the hearing and the written submissions dated February 22, 2012. The impugned order is vitiated since the Respondent has failed to appreciate that the process of cited document D7 (which has been identified as the closest prior art by the Respondent) requires homogenization to achieve stability whereas the present invention is in stark contrast with D7 since it does not require the additional step of homogenization to achieve stability of the composition. As explained in the written submissions, the avoidance of the step of homogenization involves significant economic significance since homogenisers are expensive capital items and require large amounts of energy which results in much higher manufacturing costs. Besides the economic significance, the process claimed in the subject application also has a technical advance over document D7 since homogenization exposes the composition to high pressure and shear forces, which can negatively impact the viscosity of the composition (example: Carbopol thickening agents are sensitive to shear or the stability of the active ingredient).

- 2.4 The impugned order is vitiated since the Respondent has failed to appreciate the crux-of the invention. In paragraph 2 on page 8 of the impugned order, the Respondent has relied upon D1 & D7 and has held that *"Closest prior art is document D1 and D7 describing microstructured compositions. In example 20 the oily phase comprising mineral oil, safflower oil and sesame oil as well as the aqueous phase comprising 1 % of 3-glucan are heated to 60-70°C, homogenized and cooled down to 40°C. Then the*

third part comprising phenoxyethanol and perfume is added.”

The Respondent has grossly erred in not appreciating that the invention claimed in the subject application does not comprise the additional step of homogenization to achieve stability of the composition. The Appellant submits that the impugned order is gravely erroneous since the Controller has overlooked the crux of the invention by failing to understand that by avoiding the step of homogenization, the invention claimed in the subject application involves significant economic significance since homogenisers are expensive capital items and require large amounts of energy which results in much higher manufacturing costs. The impugned order is vitiated since the Respondent has failed to appreciate the technical advance over document D7 since homogenization exposes the composition to high pressure and shear forces, which can negatively impact the viscosity of the composition or the stability of the active ingredient.

2.5 The impugned order is erroneous in as much as there is a blanket general reliance on the teachings of documents D2 to D6 without addressing the detailed comments submitted by the Appellant as to how these documents do not destroy the inventive step of the invention as elaborated under the cover of appellant's letters dated January 13, 2011.

2.6 The impugned order is vitiated since the Respondent has failed to provide its detailed reasoning for disagreeing with the detailed submissions presented by the Appellant in support of the inventiveness of the subject application in its various correspondences.

2.7 The impugned order betrays a preconceived and/or premeditated intention on the part of Respondent to refuse the subject application. In this regard, it is submitted that respondent has gravely erred in refusing the application on the ground of lack of inventive step in as much as the basis of arriving at such conclusion is unclear and flawed. The Respondent has given the following reasoning for refusing the subject application on the ground of lacking inventive step:

"The difference between the process of D7 and the present application is the lack of lipophilic and hydrophilic surfactants.

Combining the teaching of D1 and D7 with the general knowledge, the person skilled in the art was motivated to add surfactants to the microstructured composition. Hence the subject-matter of present claims does not involve an inventive step."

2.8 The impugned order is vitiated since the Respondent has provided no reasoning/justification for attributing motivation to a person skilled in the art to incorporate a hydrophilic and a lipophilic surfactant, (i.e. classical/conventional emulsifier) in the claimed process especially when D7 teaches that the compositions are free of conventional emulsifier. The Appellant submits that the impugned order is erroneous since the Respondent has failed to substantiate his assessment with adequate reasoning.

2.9 The impugned order has failed to appreciate that the closest prior art D7 (as acknowledged by the Respondent) teaches away from the invention claimed in the subject application. In this regard, the Appellant submits that D7

teaches that the compositions are free of conventional emulsifier whereas conventional emulsifiers are an essential feature of the process claimed in the subject application. The Respondent has failed to appreciate that there would be absolutely no motivation for a person skilled in the art to incorporate one or more emulsifiers known in the art into the emulsifier free compositions of D7 to arrive at the invention claimed in the subject application. Accordingly, the impugned order is vitiated and deserves to be set aside.

2.10 The impugned order is erroneous in as much its findings with respect to documents D1 and D7 are baseless and unsubstantiated. In this regard, the Appellant has referred to second last paragraph on page 6 of the impugned order wherein the Respondent has held that *"The alleged invention relates to a process for the preparation of oil in water micro emulsion composition. The Applicant submission as submitted above has been considered but it is not persuasive"*

2.11 The Respondent has committed a gross error in refusing the subject application on the ground of lacking inventive step. The Appellant submits that the Respondent has failed to appreciate the invention claimed in the subject application. The impugned order state that *"further we have to understand D7 is working in the absence of conventional emulsifier also. Hence the subject matter of present claims 1-9 does not involve an inventive step"*.

The observations of the Respondent betray a lack of understanding of the nuances of the invention claimed in the subject application since the Respondent has failed to

appreciate that the subject application does not comprise the additional step of homogenization which has significant economic significance as well as technical advance as explained in the written submissions filed on February 22, 2012.

2.12 The impugned order is erroneous in as much as the Respondent has erred in refusing the application on the erroneous assumption that *"It is clear from the description on page 6 that disrupting substances like propylene glycol or petrolatum are essential to the definition of the invention. Since independent claim 1 does not contain this feature it does not meet the requirement of inventive step as specified in its definition under Section 2 (1) (ja) of the Act. "*

2.13 The Appellant submits that the Respondent has failed to appreciate that whilst it is preferred that the "first part" of the claims includes petrolatum, this is not an essential feature of the invention. The Respondent has failed to appreciate that the critical feature is the addition of the non-surfactant amphophilic compound to the composition after the formation of the microemulsion or submicron emulsion.

2.14 The impugned order is grossly erroneous in as much as the same is based on statements which are no more than mere surmises. While the 'novelty' of the invention claimed in the subject application was never in question in the hearing notice and during the hearing, page 8 of the impugned order abruptly mentions that *"the invention defined in present claims 1-9 is disclosed by these citations. Therefore, these claims are not novel and inventive in the light of the above citations"*.

- 2.15 The Appellant submits that the impugned order consists of abrupt unsubstantiated statements which have not been weaved by any sort of reasoning. The Appellant submits that the impugned order ought to be set aside on this ground alone since the same does not meet the requirements of the principles of natural justice.
- 2.16 The impugned order has been passed without proper application of mind with a preconceived notion to refuse the application as is clear from the jarring discrepancies and illogical and irrational findings as evidenced by the impugned order itself.
- 2.17 The Respondent has not appreciated the fact that by erroneously refusing the subject application, the Appellant's rights have been seriously jeopardized.
- 2.18 The Appellant has incurred considerable expenses and has made huge investments of time and money in the Research and development of the claimed invention and therefore, should not be penalized by the erroneous and unsubstantiated stance taken by the Respondent.
- 2.19 Without prejudice, it is submitted that the Appellant is amenable to amending the claims in accordance with the auxiliary request, if the Hon'ble Board deems the said amendments necessary.
- 2.20 It is submitted that the cited document D7 does not teach preparing a solution of the nonsurfactant amphiphilic compound and the active ingredient, and then adding the solution to the composition after formation of the microemulsion or sub-micron emulsion. This desirably allows an active ingredient which is insoluble or only sparingly soluble in water to be solubilised in the aqueous phase of the emulsion by the use of a nonsurfactant

amphiphilic compound. It also allows a component (i.e. the nonsurfactant amphiphilic compound) which would otherwise disrupt formation of the microemulsion or sub-micron emulsion to be conveniently incorporated into the composition and provide beneficial properties - e.g. propylene glycol acts as a humectant and penetration enhancer.

2.21 The Respondent has failed to appreciate that whilst it is preferred that the "first part" of the claims includes petrolatum, this is not an essential feature of the invention. The Respondent has failed to appreciate that the critical feature is the addition of the non-surfactant amphiphilic compound to the composition after the formation of the microemulsion or submicron emulsion. The aforementioned aspect is further supported by the Declaration by Albert Zorko Abram which has been filed in connection with the corresponding US application number 13/873,777. The Appellant submits that the Declaration is consistent with the teachings of the examples and provides further explanation as to how the present technology was developed, including the criticality of adding the non-surfactant amphiphilic compound to the composition after the formation of the microemulsion or submicron emulsion.

3. Aggrieved by the impugned order dated September 23, 2014, the Petitioner has preferred the instant appeal.
4. For fair assessment, let's have a look on the First Examination Report (FER) issued in this case :

“Objections :

Claims 1 -21 do not constitute an invention u/s 2(1) (j) of the Patents Act, 1970, as they are not novel (also not involve inventive step) in view of the prior published documents:

D1EP1018363B1

D2 EP 1020219 B 1

D3 WO 1999/044585 A1

D4 WO 2002/056843 A2

D5 Derwent Abstract accession no, 86-205112, Class B07, DD 234611 A

D6 Derwent Abstract accession no, 86-205113, Class B07, DD 234612 A

D1 discloses a nanoemulsion comprising a surfactant and at least one oil, useful as cosmetic composition, dermatological or ophthalmological composition.

D2 discloses an oil-in water nanoemulsion including alkyl ether citrate surfactant useful as cosmetic, dermatological, ophthalmological or pharmaceutical carrier.

D3 discloses a topical formulation of oil-in-water emulsion containing galactolipid material as emulsifier and with prolonged effect of incorporated active substance.

D4 discloses a translucent oil-in water nanoemulsion useful for preparing cosmetic, dermatological, ophthalmological compositions comprising three specified surfactants.

D5 and D6 disclose the production of dermatological creams of o/w emulsion type. The creams are useful as carriers for pharmaceuticals, eg corticosteroids, dithranol, antimycotic agents and antiviral agents.

The invention defined in present claims 1-21 is disclosed by these citations. Therefore, these claims are not novel and inventive in the light of the above mentioned citations.”

5. The appellants amended the claims in the response of FER and the respondent issued a Second Examination Report on 19/08/2011, containing objections mainly as follows:

“Objections:

The submissions in your letter dated 13th January, 2011 have been considered carefully. However, the requirements of paragraph 1 and 2 of FER have not been met.

Further considering the details of examination report available for the substantially same invention filed before EPO, referring to paragraph 1, the amended claims 1-22 do not involve inventive step in view of the cited documents D1-D6 of FER along with the following other documents cited in European Search Opinion (published on 28/01/2011) on the EP national phase application:

D7: EP 0 875 244 A2 (CIBA GEIGY AG [CH] CIBA SC HOLDING AG [CH]) 4 November 1998

D8: DE 195 09 079 A1 (BEIERSDORF AG [DE]) 19 September 1996

D9: US 2003/083314 A1 (YIV SEANG [US] ET AL) 1 May 2003

D10: WO 93/15018 A1 (PETCHUL JOHN [US]) 5 August 1993

D11: WO 01/20990 A1 (BIORESPONSE L L C [US]) 29 March 2001

D12: EP 0 696 452 A1 (CUSI LAB [ES] ALCON CUSI S A [ES]) 14 February 1996

The problem to be solved is the provision of an alternative process for the preparation of an O/W microemulsion or submicron emulsion. The solution provided is a process according to claim 1. Closest prior art is document D7 describing microstructured compositions. In example 20 the oily phase comprising mineral oil, safflower oil and sesame oil as well as the aqueous phase comprising 1 % of R-glucan are heated to 60-70 °C, homogenized and cooled down to 40 °C. Then the third part comprising phenoxyethanol and perfume is added. The difference between the process of D7 and the present application is the lack of lipophilic and hydrophilic surfactants. Combining the

teaching of D7 with the general knowledge, the person skilled in the art was motivated to add surfactants to the microstructured composition. Hence the subject-matter of present claims 1-9 does not involve an inventive step [For details refer European Search Opinion for corresponding NP application published on 28/01/2011].”

6. Not satisfied by the applicant’s response to this second examination report; the respondent issued a hearing notice dated 04/01/2012 scheduling the hearing on 07/02/2012 which contained objections mainly on the grounds of ‘unity of invention’ and ‘lack of inventive’ step’ apart of mentioning the non- fulfillment of objections at para 1 and 2 of FER relating to novelty and inventive step of claims 1-21 as on record then.

7. Subsequently the applicant/appellant amended the claims and retained only claim 1-9 relating to ‘a process for the preparation of oil in water micro emulsion composition.

8. Now, Let’s have a look on the operating portion of the order of the Respondent:

“The alleged invention relates to a process for the preparation of oil in water micro emulsion composition. The applicant submission as submitted above has been considered but it is not persuasive.

The amended claims 1-9 do not involve inventive step in view of the cited documents D1-D6 of FER along with the teaching taken from D7 as stated below.

D1EP1018363B1

D2 EP 1020219 B 1

D3 WO 1999/044585 A1

D4 WO 2002/056843 A2

D5 Derwent Abstract accession no, 86-205112, Class B07, DD 234611 A

D6 Derwent Abstract accession no, 86-205113, Class B07, DD 234612 A

D7 : EP 0 875 244 A2 (CIBA GEIGY AG [CH] CIBA SC HOLDING AG [CH]) 4 November 1998 .

D1 discloses a nanoemulsion comprising a surfactant and at least one oil, useful as cosmetic composition, dermatological or ophthalmological composition.

D2 discloses an oil-in water nanoemulsion including alkyl ether citrate surfactant useful as cosmetic, dermatological, ophthalmological or pharmaceutical carrier.

D3 discloses a topical formulation of oil-in-water emulsion containing galactolipid material as emulsifier and with prolonged effect of incorporated active substance.

D4 discloses a translucent oil-in water nanoemulsion useful for preparing cosmetic, dermatological, ophthalmological compositions comprising three specified surfactants.

D5 and D6 disclose the production of dermatological creams of o/w emulsion type. The creams are useful as carriers for pharmaceuticals, eg corticosteroids, dithranol, antimycotic agents and antiviral agents.

The invention defined in present claims 1-9 is disclosed by these citations. Therefore, these claims are not novel and inventive in the light of the above mentioned citations. The problem to be solved is the provision of an alternative process for the preparation of an O/W microemulsion or submicron emulsion.

The solution provided is a process according to claim 1.

Closest prior art is document D1 & D7 describing microstructured compositions. In example 20 the oily phase comprising mineral oil, safflower oil and sesame oil as well as the aqueous phase comprising 1 % of (3-glucan are heated to 60-70°C, homogenized and cooled down to 40°C. Then the third part comprising phenoxyethanol and perfume is added.

The difference between the process of D7 and the present application is the lack of lipophilic and hydrophilic

surfactants. Combining the teaching of D1 & D7 with the general knowledge the person skilled in the art was motivated to add surfactants to the microstructured composition. Hence the subject-matter of present claims does not involve an inventive step. [Emphasis added]

It is clear from the description on page 6 that disrupting substances like propylene glycol or petrolatum are essential to the definition of the invention.

Since independent claim 1 does not contain this feature it does not meet the requirement of inventive step as specified in its definition under section 2(1)(ja) of the Act. Any independent claim must contain all the technical features essential to the definition of the invention.

claims 1-9 on record define the process for the preparation of an O/W microemulsion or submicron emulsion including the process steps of claim 1.

According to the description, the problem to be solved is the provision of a formulation method for microemulsions or submicron emulsions comprising disrupting substances like propylene glycol and/or petrolatum wherein the viscosity, appearance, stability and efficacy of the formulation is maintained.

The solution provided in claims 1-9 is a formulation made with the process according to these claims.

The problem to be solved is the provision of an alternative process for the preparation of an O/W microemulsion or submicron emulsion. The solution provided is a process according to claim 1. Further closest prior art is document D7 describing microstructured compositions. In example 20 the oily phase comprising mineral oil, safflower oil and sesame oil as well as the aqueous phase comprising 1 % of R-glucan are heated to 60-70 °C, homogenized and cooled down to 40 °C. Then the third part comprising phenoxyethanol and perfume is added. The difference between the process of D7 and the present application is

*the lack of lipophilic and hydrophilic surfactants. Combining the teaching of D7 **with the general knowledge**, the person skilled in the art was motivated to add surfactants to the microstructured composition. Person skilled in the art understand the invention better & what the difference it make after addition of emulsifier. Further, we have to understand D7 is working in the absence of conventional emulsifier also. Hence the subject-matter of present claims 1-9 does not involve an inventive step.*

So the teaching of the documents document D1-D6 & D7 taken together, the instant invention lacking inventive step. So, in view of the above the invention claimed in claims 1-9 of the alleged invention lacking in inventive step & hence not patentable under Section (2) (1) (j) of Patents Act ,1970 (as amended by Act ,2005).

Accordingly, the instant Patent Application No. 441/MUMNP/2007 is refused under section 15 of the Patents Act 1970.”

9. We have analyzed the contention of the appellant and the order of the respondent. It is clear from the highlighted portion quoted above that the respondent contradicts his own statements. Firstly, he says that *“The invention defined in present claims 1-9 is disclosed by these citations. Therefore, these claims are not novel and inventive”* and contradicts in subsequent statement that *“The difference between the process of D7 and the present application is the lack of lipophilic and hydrophilic surfactants.”* Therefore, it is very clear that the statement of lack of ‘novelty’ is totally unfounded and unsubstantiated.

10. Further, It is noticed that all the 6 prior arts documents (D1-D6), cited by the respondent in the First Examination Report (FER), were cited in International Search Report (ISR) issued by the Australian Patent Office. All the citations were of category ‘X’. We have further noted that Form -3 filed on 04/04/2012 at Indian Patent Office shows that the patent on same or substantially the same invention

has been granted in various other jurisdictions such as Australia, Canada, China, Mexico, Russia, Singapore, and South Africa. Further D7 which has been included by the respondent during hearing was also cited in other jurisdictions.

11. The finding of the respondent that *disrupting substances like propylene glycol or petrolatum are essential to the definition of the invention* is not found to be correct as per the mentioned facts at page 6 of the complete specification and brought to our notice by the appellants; e.g. *“Propylene glycol, which is desirably included in dermatological compositions....”* as shown in in paragraph 2.1 ante.
12. It is evident from the second examination report that that the respondent has wholly relied for his objections to grant of Indian Patents on European Search Opinion, in respect of corresponding National Phase application. He has not even brought out that report in its entirety but goes on to suggests referring to that report for details. This approach undermines the independent statutory responsibility of the respondent.
13. While the search and examination report of other jurisdictions may have some persuasive value but if such reports are wholly relied, without any technical input either from the examiner or from the Controller, is totally non-compliance of the teachings section 13 of the Patents Act, 1970.
14. Coming back to the analysis of inventive step of the respondent, who held that *“The difference between the process of D7 and the present application is the lack of lipophilic and hydrophilic surfactants. Combining the teaching of D1 & D7 with the general knowledge the person skilled in the art was motivated to add surfactants to the microstructured composition. Hence the subject-matter of present claims does not involve an inventive step.”*

15. Hon'ble Supreme Court held in Biswanath Prasad Radhey Shyam case¹ that *"The 'obviousness' has to be strictly and objectively judged. For this determination several forms of the question have been suggested. The one suggested by Salmond L. J. in Rado v. John Tye & Son Ltd. is apposite. It is: "Whether the alleged discovery lies so much out of the Track of what was known before as not naturally to suggest itself to a person thinking on the subject, it must not be the obvious or natural suggestion of what was previously known."*

16. While assessing the inventive step the respondent holds that *combining the teachings of D1 & D7 with the general knowledge, the invention lacks the inventive step. He neither identifies the 'person skilled in the art' nor identifies the relevant "common general knowledge". The term mentioned by him is 'general knowledge' but that too, has not been identified. Further, finding absence of propylene glycol or petrolatum in Claim 1, holding them essential, at the most, may affect the 'definitiveness' of the claims but not its 'inventive step' as held by the respondent; when he puts "Since independent claim 1 does not contain this feature it does not meet the requirement of inventive step as specified in its definition under section 2(1)(ja) of the Act."* The determination of 'inventive step' requires that the invention as a whole is required to be considered. It won't be 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.

17. Here, it is evident that the determination of 'inventive step' is far from being objective and hence the order of the respondent is not maintainable, being void of reasoning and proper assessment.

¹ Biswanath Prasad Radhey Shyam case vs Hindustan Metal Industries, Available at <https://indiankanoon.org/doc/1905157/>

18. We have considered the auxiliary request for amendment of the claims, submitted by the appellant, showing the inventive features. We are inclined to accept their submission with certain modifications.
19. Considering the above facts and circumstances, we, set aside the impugned order issued by the respondent dated 23/09/2014.
20. The learned counsel of the appellant is directed to incorporate the features of claims 2 & 3 shown in their 'auxiliary request' in the "characterized" portion of principal claim 1; and to add the feature of *"the weight ratio of the at least one hydrophilic surfactant to the at least one lipophilic surfactant being approximately 9.0:1.0 to 2.0:3.0"* from page 10 of the complete specification in both claim 1 and renumbered claim 5 suitably.
21. The leaned counsel of the appellant is further directed to file the amended claims 1-5 to the respondent within 2 weeks from the issuance of this order.
22. The respondent is directed to grant the patent on claim 1-5, strictly within two weeks from the date of filing of the amended set of claims by the appellant.
23. Appeal is allowed with above conditions. No cost.

-Sd/-

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

-Sd/-

(Justice Manmohan Singh)
Chairman

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