(2020) 11 IPAB CK 0004

In the Intellectual Property Appellate Board

Case No : Original Application No. 26 Of 2014/PT/MUM

Jina Pharmaceuticals — APPELLANT

Vs

Assistant Controller Of Patents & Designs — RESPONDENT

Date of Decision : 09-11-2020

Acts Referred:
Indian Patents Act, 1970 — Section 2(1)(ja), 2(1)(j), 3(i), 15, 59, 26(1), 117A, 142

Citation : (2020) 11 IPAB CK 0004

Hon'ble Judges : Manmohan Singh, J;Dr. B.P. Singh, Technical Member

Bench : Division Bench

Advocate : S Majumdar

Final Decision : Allowed

Judgement

,,,

1. The present appeal is filed under Section 117A of the Indian Patents Act, 1970, against the order dated 03/08/2011, passed by the Respondent,",,,

being the Assistant Controller of Patents & Designs, under Section 15 of the Indian Patents Act, refusing to grant the Appellantsâ?? Indian patent",,,

application no. 2155/MUMNP/2007.,,,

2. The Invention of the Appellant:,,,

2.1 As submitted by the learned counsel of the appellant, the invention relates to the preparation of suspension, liposomes, lipid complex, or Micelles in",,,

an aqueous system. The said invention relates to new methods of preparation of compositions comprising active components / compounds e.g.,,,

pharmaceutical compounds and lipids including complexes emulsions, liposomes etc. In all the embodiments of the said invention, the complex",,,

formation takes place in aqueous media.,,,

2.2 He further submits that the lipid components of lipid- based formulations are normally insoluble in aqueous media and organic solvents must be,,,

used in order to solubilize lipids at some stage in lipid-based formulation preparation. However, the organic solvents must be removed as much as",,,

possible from the final drug formulation because trace amounts of organic solvents can be toxic and can have adverse effects when administered to,,,

humans/animals and can also have deleterious effects on workers in manufacturing facilities.,,,

2.3 The key features of the invention as submitted by learned counsel of the appellant are as under:,,,

No organic solvent is used at any stage of preparation in the present invention.,,,

Entire process is conducted in water leading to not only economic significance but also echo-system contribution.,,,

Use of high-pressure homogenizer to disperse active compound and lipid in water.,,,

Insoluble compounds such as hydrophobic active ingredient and lipids are dispersed in the water by adjusting the pH between 1 and 8, thereby",,,

completely avoiding the use of organic solvent to make it miscible.,,,

Cholesterol derivatives specifically excluded (in prior art).,,,

Lipids are used in the invention.,,,

Specific particle size achieved by novel process.,,,

No restriction on phase transition temperature of the lipid.,,,

2.4 He further submits that the crux of the invention as disclosed and claimed is the process for preparing a lyophilized liposomal formulation.,,,

3. Facts of the case:,,,

3.1 The learned counsel of the appellant has submitted that in the FER dated 06/07/2010, the Respondent cited two prior arts namely USâ??",,,

20060110441 (referred to as D1) and US5616341 (referred to as D2.). However, only USâ??441 (D1) was actually effectively cited against the said",,,

application as evident from the Impugned order as well.,,,

3.2 The Examination report issued on 15/03/2011 objected to the patentability of the Appellantâ??s invention only on the face of the prior citation D1.,,,

3.3 The Respondent erred in considering the process steps (especially step a) of the claim 1 of the present invention in complete isolation.,,,

3.4 The Respondent erred while assuming that â??the organic solvent like ethanol in a small quantity 30 ml used in the prior art D1 is only to dissolve,,,

the lipid and hydrophobic drug and formed the solution.â? A 30-ml ethanol cannot be construed as â??small quantityâ? to dissolve 1.03 grams of the,,,

drug with 37.9 grams lipid. More so, when the present invention uses only water for dissolving the drug and lipids. Absolutely no organic solvent or",,,

ethanol is used in the invention.,,,

3.5 The Respondent ignored that D1 uses organic solvents to dissolve the unsaturated lipid and hydrophobic drug. This is the primary important step in,,,

the method of preparation of liposome and cannot be dispensed with.,,,

3.6 Instead of the interpreting the process as a whole the Respondent dissected the steps of the process claim and incorrectly compared it with D1.,,,

3.7 The Respondent further went on to compare the process steps with â??other routine step for preparation of liposomeâ? without the slightest,,,

thought that organic solvent is essential and indispensable component for dissolution of lipid and drug in the prior art.,,,

3.8 The Respondent compared the process of prior art and impugned invention and ignored the key step of using organic solvent and â??not using,,,

organic solventâ?? respectively.,,,

3.9 The Respondent further went on to compare the product characteristics of the present invention and the prior art ignoring that the processes per,,,

se are different contrary to its own statement â??During hearing, the applicant argued countering the objections already on record. The applicant's",,,

agent at the outset admitted to delete all the product claims and restricts only to the process claims. Such an amendment by the applicant was allowed.,,,

Hence, I state that any discussions on any product aspect of the invention while passing an order will not be debated.â??",,,

3.10 Though, the Respondent did acknowledge that â??major difference between the process aspect of the impugned invention over the prior art",,,

what the applicant argues and as per my assessment is that the impugned invention uses a suspension of lipid and active drug in water whereas the,,,

prior art US2006/0110441 uses suspension of lipid and active drug in hydration medium by adding solution of lipid and active drug in small quantity of,,,

ethanol.â? but eventually concluded that the effort does not make a surprising/ substantial contribution to the overall process aspect of the invention for,,,

which a patent can be granted.,,,

3.11 The Respondent failed to note that lipid components of lipid based formulations normally are insoluble in aqueous media and require organic,,,

solvent to solubilize lipids. The Respondent also failed to appreciate that the Appellant was claiming a process and the inventive step of the process,,,

,"Present invention

2155/MUMNP/2007","D1: US20060110441(Wong

et

al)","Distinguishing features

(Advantages of the

Appellantâ??s invention)

,Our invention (para (00133),Wong (Dl) para [0082]-,No organic solvent is

,"teaches very simple and

economic method of

preparation of lipid drug","Example 1) teaches first

dissolving lipid and drug

in organic solvent by","used in the present

invention.

Entire process is

,"complex in aqueous system

without using any organic

solvent. In the pending

patent: there is no use of any","incubation with stirring at

50Â°C until all of the lipid

and drug were

completely dissolved","conducted in water leading

to not only economic

significance

but also echo-system

,"organic solvent in the entire

preparation process. The entire
process in our
invention is carried out in","followed by extrusion to
achieve desired particle
size and finally the
organic solvent is","contribution.
-Use of high pressure
homogenizer to disperse
active and
","water by applying high pressure
homogenizer (internal page no
7, first para
of impugned Order","removed by diafiltration by
exchanging with sucrose
solution of pH
6.0. At the end, the","lipid in water.
- Insoluble compounds such
as hydrophobic active
ingredient and
","----------
--
No organic solvent: Instead
water is used.","formulation is concentrated
to maximize the drug
concentration
(internal page 6, last para","lipids are dispersed in
the water b y adjusting
the pH between 1 and
8, thereby completely
","The entire process of the

invention is
carried out in water by
applying high pressure","of impugned Order -------

The abstract,
specification, examples","avoiding the use of organic
solvent to make the
miscible.
-Cholesterol derivatives
","homogenizer
(page 5 of reply to hearing- July
6, 2011)
----------","and claims of the prior art
patent application no.
US200610110441
highlights the following","and others specifically
excluded (in prior art).
Lipids are used in the
invention.
","It is submitted that use of
organic solvent free process
in the Appellant's invention","restricting characteristics of
the process.
i. Use of organic","-the distinctive element of
transition
temperature as
has various benefits.
Firstly, reduces the cost of",,"(ethanolic) solvent.
ii. Use of buffer for pH","highlighted in earlier
reply (i.e., page 2 of

organic solvent.

Secondly, it reduces the steps

i.e. time period of the process

wherein the first","regulation.

iii. Mention of only the pH

of the buffer and not of

the solution.","reply to hearing dated

May 2, 2011)

-Specific particle size

achieved by novel",

step of dissolution of lipid and

hydrophobic drug in organic

solvent as well as the

later step of removal of","iv. Use restricted to only

unsaturated lipids.

v. Particle size

description, prior and","process.

-No restriction on

phase transition

temperature of the",

organic solvent are not required.

Thirdly, there is no danger

that the final drug","later.

vi. Cholesterol derivatives

specifically excluded from

the scope of the invention","lipid.

[internal pg 6,second

para of impugned Order",

formulation may contain

trace amount of organic

solvents.

Fourthly, working with","(internal page no 5, last para

of impugned Order

Organic solvents:","-In addition, vesicle-

forming lipid

derivatized with

â??hydrophilic polymerâ??",

organic solvent is hazardous for

the worker in the manufacturing

facility.","D1 uses organic solvents to

dissolve the unsaturated

lipid and

hydrophobic drug. This is","is not used in formulation

process - There is no

teaching in

Dl which even remotely",

,"the primary important step

in the method of

preparation of liposome

as disclosed inD1. This is","suggests that the

invention in Dl can be

performed without the

use of organic solvent.",

,"evident from the claims,

examples and detailed

description of D1","-the biggest advantage of

this preparation is

that the drug-lipid",

,,"complex is free from

any toxic organic

solvent",

Respondent has compared the product of the Appellantâ??s with that of D1 and arrived at the conclusion â??Had it been different, the claimed",,,

invention would be having a product distinguishable over the prior art in terms of the superiority in properties.â? These statements of the Respondent,,,

clearly go to show that the process does not have any independent existence despite the process been novel and inventive.,,,

5.2 Raj Parkash vs Mangat Ram Chowdhry & Ors â?" ILR 1977 (2) DEL 412-435 It was held in this case that â??The invention for which patent is,,,

claimed may be a product or an article or a process. In the case of an article, the patent is in the end product or the article; in the case of a process,",,,

the patent does not lie in the end product, but only in the process by which it is arrived at.â??",,,

In the Appellantâ??s invention, the inventive step lies in the process and it was total non-application of mind on the part of the Respondent to",,,

conclude that the process is not inventive by comparing the product of the Appellantâ??s invention and that of D1.,,,

5.3 Delhi High Court Cipla Ltd. vs F.Hoffmann-La Roche Ltd. & Anr, delivered on November 27, 2015.",,,

Reliance is placed on para 139 on page 42 continued to page 43. It is stated therein that,,,

â??The teaching of the prior art should be as a whole and various steps cannot be surgically put together.â??,,,

It is our humble submission that in the given case the Respondent has overlooked the use of organic solvent in the prior art D1 and separated out the,,,

other steps in D1 and a made selective comparison with the Appellantâ??s invention and observed that the product of the present invention will be,,,

the same as the product of the prior art and concluded that a similarity of the product can be achieved only by a similarity of the processes.,,,

5.4 The United States Court of Appeals of the Federal Court in Plas-Pak Industries, Inc. v. Sulzer Mixpac AG decided on January 27, 2015 held that",,,

â??[O]bviousness is a question of law based on several underlying factual findings,â? In re Baxter, 678 F.3d at 1361, including what a reference",,,

teaches, Rapoport v. Dement, 254 F.3d 1053, 1060â?"61 (Fed. Cir. 2001), and

whether proposed modifications would change a referenceâ??s",,,

â??principle of operation,â? see In re Mouttet, 686 F.3d 1322, 1332 (Fed. Cir. 2012) (finding â??the Boardâ??s determination that eliminating the",,,

optical components of Falk would not destroy its principle of operation to be supported by substantial evidenceâ?). Where â??a patent claims a,,,

structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do",,,

more than yield predictable results.â? KSR Intâ??l Co. v. Teleflex Inc., 550 U.S. 398, 416 (2007). However, combinations that change the â??basic",,,

principles under which the [prior art] was designed to operate,â? In re Ratti, 270 F.2d 810, 813 (CCPA 1959), or that render the prior art",,,

â??inoperable for its intended purpose,â?? In re Gordon, 733 F.2d 900, 902 (Fed. Cir. 1984), may fail to support a conclusion of obviousness. â?¦.",,,

(emphasis added),,,

In the Appellantâ??s invention the proposed modification (i.e. invention without organic solvent/ethanol) alters the reference's principal of operation,,,

(D1-Wong essentially with ethanol) D1, therefore fails to support the conclusion of obviousness. It is our humble submission in obviousness analysis",,,

that one cannot modify prior art in a way that disrupts the reference's contribution to the art (D1 in the present case). Such a change in a reference's,,,

'principle of operation' is unlikely to motivate a person of ordinary skill to pursue a combination with that reference.,,,

5.5 OSI PHARMACEUTICALS, LLC, Appellant v. APOTEX INC, USC, Federal Circuit, 2018-1925",,,

On appeal, the Federal Circuit reversed the Boardâ??s obviousness determination, holding that the Board misinterpreted the prior art to â??teach",,,

more than substantial evidence supports.â? The Court reasoned that the references offer â??no more than hope,â? and that no information about",,,

erlotinibâ??s success in treating NSCLC was disclosed. The Court made clear a reasonable fact finder could not find a reasonable expectation of,,,

success in this case.,,,

The Board observed: â??Obviousness is a question of law based on underlying findings of fact.â? In re Kubin, 561 F.3d 1351, 1355 (Fed. Cir. 2009).",,,

â??An obviousness determination requires finding that a person of ordinary skill in the art would have been motivated to combine or modify the,,,

teachings in the prior art and would have had a reasonable expectation of success in doing so.â? Regents of Univ. of Cal. v. Broad Inst., Inc., 903",,,

F.3d 1286, 1291 (Fed. Cir. 2018).",,,

5.6 In the present case, the prior art citation D1 does not teach beyond the use of ethanol for solubilizing the active ingredient and the lipid.",,,

Accordingly, starting from D1, there is not even a reasonable expectation of success in eliminating the use of ethanol as the solvent leave alone the",,,

suggestion or motivation to employ water as a suitable substitute for ethanol.,,,

6. It appears relevant to have a look on the brief history of the case, as under:",,,

6.1 Initially the instant patent application was filed with 38 claims, wherein claims 1-20 were oriented towards â??A method of treating a disease",,,

â?¦â?, claims 21-34 were relating to â??A process of preparation of lipid formulation of an active compound â?¦.â? And claims 35-38 were relating to",,,

â??A method of treating a cellâ?¦â??.,,,

6.2 The First Examination Report (Report) was issued on 06/07/2010 wherein claims 21-35 were objected for lacking in â??noveltyâ?? on the basis,,,

of D1 i.e. US 2006/0110441. Claims 1-20 were objected to being â??obviousâ?? based on the same document. Further, claims 1-20 and 36-38 were",,,

objected to being â??obviousâ?? based on document D2 i.e. US 5616341. Claims 1-20 & 35-38 were held as not patentable as per provision of,,,

Section 3 (i) of the Patents Act, 1970.",,,

6.3 The applicants/appellant amended the claims on 03/08/2010 to 34 in number, wherein claims 1-20 were oriented towards â??A composition for",,,

treatingâ?¦ â?? and claims 21-34 were oriented towards â??A process for preparation of lipid formulationâ?¦.â??.,,,

6.4 A hearing notice was issued on 17/12/2010 wherein the objections of FER were retained.,,,

6.5 The claims were further amended by the applicants/appellant on 02/05/2011 to 28 in numbers wherein claim 1-9 were relating to â??A process,,,

for preparation of lyophilized formulationâ?¦..â?? and claims 10-28 were oriented towards â?? A lyophilized compositionâ?¦.â??,,,

6.6 A further examination report was issued on 15/03/2011 wherein the applicants were asked to delete claims 10-28 and in respect of claim 1-9 it,,,

was held that â??The process claims (1-,,,

9) are considered because of the fact that water is used as a solvent instead of alcohol in the prior art. The process aspect are different from the prior,,,

art and not the product.â??,,,

6.7 A further hearing notice was issued on 15/06/2011 containing the following objections:,,,

â??The above said pending patent application is evaluated on the basis whether a patent can be granted or not considering carefully your reply dated,,,

02/05/2011 to First Examination Report. However, there are objections still outstanding which are as follows to be met.",,,

1. Reference is made to following documents while evaluating the patentability aspect of the invention claimed in any of the claims. Document of,,,

particular relevance is (i) D1: US2006/0110441(cited in first examination report) as well as the International preliminary report on patentability of,,,

International Bureau.,,,

Amended claim 1 dated 2 May 20011 is not satisfying requirement of section 2(1) (j) of Patents Act. being not novel. Document D1 teaches a process,,,

for preparing a lipid formulation of defined particle size (abstract) wherein said process comprises,,,

(a) preparing suspension comprising said at least one active compound and said at least one lipid in a first aqueous medium (para 0080) at pH between,,,

about 4.0- pH 8.0 (para 0082);,,,

Â (b) treating said suspension to form a lipid compound suspension of defined particle size (para 0080);,,,

(c) Lyophilizing the lipid-compound suspension of defined particle size to form lyophilized material (para 0080) such as the lyophilized cake,,,

(d) Reconstituting (para 0065) said lyophilized material with a second aqueous medium to obtain a suspension of lipid formulation of defined particle,,,

size (para 0068) said defined size having a mean particle size of less than 5 microns (para 68).,,,

Regarding claim 2. D1 teaches that treating such suspension comprising extruding said suspension through a selected size aperture; (para 71),,,

Regarding claim 3; D1 teaches treating suspension comprises high pressure split homogenization (para 71) such that the reference teaches,,,

homogenization and since it the complex is extruded through a pore it must be under high pressure.,,,

Regarding claim 4, D1 teaches said lyophilizing is in the presence of a cryoprotectant (para 0022) since it is frozen).",,,

Regarding claim 5, D1 teaches wherein said active compound comprises an active compound selected from the group consisting polyene antibiotic, a",,,

macrolide, an anticancer drug and immunosuppressant (para 0052) Regarding claim 6, D1 teaches said active compound comprises a compound",,,

selected from the group consisting of docetaxel, paclitaxel, doxorubicin, epirubicin, tamoxifen. endoxifen, endoxifen, etoposide: anthacylines.",,,

Amphotericin B? tacrolimus and sacrolimus.(para 0020) Regarding claim 7, D l teaches wherein said one lipid is egg phosphotadylcholine (EPC) for",,,

example (para 0011); Reading claim 8, D1 teaches the compound and cholesterols sulfate and (para 0040) but does not specifically recite ratio. which",,,

is obvious modification to person skilled in an. in absence of technical advancement.,,,

Regarding claim 9, D1 teaches the composition mean particle size upon reconstitution is about 10-5000 nm (para 0068).",,,

2. Claims 10-28 which seek protection for the product are characterized in terms of process steps which should be characterized by the product,,,

constituent. therefore, claim 10-28 is not definitive in terms of the product features. You have failed to demonstrate the distinguishing features of the",,,

product over the product of the prior art.,,,

3. Subject matter claimed in claim 10-28 which is incorporated as the amended claims, is not allowable according to section 59 of Patents Act, as",,,

these claims are not part of the original claims published by International Bureau of WIPO. Seeking protection for product claims which was not,,,

claimed during filing generally expands the scope of protection and not within the scope of the claims before amendment.,,,

4. The said application is entered as a national phase application without having priority (refer to the form I filed on 18/12/2007) and no extra feed for,,,

the additional priority is filed. However, the PCT pamphlet states that the said application seeks priority of two US applications. Under such",,,

circumstances, I find the said",,,

application is not filed in prescribed manner with incomplete fees. Refer to Section 142 of Patents Act: 2005, and make it convincing that the",,,

application can't be treated as an application for the reason that incomplete fees paid is unintentional.,,,

7. Letâ??s look at the operating portion of the order of the respondent:,,,

7.1 At the outset the respondent mentions in his order that the he has allowed the amendment of claims made by the applicant. He further mentions in,,,

the para shown below that the applicants restricts the claims to only process claims deleting the product claims as objected by the respondent. He also,,,

states that while passing the order, no discussion on the product aspect of the invention claims will be debated.",,,

7.2 The respondent in his order holds that the basic issue of the hearing were exclusively related to the objections raised vide letter dated 14th March,,,

2011, though his hearing letter was dated 15/06/2011(Diarized on 14/06/2011). We have reviewed the letters issued by IPO; and found that there is",,,

no such letter on record. It is either of 15/03/2011 or of 15/06/2011 (Diarized on 14/06/2011). If we consider the former, the respondent held that",,,

â??The process claims (1-9) are considered because of the fact that water is used as a solvent instead of alcohol in the prior art. The process aspect,,,

are different from the prior art and not the product.â? And the latter is the hearing notice itself. The Controller stand appears contradicting with each,,,

other. [Emphasis added],,,

7.3 Further, he considers amended claims 1-6 on record and annotates the crux of inventions quoted herein below:",,,

7.4 He analyses the prior art D1 and comments that â??it is important to note that organic solvent like ethanol in small quantity (30 ml in example 1) in,,,

the prior art is used only to dissolve the lipidâ?¦.â?. He further hold that â??Had it been different, the claimed invention would be having a product",,,

distinguishable over the prior art in terms of the superiority in properties. When the product of the prior art and the impugned invention are analyzed,,,

they are having the same characteristics like the particle size, association of a cryoprotectant, reconstitution by addition of water before administration",,,

etc. I also find the following similarity between the process of the prior art and the impugned invention: (i) input of the process like lipid and,,,

hydrophobic drug are same;,,,

(ii) in both the cases the system is suspended in a hydration medium at a selected pH; (iii) extrudation of the particles in selected sizes; (iv) separation,,,

of liposomes; and (v) addition of cryoprotectants.,,,

7.5 Here, it is noted that the Respondent again contradicts his statement. At first, he holds that the product aspect of invention will not be debated in",,,

the order and now he considers the products of the instant invention (the claims which were altogether deleted by the appellant earlier) and compares,,,

with that of prior art. The issue here is whether the process claimed in the instant invention is anticipated by the cited prior art document D1? To this,",,,

he again contradicts when he hold that prior art requires small amount of organic solvent to dissolve the lipid and tries to show the similarity in both the,,,

processes in four steps in the above quoted paragraph. Not only that, in the paragraph quoted below he annotates the major difference in the process",,,

aspect of the impugned invention over the prior art and accepts that the impugned invention uses a suspension of lipid and active drug in water directly,,,

whereas the prior art (US 2006/0110441) uses a suspension of lipid and active drug in small quantity of ethanol. Now whether the use of ethanol used,,,

in prior art is small or not can be well seen in example 1. A 30-ml ethanol cannot be construed as â??small quantityâ? to dissolve 1.03 grams of the,,,

drug with 37.9 grams lipid.,,,

7.6 He, further, holds in the parahraph quoted below that such an effort by the present inventor is very much obvious to a person skilled in the art. This",,,

statement is totally void of any assessment of the â??inventive stepâ?. The respondent holds that the use of organic solvent in prior art in place of,,,

water in the instant invention is â??not appreciatedâ?. The present invention uses only water for dissolving the drug and lipids. There is no organic,,,

solvent or ethanol used in the invention. D1 uses organic solvents to dissolve the unsaturated lipid and hydrophobic drug. It is an important step in the,,,

method of preparation of liposome and cannot be dispensed with as held by the respondent.,,,

7.7 The appellant has also drawn our attention to the opinion of Dr. Eric J Mayhew- an authority in lipid based drug delivery systems which states that,,,

â??lipid particle particularly liposome preparation necessarily requires the use of organic solvents at some point in the formulation process, therefore",,,

the method described in the patent application is not obvious.â??,,,

7.8 The appellant has submitted a table (para 4 ante) showing the distinguishing features of the instant invention with the closest prior art. We are,,,

convinced that there is marked difference of the use of organic solvent in prior art as against use of water in the instant invention.,,,

7.9 We have noted that D1 does not teach or suggest that the invention in D1 can be performed without the use of organic solvent. This is admitted by,,,

the respondent also when he holds the use of organic solvent in small quantity in prior art.,,,

7.10 We also note that the biggest advantage of the preparation with water as solvent is that the drug-lipid complex is free from any toxic organic,,,

solvent.,,,

7.11 Keeping in view the above facts the objection on â??noveltyâ? is not sustainable. The respondent has also held the invention to be lacking,,,

â??inventive stepâ?? as well. So in the following paragraphs we will confine our discussion to â??inventive stepâ?? requirements.,,,

7.12 We have noted that the invention is trying to find a solution of problem as mentioned in para 011 of the complete specification mentioned herein,,,

below:,,,

â??Several formulations have been made to solublize the taxanes and to circumvent the toxicities associated with it. All of these formulations,",,,

including lipid-based formulations (for example, liposomes), have required use of organic solvents to solubilize the active compound during the",,,

formulation process (Straubinger, et.al. US5,415,868, 1995; Bisery, et al US6,146,663, 2000). As noted above, the use of organic solvents results in a",,,

cumbersome process and hence an organic solvent-free formulation is needed to overcome the problems associated with the existing formulations.â?,,,

Further para 0043 mentions that â??The inventive method is simple, rapid and less expensive method to produce organic solvent- free aqueous",,,

liposome systemâ?¦â??,,,

8. It is the contention of the respondent that the effort of using an â??organic-free solventâ? i.e. water is â??obviousâ?? to person skilled in the art.,,,

But such a statement is void of any reasoning and objective assessment of inventive step. Honâ??ble Supreme Court of India1 has laid down the test,,,

of â??inventive stepâ??,,,

â??25. The expression ""does not involve any inventive step"" used in Section 26(1) (a) of the Act and its equivalent word ""obvious"", have acquired",,,

special significance in the terminology of Patent Law. 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 1 Biswanath Prasad Radhey Shyam vs,,,

Hindustan Metal Industries Ltd (AIR 1982 SC 1444) person thinking on the subject, it must not be the obvious or natural suggestion of what was",,,

previously known."" (Emphasis Supplied)",,,

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

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?"" (Encyclopaedia 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 ?"" Halsbury, 3rd Edn, Vol. 29, p. 42 referred to by Vimadalal J. of",,,

Bombay High Court in Farbwrke Hoechst & B. Corporation v. Unichem Laboratories.? (Emphasis Supplied).,,,

9. We have also considered the case laws submitted by the learned counsel of the appellant and quoted above (para 5 ante) and find that the,,,

respondent has not followed any of the well- settled principles of the assessment of â??inventive stepâ?? and therefore his order is not sustainable.,,,

10. We have reviewed the claims and found that though the use of water is apparently mentioned therein; the fact that the process is using an,,,

â??organic- free solventâ??, is not clearly mentioned in the claims.",,,

11. We, therefore, direct the learned counsel of the appellant to file amended set of claim, bringing out this fact of â??organic- free solventâ? clearly",,,

in the principal claim, to the respondent within 2 weeks from the issuance of this order.",,,

12. The respondent is directed to grant the patent on claims 1-6 strictly within two weeks from the date of filing of the amended set of claims by the,,,

appellant.,,,

13. Appeal is allowed with above conditions. No cost.,,,

