



**IPAB** Intellectual Property Appellate Board  
balancing ip-protection

**Delhi Registry –Cum-Bench**

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**OA/67/2020/PT/DEL**

**FRIDAY, THIS THE 4<sup>th</sup> DAY OF DECEMBER, 2020**

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

**CHAIRMAN**  
**TECHNICAL MEMBER (PATENTS)**

1. PHARMATOP SCR.

A corporation organized under the laws of France,  
10 square St Florentin 75150, Le Chesnay, FRANCE

.....Appellant

(Represented by -Mr Shukadev Khuraijam)

Versus

1. The Controller of Patents & Designs

The Patent Office, Boudhik Sampada Bhawan,  
Plot No. 32, Sector-14  
Dwarka, New Delhi-110 078

(Represented by -None)

2. VENUS REMEDIES LIMITED

51-52, Industrial area,  
Phase 1,  
Panchkula-134113  
Haryana

.....Respondents

(Represented by -Dr Vikrant Narayan Vasudeva)

**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 24/12/2018, passed by the Respondent no.1, being the Deputy Controller of Patents & Designs, under Section 25(4) of the Indian Patents Act, 1970, revoking the Appellants' Indian patent no. 238164, granted on patent application no. IN/PCT/2003/00014/DEL.
2. The appellant herein filed a writ petition No 5755/2019 at Hon'ble High Court of Delhi on 24/04/2019. As informed by the appellant, as per the oral direction of the Hon'ble High Court during the hearing of the said writ petition on 24/05/2020, they filed this appeal at IPAB.
3. Further, Hon'ble High Court of Delhi, vide its order dated 05.03.2020, transferred the matter to IPAB.
4. Facts of the Case:
  - 4.1 A patent Application No. IN/PCT/2003/00014/DEL was filed on 02/01/2003, pursuant to PCT INTERNATIONAL APPLICATION NUMBER PCT/FR01/01749 filed on 06/06/2001; for the invention titled "METHOD FOR PRODUCING AN AQUEOUS SOLUTION OF AN ACTIVE INGREDIENT OF PHENOLIC NATURE. On following the due procedure in accordance with the provisions of the Patents Act, 1970, the patent was granted with patent no. 238164 to the appellants and was published u/s 43 (2) of the Patent Act, 1970 on 29/01/2010.
  - 4.2 A notice of post- grant opposition under section 25(2) of the Patents Act, 1970 was filed by the respondent no.2 herein, on 31/01/2011.
  - 4.3 The Respondent no. 2 filed the written statement and evidence under Rule 57 of the Patents Rules, 2003 on 30/03/2011.

4.4 The appellant filed reply statement under Rule 58 of the Patents Rules, 2003; on 30/06/2011, taking a month's extension. However, they choose not to file any evidence along with the statement in support of their submissions.

4.5 The post-grant opposition was filed on the following grounds, namely:

- (i) Lack of Novelty -Section 25 (2)(b)
- (ii) Lack of inventive Step -Section 25 (2) (e)
- (iii) Not an invention under Section 3(d)-Section 25(2) (f)
- (iv) Not an invention under Section 3(e)-Section 25(2)(f)
- (v) Not an invention under Section 3(f)- Section 25(2) (f)
- (vi) Specification not sufficiently and clearly describes the invention-Section 25(2) (g)

4.6 It's the submission of the respondents no.2 that they relied on the following documents in support of their contention:

D1: Cooper and Gunn's, Dispensing for Pharmaceutical, Published in 1987

D2: Lachman and Lieberman, the theory and Practice, Published in 1991

D3: WO1998005314, Priority date 05.08.1996

D4: US 4259360, Priority date 16.04.1979

D5: US 5096926, Priority date 06.12.1990

D6: JP 63132833, Priority date 25.11.1986

D7: Alfonso R Gennaro, published in 2000

D8: Carol et al, published in 1993

D9: US 4952566, Priority date 05.08.1987 and

D10: US 5254579, Priority date 29.05.1991

4.7 The respondent no.1 appointed a hearing which was held on 13/04/2018 and issued the impugned order on 24/12/2018.

4.8 Aggrieved by the said order the appellant has preferred this appeal.

5. The case of the appellant:

5.1 That the impugned order is vitiated since Respondent No. 1 considered Documents D1 and D2 (for the purpose of ascertaining inventive step) FOR THE FIRST TIME ONLY in the impugned order. Since, the Appellant did not get any opportunity to rebut the objection against documents D1 and D2, the impugned order has been passed in violation of the principles of natural justice.

5.2 The Appellant submits that the stance taken by the Respondent no.1 contravenes the doctrine of *audi alteram partem* which stipulates that no man shall be condemned unheard. The order is vitiated on this ground alone.

5.3 The Appellant submits that the conduct of the Respondent no.1 in raising an objection which was not communicated in the hearing notice is in contravention of the directions laid down by this Hon'ble Board in the matter of Resprotect GmbH vs The Controller of Patents & Designs & Anr., OA/23/2010/PT/DEL (hereinafter referred to as 'the Resprotect Case') wherein it was clarified that:

*“A quasi-judicial authority is not an adversary of the patent applicant. Therefore any objection that may arise in this regard, any prior art that will be relied on must be made known to the applicant before the date of hearing.”*

5.4 The impugned order is manifestly arbitrary and discriminatory since the Respondent No. 1 has not given due consideration to the fact that by taking new documents on record (for the purpose of adjudicating the ground of 'lack of inventive step') at the very last step of the proceedings (i.e. at the time of rendering a final order), has deprived the Appellant of the opportunity to present its defense.

5.5 In view of the foregoing, the impugned order has clearly been passed in breach of the principles of natural justice and is also in contravention of the directions laid down by this Hon'ble Board in the Resprotect Case.

5.6 In the case of Competition Commission of India v. Steel Authority of India Ltd. and Anr., (2010)10 SCC744, the Hon'ble Supreme Court held that

*“The principles of natural justice has twin ingredients; firstly the person who is likely to be adversely affected by the action of the authorities should be given notice to show cause thereof and granted an opportunity of hearing and secondly, the orders so passed by the authorities should give reason for arriving at any conclusion showing proper application of mind. Violation of either of them could in the given facts and circumstances of the case, vitiate the order itself.”*

5.7 In the case of Accenture Global Service Gmbh Vs The Assistant Controller of Patents & Designs & Anr. (IPAB Case No. OA/22/2009/PT/DEL), the Hon'ble IPAB held that:

*“... the order issued is influenced by incorrect facts and without application of mind and should be subjected to correction (Paragraph 6).....*

*It is the important principle of law that the quasi judicial tribunal must follow the principle of natural justice and give reasoned decision based on the facts of the case and position of the law. A person must be given an opportunity to present his case before any adverse decision is taken. We are convinced that the respondent has not applied his mind based on the existing facts and relevant provision of the patent law.” (Paragraph 13)*

5.8 In the case of Otsuka Pharmaceutical Co. Ltd. Vs. The Controller General of Patents & Designs & Anr. (IPAB Case number OA/24/2010/PT/DEL), the Hon'ble IPAB held that:

*“Any document that will be relied on must be made known to the appellant before the date of hearing for their reply.”*

5.9 Respondent No. 1 failed to appreciate that it was required to exercise the powers under Section 25 (2) of the Patents Act by strictly following the procedure laid down in Rules 55 to 62 of the Patents Rules, which nowhere authorizes the Respondent No. 1 to RE-EXAMINE THE PATENT APPLICATION. In post-grant opposition proceedings under Section 25 (2), the Respondent No. 1 was required to assess only the merits of the grounds pleaded by the Opponent (Respondent No. 2). Therefore, the impugned order is arbitrary and ultravires. Respondent No. 1 has miserably failed to understand the scope of proceedings under Section 25 (2) of the Patents Act (and has clearly exceeded his jurisdiction by assuming the role of an Examiner/Controller by re-examining the subject patent under Sections 12 to 15 of the Patents Act), which led to the subversion of justice.

5.10 The impugned order is bad in law, arbitrary and discriminatory in nature. The order passed is vitiated in as much as the same is ultra vires and has been passed after 're-examination' of the granted patent standing in favour of the patentee and goes beyond the grounds pleaded and argued by the Opponent (Respondent No. 2). The impugned order ought to be set aside since the Patents Act does not empower Respondent No. 1 to conduct a fresh examination of a granted patent under Sections 12 to 15 of the Patents Act, while deciding a post-grant opposition under Section 25 (2) of

the Patents Act. Respondent no.1 has apparently and wrongly subsumed his powers in a pre-grant opposition proceedings which cannot be applied in a post-grant or revocation proceedings.

5.11 Attention of this Hon'ble Board is invited to the decision passed by the Hon'ble Delhi High Court in the matter of M/s UCB Farchim SA Vs M/s Cipla Ltd. & Ors, 2010(42)PTC425(Del), wherein inter alia the distinction between pre-grant and post-grant oppositions was appreciated.

*“13. In the first instance a distinction has to be drawn between a pre-grant opposition and a post-grant opposition. .... This Court finds merit in the contention that the pre-grant opposition is in fact in aid of the examination of the patent application by the Controller. The procedure is however different aspect as far as the post-grant opposition is concerned.”*

5.12 Respondent No. 2 while pleading the ground under Section 25 (2) (e) of the post-grant opposition included only prior art documents D3 to D10 (page 17 to 25 of the post-grant opposition). However, Respondent No. 1 while deciding the ground on Section 25 (2) (e) considered documents D1 and D2 in addition to documents D3 to D10, which were never pleaded by Respondent No. 2 under Section 25 (2) (e) [ground on obviousness/ lack of inventive step] in the 'post-grant opposition'. While adjudicating a matter under Section 25 (2), Respondent No. 1 was required to decide whether the grounds pleaded by the Opponent are maintainable in view of the pleadings of the Opponent. Since the Opponent (Respondent No. 2) had not relied upon D1 & D2 for arguing its case on inventive step in the post-grant opposition, the

Respondent No. 1 has exceeded its jurisdiction by drawing upon the contents of D1 & D2 to decide the ground of lack of inventive step. The impugned order is ultravires in as much as the Respondent No. 1 has held that:

*“It is wrong on the part of Patentee that documents (D1 and D2) missed by the opponent in their reply evidence for inventive step objection cannot be taken on record to evaluate obviousness. If any document is brought to the notice of the Controller, the Controller is free to consider all the documents for objections raised by the opponent under various grounds. So, for the present application, it is immaterial whether the opponent has cited those documents for inventive step or not.”*

5.13 The Appellant submits that Respondent No. 1 has clearly exceeded the jurisdiction conferred upon him by the Patents Act. As the adjudicating authority of the post-grant opposition proceedings, Respondent No. 1 was required to assess whether the ground pleaded under Section 25 (2) (e) was sustainable in view of the arguments and supporting documents D3 to D10 . Moreover, the Respondent No. 1 was to be guided by Section 25 (2) along with Rules 55 to 62 of the Patents Rules. However, Respondent No. 1 chose to re-examine the application under Section 12 to 15, without having any statutory authority to do so.

5.14 The impugned order is ultra vires because the Respondent No. 1 exceeded his authority by RE-EXAMINING the subject patent (by considering grounds not pleaded) instead of adjudicating the post-grant opposition (based on the grounds pleaded).

5.15 The Appellant submits that the stance taken by the Respondent No. 1 is contrary to the well established

principles laid down by the Hon'ble Supreme Court and has entertained and relied upon submissions not expressly pleaded and proved. Attention of this Hon'ble Board is invited to the decision of the Hon'ble Supreme Court in the matter of Shankar Chakravarti vs. Britannia Biscuit Co. Ltd. and Ors., AIR1979SC1652, wherein it held that:

*“A contention to substantiate which evidence is necessary has to be pleaded. If there is no pleading raising a contention there is no question of substantiating such a non-existing contention by evidence. It is well settled that allegation which is not pleaded, even if there is evidence in support of it, cannot be examined because the other side has no notice of it and if entertained it would tantamount to granting an unfair advantage to the first mentioned party. We are not unmindful of the fact that pleadings before such tribunals have not to be read strictly, but it is equally true that the pleadings must be such as to give sufficient notice to the other party of the case it is called upon to meet. This view expressed in Tin Printers (Private) Ltd. v. Industrial Tribunal 1967 L.L.J. 677 commends to us. The rules of fair play demand that where a party seeks to establish a contention which if proved would be sufficient to deny relief to the opposite side, such a contention has to be specifically pleaded and then proved. But if there is no pleading there is no question of proving something which is not pleaded. This is very elementary.”*

5.16 Even in the matter of Chemtura Corporation Vs Union of India, Bombay High Court, W.P. (C) 1919/2014, the Hon'ble Bombay High Court denounced the practice of *suo*

*moto* adjudication by a tribunal. In the facts of this case, a revocation petition was filed by the Petitioner VRC Continental against patentee Chemtura on February 04, 2009. On August 27, 2009, VRC sought to withdraw the revocation Petition. The Hon'ble IPAB's registry directed VRC to file a Miscellaneous Petition (MP) for 'withdrawal'. MP for withdrawal was filed by the Petitioner. The Hon'ble IPAB did not consider/allow the MP for withdrawal and proceeded to revoke Chemtura's patent. The Hon'ble Bombay High Court quashed the order of revocation and restored the patent. A copy of the judgment is being provided along with the present written submissions.

5.17 The impugned order is vitiated and is ultra vires since the Respondent No. 1 has failed to discharge its function as a statutory authority under Section 73 of the Patents Act and has instead assumed the role of a 'person interested' by playing the role of an adversary and has 'enlarged the grounds of appeal' to the detriment of the Appellant.

5.18 This is clearly evident from the Respondent No. 1's findings in the impugned order wherein it is stated that:

*"It is wrong on the part of Patentee that documents (D1 and D2) missed by the opponent in their reply evidence for inventive step objection cannot be taken on record to evaluate obviousness. If any document is brought to the notice of the Controller, the Controller is free to consider all the documents for objections raised by the opponent under various grounds. So, for the present application, it is immaterial whether the opponent has cited those documents for inventive step or not."*

5.19 This Hon'ble Board has denounced the practice of 'enlargement of grounds of opposition' in the case of Newage Laminators Pvt. Ltd. Vs. SPL's Sidhartha Limited, M.P. No. 27/2011 in TA/9/2007/PT/DEL & TA/9/2007/PT/DEL. The relevant portion of the judgment is reproduced below:

*"We shall see the grounds of opposition stated in Form 7 and the observations of the Controller which are reproduced below:*

*The Rodent repellent composition and a process for preparation thereof was existing, known and used since long before and is not an invention as wrongfully claimed by the applicant.*

*Since the opponents M/s New Age Laminators Pvt Ltd. appears to be not familiar with the opposition proceeding under the patent law, it can be asserted from the Form 7 that they want to oppose the grant of patent on the ground namely (a) prior public knowledge and prior public use ( Section 25(d), (b) not an invention (section 25(f) and (c) wrongfully claimed (obtained).*

*We agree with the Controller observation that the ground stated by the opponents were not clear. But the Controller's observation that the "wrongfully claimed (obtained)" is also a ground stated by opponent/appellant based on his assumption is not correct. Therefore we disagree with the finding of the Controller relating thereto. The Controller should not have unnecessarily ventured on assumption to decide on a ground of opposition not relied on by the opponent."*

5.20 The Respondent No. 1 has failed to appreciate the position that burden of proof lies on the Opponent in case of post-grant opposition proceedings

5.21 Sections 101 and 102 of the Evidence Act stipulate that:

*“101. Burden of proof. - Whoever desires any Court to give judgment as to any legal right or liability dependent on the existence of facts which he asserts, must prove that those facts exist. When a person is bound to prove the existence of any fact, it is said that the burden of proof lies on that person.*

*102. On whom burden of proof lies.- The burden of proof in a suit or proceeding lies on that person who would fail if no evidence at all were given on either side.”*

5.22 The Appellant submits that in a post-grant opposition, it is the Opponent, who at the first instance, must plead the grounds raised by it. It is not open to the adjudicating authority to bridge the deficiencies in the plaint by citing additional documents which were not brought forth by the Opponent (Respondent No. 2).

5.23 As evident from the post-grant Opposition pleadings, the Opponent (Respondent No. 2) has not relied upon documents D1 and D2 while arguing the case on lack of inventive step under Section 25 (2) (e). The impugned order is vitiated since it was passed with the premeditated intention of revoking the subject patent of the Petitioner.

5.24 It is a well settled principle in patent law, that it is the challenger who has to discharge the onus through filing of “verifiable evidence”. Even the Intellectual Property Appellate Board (IPAB) applies the same principles while adjudicating revocation actions. It is well settled law that mere allegation is

not sufficient to dislodge a validly granted patent. In the matter of The Travancore Mats & Matting Co Vs. Controller of Patents and Ors, ORA/44/2009/PT/CH, the Hon'ble IPAB has held that:

*“17. It is trite law that person who seeks revocation must prove it. The onus of proving invalidation of a patent is on the applicant. The applicant in this case failed miserably to prove his case. Mere allegation is not sufficient to dislodge a validly granted patent.”*

5.25 Instead of acknowledging that the Respondent No. 2 has failed to discharge its burden of proving the allegation under Section 25 (2) (e) of the Act, Respondent No. 1 has stepped into the shoes of the adversary and has played the role of an Opponent by considering additional documents D1 and D2 which were not pleaded by the Respondent No. 2 in its ground under Section 25 (2)(e).

5.26 The Appellant submits that the stance of Respondent No. 1 is contrary to the well-established practice of the Patent Office wherein enlargement of grounds beyond pleadings is not allowed. In this regard, attention of the Hon'ble Board is invited to the decision of the Patent Office in Premier Evolyics Pvt., Ltd. vs. Shanmuga Sundarm Thiyagu, Indian Patent Number 223959, wherein it was held that:

*“The patentee alleged that the ground U/S 25(2) (h) is new ground which was not taken up earlier by the opponent at the time of filing the opposition. Further no amendment of form -7 has been sought for the incorporation of a new ground. Accordingly the new ground U/S 25(2) (h) cannot be taken at a later stage without the leave of the Controller. Therefore, all pleadings and submission with respect to the new*

*ground taken in the later stage of the proceedings on the opponent own motion without obtaining leave of the Controller ought to be ignored and treated as null and void.*

.....

*Upon analyzing the above facts, I would like to go with the patentee's argument, because Section 25(2) (h) is a new ground and there is no support from the Patents Act, 1970 that at any time during the post grant opposition new ground can be raised. Hence, Section 25(2) (h) is not considered as a ground of opposition”*

5.27 Likewise, in the matter of Sun Pharmaceutical Industries Ltd. V/s. Cipla Ltd., Indian Patent Number 206218, the Indian Patent Office adopted the same stance and did not allow new grounds which were not a part of the pleadings to be taken by the Opponent.

5.28 The written arguments were time barred and was not accompanied by any petition for condonation of delay/ application for extension of time and also expanded the scope of the arguments presented at the hearing.

5.29 Rule 28 (7) of the Patents Rules clearly stipulates that “in all cases of hearing, written submissions and the relevant documents, if any, shall be filed within fifteen days from the date of hearing”.

5.30 Respondent No. 2 did not file its written submissions within the due date prescribed the Patents Rules. Despite the written submissions being time barred and not being accompanied with a Petition for condonation of delay/ application for extension of time, Respondent No. 1 took the written submissions on record and relied upon the same

while rendering the decision, which constitutes a glaring procedural irregularity by Respondent No. 1.

5.31 Attention of this Hon'ble Board is invited to the decision of the Hon'ble Delhi High Court in the matter of The Regents of The University Of California Vs. Union Of India & Ors., 2019(79)PTC55(Del) wherein it observed that :

*“47..... Clearly, post hearing written submissions cannot expand the scope of submissions made in the oral hearing. Such submissions are clearly meant to record only the oral submissions made at the hearing in order to assist the decision maker.”*

5.32 The impugned order is vitiated since Respondent No. 2 expanded the scope of the arguments presented at the hearing [by introducing D1 and D2 for the purpose of challenging inventive step & reintroducing the ground of insufficiency under Section 25 (2) (g)] and Respondent No. 1 proceeded to take the submissions on record.

5.33 The Respondent No. 1's decision on Section 25 (2) (g) is perverse since the aforementioned ground was surrendered/ not argued by Respondent No. 2 during the hearing.

5.34 The impugned order reflects non-application of mind by the Respondent No. 1 inasmuch as the concluding lines on page 34 of the impugned order indicates that the patent has been revoked only under Section 25 (2) (e) [ground of 'lack of inventive step'], however the findings with respect to the ground of opposition under Section 25 (2) (g) [insufficiency of description], has been decided against the Appellant.

5.35 Assuming without admitting that the ground under Section 25 (2) (g) has been held against the Appellant, the Appellant submits that the Respondent No. 1's decision on Section 25 (2) (g) is perverse since the aforementioned ground

was surrendered/given up by Respondent No. 2 during the hearing. The Appellant has documented this fact on the opening pages of the written arguments. Having given up the ground on Section 25 (2) (g), Respondent No. 2 did not have the liberty to raise fresh grounds at the stage of filing written notes/arguments, which were required to be restricted to the grounds pursued at the post-grant opposition hearing proceedings. The impugned order is vitiated since Respondent No. 2 has re-opened the issue of insufficiency (at the stage of filing time barred written arguments thus depriving the Appellant of the opportunity to rebut the objection) after the ground was surrendered by the Opponent during the post-grant hearing.

5.36 The principles of natural justice are also contravened since the Appellant did not get a chance to rebut the objection on the ground of 'insufficiency' since the Appellant did not present any arguments (after Respondent No. 2 dropped this ground during oral arguments).

5.37 Even on merits, Respondent No. 1's evaluation on the ground of insufficiency under Section 25 (2) (g) is erroneous. Assuming without conceding that the ground under Section 25 (2) (g) was validly considered by Respondent No. 1 (despite the said ground having being surrendered/ not pressed by Respondent No. 2 at the post-grant opposition hearing), even then the impugned order *vis-a-vis* the ground under Section 25 (2) (g) is erroneous and unsustainable on merits.

5.38 The Appellant submits that Respondent No. 1 has erred in observing that the description is insufficient since 'the claims require the pressure to be less than 65,000 Pa whereas support in the specification is for pressure valueless than 10,000 Pa'. The Appellant submits that the claims are

supported by lines 15-16 on page 8 of the complete specification of the patent application which clearly states that the maximum pressure is 65,000 Pa.

5.39 Moreover, the Respondent No. 1 has also erred in upholding the ground of insufficiency on the incorrect premise that 'the experiments and examples do not support all possible alternatives of the hydro polycarboxylic acid or antioxidants'. The Appellant submits that the refusal under Section 25 (2) (g) is erroneous since the specification does not contravene any of the requirements of Section 10 (4) of the Patents Act.

5.40 Moreover, the interpretation of Respondent No. 1 is not in consonance with paragraph 05.03.08 of the Manual of Patent Office Practice and Procedure' which stipulates that 'The details of invention described should be sufficient for a person skilled in the art to perform the invention. It may include examples / drawings or both for clearly describing and ascertaining the nature of invention.'

5.41 It is evident that 'support' must be assessed from the specification and not merely from the examples. In view of the foregoing, the impugned order is arbitrary and erroneous with respect to its findings under Section 25 (2) (g).

6. The Respondent no.2 herein refutes the contention of the appellant and submits as under:

6.1 That the ground raised by Petitioner that all the documents D1-D10 were considered while analyzing the inventive step even though the Respondent No.1 (Opponent) failed to mention D1-D2 for lack of inventive step while filing the opposition is wrong and denied.

6.2 That the Respondent/Opponent in its statement of Opposition clearly stated and cited documents D1 and D2. It

specifically stated the following under grounds of opposition of lack of inventive step -section 25 (2) (e) **(pg. 156, 177-179 of writ petition as filed by Petitioner in W.P.(C) 5755/2019)**:

*“In view of the foregoing evidences and on the basis of beneficial overall teaching of the provided by cited document D1 to D10...Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made and clearly does not involve any inventive step...Hence the impugned patent falls within the scope of 25(2)(e)...”*

6.3 That similarly the Respondent/Opponent clearly stated and cited documents D1 and D2 in their Reply Statement and Evidence. It specifically stated the following under ground of opposition of lack of inventive step -section 25 (2) (e) **(pg. 269, ; 270; 274 of writ petition as filed by Petitioner in W.P.(C) 5755/2019)** thus: “Therefore in light of the teachings, suggestions and predictability of the prior arts found in D1 to D10 ...the impugned patent clearly does not involve and inventive step and hence the impugned patent is liable to be dismissed u/s 25(2)(e)...”

6.4 Further D1 and D2 were argued at length during the hearing for this ground and also stated so in the written note submitted thereafter.

6.5 It needs to be noted that S.25(5), Patent Act, 1970 states that "While passing an order under sub-section (4) in respect of the ground mentioned in clause (d) or clause (e) of sub-section (2), the Controller shall not take into account any personal document or secret trial or secret use". Thus the only ground on which a document can be excluded is if it is a personal document.

6.6 It needs to be noted that Rule 62, Patent Rules, 2003 (Hearing) states that: "(4) If either party intends to rely on any publication at the hearing not already mentioned in the notice, statement or evidence, he shall give to the other party and to the Controller not less than five days' notice of his intention, together with details of such publication." Thus, the Patent Rules too allow any additional document to be filed at any stage of post-grant opposition including at the stage of hearing.

6.7 It needs to be noted that Rule 62, Patent Rules, 2003 states that "(5) After hearing the party or parties desirous of being heard, or if neither party desires to be heard, then without a hearing, and after taking into consideration the recommendation of Opposition Board, the Controller shall decide the opposition and notify his decision to the parties giving reasons therefor." Thus, the Ld. Controller has to heed the recommendations of the Opposition Board in reaching its decision. It needs to be noted that the Opposition Board recommended that the person skilled in the art in view of the good results of D4 would combine D1 to D4 and arrive to the subject-matter of present claims as all critical elements of claimed process have been already disclosed in the prior art.

6.8 It needs to be noted that Guidelines For Search And Examination Of Patent Applications Indian Patent Office, 2015 specifically state:

#### Hearing In Post Grant Opposition Matters

If either party intends to rely on any Publication at the hearing not already mentioned in the notice of opposition, statement or evidence, he shall give to the other party and to the Controller a notice of his intention to do so, together with

details of such publication. Such notice shall be given at least five days before the date of hearing.

6.9 In OA/13/2011/PT/MUM IPAB held “in patent cases we cannot ignore the prior art citations even where the additional documents are filed at the appeal stage particularly when they are relevant. However to meet the requirement of natural justice the contesting party shall be given an opportunity to defend and present their argument which was given to the appellant in the present case.

6.10 It is not the Appellant's case that they were not aware of said documents D1 and D2. It can also not be argued that there has been any denial of natural justice, as Appellant was given due opportunity to rebut use of documents D1 and D2 in their reply, hearing and written submissions. The documents D1 and D2 were very well cited and relied upon in the notice of opposition. The documents D1 and D2 were also relied upon by the Board of Opposition in reaching their conclusion specifically as regards lack of inventive step. Since the Appellant was not able to rebut the documents on merit or shake the standing of documents D1 and D2, either in their reply, or during the hearing or in their written submissions, therefore, the Appellant has sought to have the documents struck off. This is a malafide attempt of the Appellant to have the entire controversy decided de-novo where only D3-D10 be relied upon and D1-D2 not be relied upon.

6.11 Even otherwise, it is submitted that it is immaterial whether Respondent No.1 (Opponent) has cited documents D1 and D2 for inventive step. If documents D1-D2 are specified in the notice of opposition, they can certainly be used for assessing the obviousness of the invention.

6.12 That further D1 and D2 are books which are basic study material taught at the level of B.Pharm to every pharmacy student.

6.13 The question of determining inventive step of alleged invention does not require any exact citation (prior art). This can be drawn from a number of prior arts. If such prior arts enable any skilled person in the field obvious to arrive at that invention, it means the alleged invention does not involve an inventive step. It may be noted that report of the Opposition Board (constituted by the official procedures) also recommended that the granted patent does not involve any Inventive step. Ld. Controller of Patents also arrived at the same conclusion in the impugned order.

6.14 Moreover, the Respondent/Opponent would like to point out a part of the specification of the impugned patent which says that :

“Complementary tests have shown that the problem of stabilization of the formulations according to the invention was appreciably more complex than anticipated, and it has notably been established that, without antioxidant, an essentially deoxygenated solution became pink in colour after a certain time at ambient temperature. In this respect it has been observed that injectable solutions which are not completely deoxygenated do not become appreciably coloured if an  $\alpha$ -hydroxypolycarboxylic acid is previously added to the solution, in particular the addition of citric acid, or an alkaline citrate, or a mixture of the two, makes it possible to slow down the appearance of a coloration.”

6.15 This clearly established an admission by the Petitioner that motivation, suggestion and teaching was always been there and inventors have done mere routine experimentation

to arrive at the impugned claimed patent. The impugned patent has added nothing in the total stock of knowledge, but has merely brought together segments of prior art and claim them in congregation as monopoly.

**REVOCAION OF PATENT U/ 25(2)(E) AND NOT U/S 25(2)(G)**

6.16 The ground raised by Petitioner that Ld. Controller of Patents only revoked the patent u/s.25 (2)(e) and not u/s 25(2)(g) even though the objection u/s 25(2)(g) was sustained is wrong and denied. It is submitted that Ld. Controller of Patents revoked the patent because of lacking inventive step as a main ground based on the cited prior arts. However, that does not mean that the other grounds stated in the impugned order will not sustain. The impugned order is a speaking order, and it clearly states the following:

“Controller view: Claims are very broad in respect of technical features ‘hydroxypolycarboxylic acid’ and ‘antioxidant’. However, the experiments and examples provided in the specification do not support all possible alternatives of hydroxypolycarboxylic acid or antioxidants. Only examples in support of sodium citrate or citric acid (example III) and cysteine are provided in the specification which leaves the scope of speculation. Further, the claims require the pressure to be less than 65,000 Pa whereas support in specification is for pressure value less than 10,000 Pa (examples on pg. 17). Thus, the whole range as claimed is not supported by description.”

6.17 From the above it is clear that Respondent No. 2 has expressly held the ground of insufficiency of description against the Petitioner.

**S 25(2)(G) NOT PRESSED BY RESPONDENT**

6.18 The ground raised by Petitioner that Respondent No.1 had surrendered its objection u/S. 25(2)(g) of Patents Act is wrong and denied. It is repeatedly stated in the Opposition filed by Respondent No. 1 (Opponent) that the grounds of opposition also include S. 25(2)(g) of Patents Act, i.e. insufficient description of the invention that the complete specification does not sufficiently and clearly describe the inventions or the method by which it is to be performed. At no point did Respondent No. 1 ever surrender their right on maintaining insufficiency of description as a ground for opposition under S. 25 (2) (g) as is averred by the petitioner.

#### **EVIDENCE IN SUPPORT OF OPPOSITION**

6.19 That Petitioner is attempting a very restrictive interpretation to Rule 59 of the Patent Rules, 2003. In the present matter, Respondent No.1 (Opponent) filed its notice of opposition, written statement and evidence u/r 57 of the Patent Rules, 2003 on 30.06.2001 and Respondent No.1 (Opponent) relied upon documents D-1 to D-10. The Petitioner filed the Reply u/r 58 of the rules and the Respondent No.1 (Opponent) filed its Reply evidence u/r 59. Hence all the documents and materials were submitted along with the notice of opposition and Evidence filed under Rule 57. Hence the impugned order is passed based on the Documents D-1 to D-10 filed along with the Evidence under Rule 57. The answering Respondent's action is strictly in accordance with the Act and the Rules framed there under and there is no illegality or irregularity.

6.20 Further, Rule 60 of Patent Rules 2003 specifically allows further evidence to be filed with leave of Controller, which the Petitioner never availed of.

6.21 It needs to be noted that while filing the notice of opposition, the Respondent, specifically prayed for leave to file further evidence.(pg. 187 of writ petition as filed by Petitioner in W.P.(C) 5755/2019)

6.22 The Respondent submits that an expert affidavit is not necessary if sufficient documentary evidence has been provided under each ground. It is important to note that under Evidence Act, both documentary evidence & oral testimony are considered as evidence. The members of the opposition board essentially possess scientific degree(s) with skills to understand the scientific principles and filing of expert affidavit is not mandatory in each case and the matter is case specific. Rule 57 of the Patents Rules, 2003 specifically makes clear that filing of evidence is not mandatory, rather it is optional and the decision about its filing is left to the opponents and the merits of documentary evidence supporting the written statement. The prior art forming part of pleadings present the state of art and matters of common general knowledge. The Ld. Controller having being appointed to the position due to his technical qualifications is required to possess the capacity to appreciate the technical contents of an invention and the prior art and is not obvious to a person skilled in the art. If the Ld. Controller did not have such capability the entire scheme of the patent examination would fall apart. The Ld. Controller under the provisions of sections 12-15 of the Act finally determines the patentability of an invention without mandatorily requiring the services of an expert.

#### **SUBMISSION OF WRITTEN NOTES**

6.23 The Petitioner is firstly trying to imply that the written notes by Respondent No. 1 dt. 11.05.2018 were time barred,

secondly that the decision in the impugned Order dt. 24.12.2018 with regard to ground of insufficiency of description under Section 25(2)(g) relies extensively on the written notes dt. 11.05.2018 and thirdly that since Dr. Manu Chaudhry, Joint Managing Director of Respondent No. 1 company, did not attend the hearing, therefore is in no position to submit the written notes. That all three grounds are wrong and denied.

6.24 The ground raised by Petitioner that written submission by Respondent No.1 (Opponent) was filed after the time limit as specified in Rule 28(7) is wrong and denied. This Rule is not applicable for post-grant opposition proceedings. Respondent submits that Rule 28 is under Chapter 4 of the Patent Rules, 2003 titled "Publication and Examination of Applications".

6.25 Respondent submits that this Chapter does not deal with post grant opposition at all as is sought to be made out by the petitioner. Opposition to patent is dealt with under Chapter 6 of Patent Rules, 2003. Further, in the proceedings, both the parties, Petitioner as well as Respondent No.1 (Opponent) filed the written submissions after 15 day's time. There is no specific provision in The Patent Rules for submission of written submission in post-grant opposition. However the same is considered and taken on record in the interest of justice. Further there are no new points taken in the Written Submission. There is no law barring a quasi-judicial authority to take the written submission on record after 15 days.

6.26 Respondent No. 1 submits that there is no reference to the written notes in the Controller's view as given in the

impugned Order dt. 24.12.2018 with regard to the ground of insufficiency of description under Section 25(2)(g).

6.27 The ground raised by Petitioner that Written submission of the Respondent No.2 (Opponent) was filed by Dr. Manu Chaudhary who was not present during the hearing is wrong and denied.

6.28 It is submitted that there is no legal requirement under law for the person signing the documents to attend the hearing in person. In the proceedings, both the parties were duly and adequately represented. Dr. Manu Chaudhry is the authorised representative of Respondent No.1 company and has been pursuing the opposition from the very beginning and majority of the pleadings bear her signatures. It is pertinent to note that the Petitioner has not raised any such objections during the proceedings before the Controller of Patent and Design as is evident in the impugned Order dt. 24.12.2018 and these grounds are being raised by the Petitioner as an afterthought. It is further pertinent to note that the Petitioner has not adduced any documents or cited any provisions to substantiate its claims.

#### **RE-EXAMINATION**

6.29 The ground raised by Petitioner that Ld. Controller of Patents conducted a re-examination in an opposition proceeding is wrong and denied. The case was decided on merit i.e. on technical grounds. The post-grant opposition was decided on merit based on the documents placed before the Ld. Controller of Patents. No re-examination was conducted. But rather only claim 1 of the granted patent was considered in the said opposition. That the impugned order is a judiciously passed order within the provisions of The Patents Act and Rules. The said order cannot be termed as arbitrary

and discriminatory only because it is against the interest of the Petitioner.

### **INVENTION IS NOT PATENTABLE**

6.30 Respondent states that the impugned patented invention neither involves any novelty and/or inventive step, nor any technical advancement, as is also corroborated by the Annexures D-1 to D-10 produced by the Respondent in support of the present opposition. Furthermore, the Respondent submits that the claimed method of preparation of Storage-stable formulation of oxidation-sensitive phenolic drug, especially paracetamol wherein aqueous drug solution is deoxygenated by inert gas or vacuum and stored in closed container, for which the priority date is 06-June-2000, was known before this date and does not qualify for Novelty and Inventive step under the provisions of section 25(2)(b), 25(2)(c), 25(2)(e), 25(2)(f) and 25(2)(g) of the Patent Act 1970. Each claim element as found in the different cited prior art performs the same individual functions in the impugned patent and neither the specification of the impugned patent nor the reply of the Petitioner could explain as to why the individual features found in the prior art perform a different function in the impugned invention and they are not juxtaposition of each feature or there is any interoperability/interdependence of each feature.

6.31 Petitioner has also failed to establish in the specification and in the reply as to why end result of the impugned invention not the same as the sum of the effect of each feature. Therefore, in the light of the teachings, suggestions and predictability of the prior arts found in D1 to D10, the impugned patent is nothing but a obvious extension of the prior art with predictable end results representing

conventional wisdom of prior art teachings and therefore the impugned patent “clearly does not involve an inventive step” and hence the impugned patent is liable to be dismissed u/s 25 (2)(e) of the Patent Act, 1970 by the Ld. Controller in this opposition.

7. We have reviewed the documents and noted that in para 9 of the notice of the opposition the opponents/respondents no.2 have referred to documents D1-D10 for attacking novelty and/or inventive step. The relevant paragraph is quoted herein below:

9. **PRELIMINARY OBJECTIONS :**

At the very outset, it is most humbly submitted that the impugned patented invention neither involves any novelty and/or inventive step, nor any technical advancement, as is also corroborated by the **Annexure D-1 to D-10** produced by the opponent in support of the present opposition. Furthermore, the Opponent submits that the claimed method of preparation of Storage-stable formulation of oxidation-sensitive phenolic drug, especially paracetamol wherein aqueous drug solution is deoxygenated by inert gas or vacuum and stored in closed container, for which the priority date is 06-June-2000, was known before this date and does not qualify for Novelty and Inventive step under the provisions of section 25(2)(b), 25(2)(c), 25(2)(e), 25(2)(f) and 25(2)(g) of the Patent Act 1970.

8. We further analysed the order of the respondent no.1 the relevant portions of which are quoted herein below:

*“Let us examine the pros and cons of each ground.*

**A. 25(2)(b) Lack of Novelty : Section 25(2)(b); anticipation by prior publication**

*Controller View: It is true that no single cited document can be held exactly matching the claimed invention to kill the novelty of the claimed process, though some features resemble. D1 and D2 are the closest prior arts pertaining to present application. D1 discloses the*

stability of the medicament by: (i) Replacement of the oxygen in the final container with an inert gas after distribution of the solution for which inert gases used; (ii) Addition of antioxidant such as ascorbic acid; and (iii) Use of citric acid (a hydroxypolycarboxylic acid) as sequestering agent. Similarly, D2 discloses saturating the aqueous solution with nitrogen, displacing the air above the solution with inert gas and addition of stabilizers such as citric acid and ascorbic acid. However, neither of D1 or D2 discloses the oxygen level of the obtained solution to be below 2 ppm which is the main feature of present claims. So process claim may be considered novel over the cited prior arts.

**B. 25(2)(e) Lack of Inventive Step: Section 25(2)(e); obviousness and lack of inventive step.**

Controller view: Firstly, it is noted that while accessing the inventive step, the patentee has considered all the features as essential features, which in turn is not supported by the language of claims. The process features (a)-(d) mentioned below are discernible from the language of claims. Secondly, it is wrong on the part of Patentee that documents (D1 and D2) missed by the opponent in their reply evidence for inventive step objection cannot be taken on record to evaluate obviousness. If any document is brought to the notice of the Controller, the Controller is free to consider all the documents for objections raised by the opponent under various grounds. So, for the present application, It is immaterial whether the opponent has cited those documents for inventive step or not. If documents D1-D2 are specified in the notice of opposition, they can certainly be used for assessing the obviousness of the invention.

Consequently, it is considered obvious for a person skilled in the art to have prepared aqueous solution of paracetamol via the process suggested in D1 and modifying it by incorporating an additional step

*of saturating the liquid with an inert gas as disclosed in D2 so as to arrive at the present claims.*

*Furthermore, it is noted that neither of D1 or D2 discloses purging with inert gas until the oxygen content is below 2 ppm. The patentee asserts that achieving this value of '2 ppm' is the basis for the inventive step of the present claims. However, the Controller is of the opinion that this feature 'oxygen content below 2 ppm' is a mere property of the solution which is obtained by using the process disclosed in D1 and D2. So, merely highlighting the oxygen content does not result in any technical advancement. The evaluation of such characteristics of a solution can be easily carried out by any person skilled in the art by deriving motivation from the general state of the art and using routine laboratory techniques and does not involve any enhanced effect.*

*Rest of the prior arts D3-D10 form general state of the art as they teach one or more technical features employed in present claims. D3 or D4 teaches bubbling a water-insoluble inert gas through the aqueous solvent to remove oxygen from an aqueous medium. D4 specifically suggests on page 2, lines 36-40 that the oxygen limit should be below 2 ppm. D5 or D6 or D9 or D10 teaches the use of cysteine derivatives for stabilization. D7 teaches displacement of oxygen above the solution with inert gas. D9 provides the teaching of addition of antioxidant and N<sub>2</sub> purging to eliminate dissolved oxygen. Thus, documents D3- D10 are relevant and form general state of the art for the subject matter of present claims.*

*Therefore, all citations (D1 to D10) in combination do reveal the steps of impugned process patent claimed and all these steps are more obvious to the person skilled in the art like opponent.*

**C. 25(2)(f) Not an invention under Section 3(d)**

*Controller view: The patentee is producing an aqueous solution of paracetamol containing the oxygen content  $\leq$  2ppm whereby preserving the aq. solution for a longer period by following a sequence of steps which include a) Bubbling the aqueous solution of paracetamol with an inert gas, namely nitrogen; b) Placing the aq. solution under vacuum until the oxygen content reaches below 2ppm in the aq. solution; c)(optional) Topping the space above the aq. solution in a container with argon inert gas keeping the pressure  $\leq$  65000 Pa; and d) Deoxygenating the aq. solution by antioxidant and hydroxypolycarboxylic acid. However, all these process features (a) to (d) are not disclosed in a single prior art. Therefore, the claimed process cannot be regarded as a known process. So, the present claims do not fall within the purview of section 3(d).*

**D. 25(2)(f) Not an invention under Section 3(e)**

*Controller view: The claimed process is outside the preview of section 3(f) as the invention does not pertain to a device.*

**F. Section 25(2)(g)**

*Controller view: Claims are very broad in respect of technical features 'hydroxypolycarboxylic acid' and 'antioxidant'. However, the experiments and examples provided in the specification do not support all possible alternatives of hydroxypolycarboxylic acid or antioxidants. Only examples in support of sodium citrate or citric acid (example III) and cysteine are provided in the specification which leaves the scope of speculation. Further, the claims require the pressure to be less than 65,000 Pa whereas support in specification is for pressure value less than 10,000 Pa (examples on pg. 17). Thus, the whole range as claimed is not supported by description.*

**Decision :** *The patented application is being revoked u/s 25(4) of the Patent Act 1970 and under patent rules 62(5) of the Patents Rules 2003 on ground of opposition u/s 25(2) (e) i.e. lacking inventive step based on foregoing facts of the case.*

9. We have observed that the main contention of the appellant is that documents D1 and D2 were relied upon by the opponents for lack of novelty and other documents e.g. D3-D10 were relied on, for lack of inventive step by Respondents no. 2. The Controller considering these two documents D1 & D2 held that *“However, neither of D1 or D2 discloses the oxygen level of the obtained solution to be below 2 ppm which is the main feature of present claims. So process claim may be considered novel over the cited prior arts.*
10. However, at page 27 of the order of the respondent no. 1, he holds that *“Secondly, It is wrong on the part of Patentee that documents (D1 and D2) missed by the opponent in their reply evidence for inventive step objection cannot be taken on record to evaluate obviousness. **If any document is brought to the notice of the Controller, the Controller is free to consider all the documents for objections raised by the opponent under various grounds. So, for the present application, It is immaterial whether the opponent has cited those documents for inventive step or not. If documents D1-D2 are specified in the notice of opposition, they can certainly be used for assessing the obviousness of the invention.**” [Emphasis added].*
11. As quoted earlier, in paragraph 7 ante, the opponents/respondents no. 2 mentioned at para 9 of their notice of opposition filed at Indian Patent office (IPO) on 31/01/2011 that the patented invention lacks in novelty and /or inventive step in view of cited documents D1 to D10. However, in the very next paragraph 10 of the same document, while explaining the grounds of the opposition in details, they relied on documents D1 & D2 for lack of novelty and rest documents e.g. D3 -D10 are relied upon by them for lack of inventive step.

12. As is evident from the order of respondent no. 1 and the submission of the appellant that these documents D1 & D2 couldn't prove to be destroying novelty of the invention.
13. It is the contention of the appellant that while considering the other grounds such as under section 25 (2)(e) e.g. for lack of inventive step, the respondent no.1 should have considered the documents as relied by the opponents rather than using D1 & D2 holding that ***the Controller is free to consider all the documents for objections raised by the opponent under various grounds.***
14. Further, the Controller never gave any chance to the patentee as alleged by them, to argue their case if at all documents D1 & D2 were to be considered, for lack of inventive step. However, the opponents/ respondent no. 2 hold that during the hearing these points were discussed.
15. We find that while the statement at para 9 and 10 of notice of opposition filed by the opponents/ respondent no. 2 is inconsistent, Also the statement of the respondent no. 1 that "*the Controller is free.....*" do not hold water as the role of Controller in post grant hearing under section 25(2) of the Patents Act, 1970 is not adversarial rather he is a quasi-judicial authority responsible of deciding the case based on facts and evidence produced before him. He is not empowered by the Act or the Rules made thereunder to adduce evidence of his own.
16. The point of appellant is not without merit that they couldn't advance their arguments in respect of documents D1 & D2, as it was never relied upon by the opponents for lack of inventive step. Also respondent no.1 didn't reveal during the hearing, as informed by the appellant, that he will be using these two documents for the purpose of determination of inventive step before issuance of the order and hence they couldn't have any opportunity to confront before him on this point at all.

17. We are of the view that the appellant deserve to be heard by Respondent no.1 giving them a fair opportunity on the sole aspect of “inventive step” based on the available cited documents on records.

18. Therefore, keeping in view the above facts and circumstances, we set aside the impugned order of respondent dated 24/12/2018. The matter is remanded back to respondent no. 1, who is directed to decide the matter on merit, strictly within 3 months from the date of issuance of this order, after giving both the parties a fair opportunity of being heard.

19. Appeal is allowed on condition mentioned above. No cost.

-Sd/-

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



-Sd/-

**(Justice Manmohan Singh)**  
Chairman

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