# Canbas Co., Ltd. Vs Controller Of Patents

**Court:** Intellectual Property Appellate Board, Chennai Circuit Bench At Kolkata

**Date of Decision:** Feb. 10, 2021

**Acts Referred:** Indian Patents Act, 1970 â€" Section 2(1)(j), 2(1)(ja), 3(d), 14, 15, 117A
Patents Rules, 2003 â€" Rule 21(4)

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

**Bench:** Division Bench

**Advocate:** Swarup Kumar

**Final Decision:** Allowed

## Judgement

1. The present appeal is filed under Section 117A of the Indian Patents Act, 1970, against the order dated 04/11/2015, passed by the Respondent,

being the Assistant Controller of Patents & Designs, under Section 15 of the Indian Patents Act, 1970, refusing to grant the AppellantÃ¢â‚¬â„¢s Indian

patent application no. 3919/KOLNP/2009.

2. The invention as explained by the appellant:

The present invention provides compounds to treat cell proliferation disorders. In particular, the invention provides compounds including: tert-butyl 3-(l-

{[6-chloro-5- (trifluoromethyl)(2-pyridyl)]amino}-4-methyl-2,5-dioxoazolin-

3-yl) propanoate (interchangeably referred to as S001860, S01860, or S1860, i.e., S001860 = S01860 = S1860); l-{[6-chloro-3-(trifluoromethyl)(2-

pyridyl)]amino}-3,4- dimethylazoline-2,5-dione (SOO 109 = SO 109 = S 109); 3-(Butoxymethyl)-l-{[6-chloro-5-(trifiuoromethyl) (2-pyridyl)] amino}-4-

methylazoline- 2,5-dione (S03518); l-{[6-Chloro-5- (trifluoromethyl) (2-pyridyl)] amino}-4-methyl-3-[(3- methylbutoxy) methyl] azoline-2,5-dione

(S03405); 3-[(3,3- Dimethylbutoxy) methyl]-l-{[6-chloro-5-(trifluoromethyl) (2- pyridyl)] amino}-4-methylazoline-2,5-dione (S03747); and related

compounds, wherein these compounds, when administered to cells or to a subject, have effects that may include killing or suppressing undesirably

proliferating cells associated with a cell proliferation disorder.

3. It is the case of the appellants that:

Ã, The Respondent erroneously refused the application on the ground of lacking inventive step under Section 2(1)(j) and/or Section 2(1)(ja), which

resulted in vitiation of her/his decision. From the impugned order, it is apparent that the Respondent has misdirected her/himself in the appraisal and

appreciation of the submissions made by the attorneys for the Appellant in their various correspondences addressed to the Respondent, and this

resulted in vitiation of the decision. The said application should have proceeded to grant of a patent.

Ã, The Respondent failed to appreciate the notable distinguishing features of the present invention over the prior art- None of the cited prior art, either

read alone or in combination with any other prior art document(s), teaches or suggests the compounds of the presently claimed application.

Ã, None of the cited prior art, either read alone or in combination with any other prior art document, teaches or suggests the electronic heteroatom-

heteroatom alpha effect exhibited by the claimed compounds, thereby rendering an unpredictability in the structure-function relationship.

Ã, The Respondent failed to determine the scope and content of the prior art to which the invention pertains.

Ã, The HonÃ¢â‚¬â„¢ble Board will appreciate that in the present invention, the maleimide nitrogen is bonded to a group X which is a heteroatom O or

NR3. In contrast, in D1, the maleimide nitrogen is bonded to a carbon atom. The main claim of the present invention relates to:

1. A compound to treat cell proliferation disorders having

the formula of Structure (II) wherein R1 and R2 are independently chosen from alkyl, substituted alkyl, alkoxy, or arylthio, where when X is not O, R1

and R2 can also be part of a cyclic alkylene chain that form a fused ring structure; X is O or NR3; wherein when X is NR3, Aryl or substituted aryl in

the optionally substituted aryloxy or optionally substituted arylthio includes carbocyclic aryl, heterocyclic aryl, monocyclic aryl, polycyclic aryl, and aryl

fused with non-aryl (non- aromatic) rings; R3 is H, alkyl, or as part of a ring structure that connects the N to the Ar ring; A is N or CH; wherein when

A is CH, R6, R7, R8 and R9 are not all hydrogen; B is CR8; and R6, R7, R8 and R9 are independently chosen from H, alkyl, substituted alkyl,

halogen, optionally substituted aryl, wherein R6 and R7, or R7 and R8, or R8 and R9 can be part of a cyclic alkylene group forming a fused ring

structure; or a salt thereof;

Ã, further wherein the compound does not have any of the following structures:

The Respondent has failed to appreciate that the electronic heteroatom-heteroatom alpha effect (because X is a heteroatom) renders the claimed

compounds substantially structurally different from D1 which bears a heteroatom- carbon atom bond. As a result of this significant structural

difference, the skilled artisan would expect very different activity due to the heteroatom-heteroatom bond motif compared to a heteroatom-carbon

bond.

Ã, The aforesaid effect renders unpredictability in the structure- function relationship and therefore, one of skill in the art would not have predicted

function based upon the significantly different structure in D1 compared to the claimed compounds.

Ã, The said aspect is clearly illustrated in the specification of the subject application which discloses that there is high variability of activity among

different compounds as evidenced throughout Tables 1 and 2 (pages 91 to 99 and pages 100 to 108 of the Paper Book respectively). In view of the

variability between the structures disclosed in the specification, and the fact that the cited prior art structure is even further structurally divergent, one

of skill in the art clearly would not have predicted function of the claimed compounds based upon the significantly different structure in D1.

Consequently, the RespondentÃ¢â‚¬â„¢s findings on lack of inventive step are grossly erroneous and ought to be set aside.

Ã, The Respondent failed to appreciate that the claimed compounds do not relate to Ã¢â‚¬Å“new form of a known substanceÃ¢â‚¬ as envisaged in Section

3(d) of the Act-

Ã, The HonÃ¢â‚¬â„¢ble Board will appreciate that the compounds claimed in the present invention are structurally dissimilar from D1 since the compound

claimed in the subject application has the electronic heteroatom-heteroatom bond (because X is a heteroatom) whereas the compounds of D1 bears a

heteroatom-carbon atom bond. As a result of this significant structural difference, the compounds claimed in the present application cannot be

considered to be new forms of the compounds disclosed in D1.

Ã, The impugned order passed by the Respondent contravenes the well-established judicial precedent.

The Respondent has gravely erred in overlooking the clear judicial precedent laid down in the HonÃ¢â‚¬â„¢ble Delhi High Court in the case of F.

Hoffmann-La Roche Ltd. and Ors. v. Cipla Ltd. [2012(52)PTC1(Del)]. The relevant portion of the decision is reproduced hereinbelow for the ready

reference of the IPAB:

Ã¢â‚¬Å“It is also conceded position that the EP '226 was based on the treatment of Methyl component whereas the plaintiff's patent is based on the

treatment of the said compound with Ethynyl component. All these are attending circumstances which would reveal that the defendant is not able

discharge the onus on the defendant to show that the suit patent IN'774 is new form of old substance which is EP '226. However, that EP '226 relates

to quinazoline derivatives also contain some compounds, which are structure wise akin to the suit compound excepting the reaction of ethynyl at the

third position, would do not axiomatically permit this Court to believe that the suit patent IN'774 is a new form of EP'226 unless shown clinically with

some evidence.Ã¢â‚¬â€‹

Ã, In the present case, the structural differences are pronounced inasmuch as the compound claimed in the subject application has heteroatom-

heteroatom bond (because X is a heteroatom) which renders the claimed compounds substantially structurally different from D1 which bears a

heteroatom-carbon atom bond. As a result of this significant structural difference, the compound claimed in the present application cannot be

considered to be a new form of the compound disclosed in D1.

Ã, The impugned order has been passed in violation of the principles of natural justice inasmuch as the hearing notice ought to have clearly specified

the prior art compound with respect to which the objection under Section 3(d) of the Act was raised.

Ã, Vide paragraph 3 of the hearing notice dated September 16, 2015, the Respondent communicated as under:

Ã¢â‚¬Å“Claims 1-7 attract sec 3(d) of the Patents Act 1970 because the compounds claimed in claim 1 still lack novelty as well as inventive step with

respect to D1 and other documents (D2-D8) mentioned above. Moreover, it should be borne in mind that a substance in spite of being novel and

inventive may still fall under the ambit of sec 3(d) as far as there is close structural similarity exist in the claimed compound with that disclosed in prior

art, the claimed compound does not qualify the condition of sec 3(d) without establishing the superior effect (in case of pharmaceutical drug it is

specifically enhanced therapeutic efficacy over the compound of prior art).Ã¢â‚¬â€‹

Ã, As evident from the above objection, the closest prior art compound was not specified in the hearing notice. In this respect, it is pertinent to mention

that this HonÃ¢â‚¬â„¢ble Board while rendering its decision in the case of Resprotect GmbH v. The Controller of Patents & Designs & Anr

[OA/23/2010/PT/DEL; hereinafter referred to as Ã¢â‚¬Ëœthe Resprotect CaseÃ¢â‚¬â„¢] held as under:-

Ã¢â‚¬Å“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 hearingÃ¢â‚¬â€‹.

Ã, Furthermore, the HonÃ¢â‚¬â„¢ble Supreme Court observed in Union of India And Another v. Tulsiram Patel And Others [1985 AIR 1416, 1985 SCR

Supl. (2) 131] that Ã¢â‚¬Å“the rule of natural justice with which we are concerned in these Appeals and Writ Petitions, namely, the audi alteram partem

rule, in its fullest amplitude means that a person against whom an order to his prejudice may be passed should be informed of the allegations and

charges against him, be given an opportunity of submitting his explanation thereto, have the right to know the evidence, both oral or documentary, by

which the matter is proposed to be decided against him, and to inspect the documents which are relied upon for the purpose of being used against him,

to have the witnesses who are to give evidence against him examined in his presence and have the right to cross examine them, and to lead his own

evidence, both oral and documentary, in his defence.Ã¢â‚¬â€‹

Ã, In the instant case, the specific compound in the prior art with respect to which the objection under Section 3(d) was raised was never made known

to the Appellant, thus depriving the Appellant of a fair opportunity to present its case at the hearing before the Respondent. Therefore, 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 the HonÃ¢â‚¬â„¢ble

Supreme Court in the Tulsiram case and this HonÃ¢â‚¬â„¢ble Board in the Resprotect Case.

Ã, The impugned order is manifestly arbitrary and discriminatory as the Respondent has not given due consideration to the fact that the prior art

compounds may be remotely structurally similar to the claimed compounds. Thus, the compounds of the present invention cannot be considered a

Ã¢â‚¬Ëœderivativeâ€™. The Appellant submits that a person ordinarily skilled in the art would not be able to arrive at the instantly claimed compounds from

the prior art teachings since there is simply no teaching or suggestion to do so. The Appellant submits that the instantly claimed compounds are novel

and inventive new chemical compounds and even if there is some degree of structural similarity between the instant compounds and those found in the

prior art, it does not connote that the instant compounds are Ã¢â‚¬Å“derivativesÃ¢â‚¬â€‹ of the prior art compounds.

Ã, Notwithstanding the above, the Appellant reiterates that in the present case, as shown in the Examples of the present application (in particular

Example 1 and Example 2 on pages 83 to 85 and 85 to 87 of the Paper Book respectively), compounds of the invention can induce cells in G2 cell

cycle arrest (i.e., cells having pre-existing DNA damage) to re-enter the cell cycle, proceed through the G2 and M phases and enter G1 phase with

unrepaired DNA damage leading to cell death or cell suppression, usually by mitotic catastrophe or apoptosis. The claimed compounds can have a

cytotoxic effect on cancer cells, without any additional anti-cancer treatment. As described in Example 4 (pages 88 to 90 of the Paper Book) and

shown in Figures 6, 7 and 8 (pages 209 to 211 of the Paper Book), treatment with several exemplary compounds alone was sufficient to prolong the

survival of mice with xenografts of human myeloma cells. In addition, compounds of the invention can increase, or exacerbate the cytotoxic effects of

other treatment (see Example 2 on pages 85 to 87 and Figures 3 and 4 on pages 206 and 207 of the Paper Book). Example 7 (pages 110 to 112 of the

Paper Book) and Tables 4 to 11 (pages 118 to 133 of the Paper Book) show that compounds of the invention are not cytotoxic for normal cells at

concentrations at which they have severe cytotoxic effects on cancer cells and DNA- damaged cells, illustrating the selectivity of the claimed

compounds.

Ã, In view of the above, the HonÃ¢â‚¬â„¢ble Board will readily appreciate that the claimed compounds are new chemical entities that cannot be

considered as Ã¢â‚¬Å“derivativesÃ¢â‚¬ as envisaged under Section 3(d) of the Act. The Appellant submits that the Respondent has failed to establish a case

for application of Section 3(d) against the subject invention and therefore the impugned order is erroneous and liable to be set aside in the interest of

justice.

Ã, The Respondent failed to follow procedural timelines provided in the Act-

Ã, The Respondent refused the subject application in contravention of the procedure stipulated in the Patents Act which has resulted in vitiation of the

impugned order. The Appellant submits that the impugned order suffers from a grave procedural irregularity inasmuch as the subject application was

refused in contravention of Rule 21(4) of the Patents Rules which provides the Applicant with a time frame of twelve months from the date of

issuance of the First Examination Report, to comply with the RespondentÃ¢â‚¬â„¢s requirements. The Appellant submits that the subject application was

refused on November 04, 2015, i.e., 76 days prior to the stipulated period of placing the application in order for grant. The rushed manner in which the

subject application has been refused connotes a preconceived and premeditated intention on the part of the Respondent to dismiss the subject

application without even providing the prescribed period of twelve months to the Appellant from date of issuance of the First Examination Report.

Ã, The HonÃ¢â‚¬â„¢ble Board will readily appreciate that grave injustice has been caused to the Appellant by the premature refusal of the subject

application by the Respondent without exercising the discretion vested upon the Respondent under Section 14 and 15 of the Patents Act as it is settled

law that non-exercise of discretionary powers is bad in law. The Respondent has failed to appreciate that the intention of the Patents Act is the grant

of patents and not the refusal of patent applications. Accordingly, the Respondent ought to have at least provided the complete statutory period of

twelve months from date of issuance of the First Examination Report, to the Appellant for amending the claims, specifications or other documents of

the application to her satisfaction instead of refusing the application in toto before the statutory period.

Grant of corresponding Foreign Applications

The Respondent has failed to appreciate that the inventive step of the claimed invention has been acknowledged in corresponding applications in major

jurisdictions inter alia, USA, Japan, Australia, New Zealand, Russia, Singapore and South Korea, which has led to grant of patents in all the

aforementioned jurisdictions. Moreover, the attention of this HonÃ¢â‚¬â„¢ble Board is invited to the fact that the corresponding European application has

been allowed with a broader claim scope than that being pursued in the present invention. The HonÃ¢â‚¬â„¢ble Board will readily appreciate that this

clearly supports patentability of the present invention.

Ã, Moreover, it is emphasized that when the Appellant advanced persuasive submissions towards the inventive step of the invention further

supplemented by the grant of corresponding applications in various jurisdictions, the RespondentÃ¢â‚¬â„¢s conclusion that the application does not involve

an inventive step is not tenable and ought to be set aside.

Ã, The attention of the HonÃ¢â‚¬â„¢ble Board is also invited to page 8 (page 30 of the Paper Book) of the RespondentÃ¢â‚¬â„¢s Decision wherein the

Respondent states that Ã¢â‚¬Å“In the present scenario I am skipping the discussion related to rest objection as raised by hearing letter dated 25/08/2015 as

the said discussion does not have meaningful and significant contribution to the same over the above mentioned paragraphs.Ã¢â‚¬ Appellant submits that

this statement by the Respondent tantamount to an acknowledgement that all other requirements stand complied. In any case, it is submitted that the

objections raised and/or formal requirements stated in paragraphs 4 to 12 of the hearing notice were either duly complied with or techno-legally

rebutted as is clearly decipherable from the written submissions dated October 12, 2015 (pages 524 to 527 of the Paper Book).

4. The operating portion of the order of the respondent is shown herein below:

Ã, Upon consideration of the objection vis a vis the arguments placed by the agent of the applicant under the provision of section of the Patent Act I

shall turn my eyes one by one to of the objections raised in hearing letter dated 25/08/2015 and submission thereby.

Ã, Regarding inventive step and section 3(d) of the Act the combined submission of the applicant is considered and It has been observed on further

scrutiny the present claims are selected claim of initially filed ones where claim 1 states categorically N-C bonded compounds along with hetero atom

O or NR3 and in the further proceedings it has been amended to present heterocyclic compounds which is bonded to heteroatom O or NR3.

Moreover it is submitted that due to heteroatom Ã¢â‚¬" heteroatom alpha effect which renders the claimed compounds structurally different with regard

to D1 compounds which bears a heteroatom Ã¢â‚¬"carbon bond. As both the D1 prior art compounds and subject application compounds are acting as

anti -cancer drugs, I am in the opinion that said argument of alpha effect is not tenable and office objection against inventive step are not addressed in

appropriate manner as the specification lacks the comparative clinical studies data of the prior art compounds vis a vis the claimed compounds. Hence,

it is concluded that there is no effort observed to prove upon the therapeutic efficacy of present compound having N-N or N-O bond over N-C bonded

compounds of prior art in the specification and on further scrutiny it is found that in the initially found specification there is definite claim of compound

with N-C bond with considerably high IC 50 value as evident from the Table of IC 50 value against serial no. 13 in page no. 60 of the specification. It

is already stated that the compound of D1 are also used as anti cancer drug which are N-C bonded compound. So the superior effect of subject

pharmaceutical compounds with regard to therapeutic efficacy are not at all established in the specification in consideration of prior art compounds.

Moreover, it is found that compounds similar to D1 with N-C bond claimed initially possesses considerable therapeutic activity as disclosed and

mentioned above. Hence , it cannot be inferred that different class of heterocyclic compound having N-O or N-N bond with alpha effect shall lead to

remarkable therapeutic efficacy over the prior art compound or previously disclosed compounds. If it so, it is needed to be established through

comparative clinical data only. Only statement does not help the subject compounds to prove its superiority over the prior art compounds. Hence, I am

in the opinion that the subject application is unable to overcome the problem related to above mentioned issue with regard to prior art compounds and

also found that the initially filed subject C - N compounds are well within the scope of present invention having considerable high Ic50 value as

disclosed in D1. In later proceedings the claims have been narrowed down to address the official objection only which cannot be stated as the

invention with N-O or N-N bonded hetero compounds per se having considerable anticancer activity.

So in this context I am still in the opinion that the mere trial of already described method and compounds in prior art (also the subject application per se

initially filed) are considered as a matter of mere judicious selection and routine optimization of the same by the skilled person to arrive at the desired

result. In this juncture I need to mention in the section 2(1)(j) of the Act which states that invention means a new product or process involving an

inventive step and capable of industrial application and as per section 2(1) (ja) inventive step means a feature of an invention that involves technical

advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in

the art.

Ã, In the light of above definition of the Act it can be summarized that inventive step of the subject pharmaceutical compound is not at all substantiated

with enhanced therapeutic efficacy through selection of compounds in amended stage for the subject application and moreover the claimed invention

lack in support in description with regard to enhanced therapeutic efficacy of the claimed compounds by clinical comparison of prior art compounds

having similar pharmaceutical activity of anti-cancer agent. So, it can be stated that the subject invention is unable to qualify for waiving the objection

against inventive step ground over the cited document.

Ã, As section 3(d) stipulates an incremental invention based on already existing substance having established medicinal activity which shall be deemed

to be treated as a same substance. In my consideration I opine that against the submission of section 3(d) along with inventive step that the subject

application still attracts section 3(d) of the Act as mere amendments of substituted group without establishing therapeutic efficacy of the claimed

compounds and lacking of comparison with prior art compounds through clinical trial makes the application to remain as mere discovery not an

invention which is not allowable under the said provision and eventually failed to address the said section and unable to overcome the section 3(d) of

the Act.

Ã, In the present scenario I am skipping the discussion related to rest objection as raised by hearing letter dtd. 25/08/2015 as the said discussion does

not have meaningful and significant contribution to the same over the above mentioned paragraphs.

So in view of the facts and circumstances of the application as above and outstanding objections of this hearing notice 3919/KOLNP/2009 dtd.

11/11/2009 which are still outstanding due non-compliance thereof by the applicants I hereby refuse the application no. 3919/KOLNP/2009 dtd.

11/11/2009 against the hearing notice 3919/KOLNP/2009 dtd.25/08/2015 application under section 15 of the Patents Act, 1970 (as amended).

5. Novelty and Inventive Step:

Ã, We have reviewed the complete specification vis- a- vis the order of the respondent. The respondent agrees that the compound of the instant

invention are structurally different than that of the cited prior art D1 (D1: WO2005/02475) when she admits that Ã¢â‚¬Å“due to heteroatom Ã¢â‚¬"heteroatom

alpha effect which renders the claimed compounds structurally different with regard to D1 compounds which bears a heteroatom Ã¢â‚¬"carbon bondÃ¢â‚¬.

But very next sentence her opinion that D1 prior art compounds and subject application compounds are acting as anti -cancer drugs , I am in the

opinion that said argument of alpha effect is not tenable, appears to negate all the set rules of determination of novelty. Can the novelty of the

compound claimed in the instant application be denied just because both the compounds are used for similar treatments, even if acknowledging that

they are structurally different? This is an absurd argument and cannot pass the scrutiny of tests of determining the novelty.

Further, it also a fact that D1 does not disclose a compound to treat cell proliferation disorders having the formula of Structure (II) as defined in claim

1.

HonÃ¢â‚¬â„¢ble Delhi High Court F. Hoffmann-La Roche Ltd. and Ors. v. Cipla Ltd. [2012(52)PTC1(Del)] in F. Hoffmann-La Roche Ltd. and Ors. v.

Cipla Ltd. held that if there is a minor structural differences such as replacement of Ã¢â‚¬Å“methyl groupÃ¢â‚¬ with Ã¢â‚¬Å“ethynyl groupÃ¢â‚¬, a compound cannot

be considered as a new form of the prior art compound, unless it is shown with some evidence. Therefore once admitting that the compound of the

instant invention and the compounds of the prior art are structurally y different the lack of novelty cannot be proved by the reason that both the

compounds are used for similar treatment.

Further, the respondent goes on to hold that since the specification lacks the comparative clinical studies data of the prior art compounds vis a vis the

claimed compounds, the invention lacks inventive step.

We have also noted that the electronic heteroatom- heteroatom alpha effect renders unpredictability in the structure-function relationship and hence

person skilled in the art would not have predicted function based upon the significantly different structure in D1 compared to the claimed compounds.

We have reviewed that the specification of the instant application describes that there is high variability of activity among different compounds as

evidenced throughout Tables 1 and 2. Hence we do not find any reason to sustain this objection either.

We have reviewed that the claimed compounds can have a cytotoxic effect on cancer cells, without any additional anti-cancer treatment. As

described in Example 4 (pages 88 to 90 of the Paper Book) and shown in Figures 6, 7 and 8 (pages 209 to 211 of the Paper Book), treatment with

several exemplary compounds alone was sufficient to prolong the survival of mice with xenografts of human myeloma cells. In addition, compounds of

the invention can increase, or exacerbate the cytotoxic effects of other treatment (see Example 2 on pages 85 to 87 and Figures 3 and 4 on pages 206

and 207 of the Paper Book). Example 7 (pages 110 to 112 of the Paper Book) and Tables 4 to 11 (pages 118 to 133 of the Paper Book) show that

compounds of the invention are not cytotoxic for normal cells at concentrations at which they have severe cytotoxic effects on cancer cells and DNA-

damaged cells, illustrating the selectivity of the claimed compounds.

Also it is pertinent to mention here that though the grant of patent in any other jurisdiction do not have any binding effect on the Indian Patent Office,

but if the patents are granted in other jurisdictions, considering the identical citations; refusal of the same case at IPO without adding any further

citations and/or putting forward any new arguments is also not tenable. This Board in a series of orders have held that refusing any case on the

grounds of Ã¢â‚¬Ëœnovelty Ã¢â‚¬â„¢ and Ã¢â‚¬Ëœinventive step Ã¢â‚¬â„¢ considering the identical citations, on which the patents stands granted in other jurisdictions is

against the principles of equity unless some other arguments are put forward.

Here, it is observed that on all the citations considered herein have been considered in the international stage as well as during national phase

prosecution in different countries and the patents have been granted there. We do not find any other reasoning by the respondent to sustain her

arguments either.

Now lets us consider the other objection that is non- patentability under section 3(d) of the Patents Acts, 1970. The respondent holds that section 3(d)

stipulates an incremental invention based on already existing substance having established medicinal activity which shall be deemed to be treated as a

same substance. In my consideration I opine that against the submission of section 3(d) along with inventive step that the subject application still

attracts section 3(d) of the Act as mere amendments of substituted group without establishing therapeutic efficacy of the claimed compounds and

lacking of comparison with prior art compounds through clinical trial makes the application to remain as mere discovery not an invention which is not

allowable under the said provision and eventually failed to address the said section and unable to overcome the section 3(d) of the Act.

Let us look at the statutory provisions relating to section 3(d) of the Patents Act, 1970:

Section 3

What are not inventions

The following are not inventions within the meaning of this Act,Ã¢â‚¬¬

(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the

mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such

known process results in a new product or employs at least one new reactant. Explanation.Ã¢â‚¬"For the purposes of this clause, salts, esters, ethers,

polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance

shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;

Ã, The essence of section 3(d) is Ã¢â‚¬Å“mere discovery of a new form, new property or new use of known substanceÃ¢â‚¬¬. The qualifications and the

exceptions follow thereafter. Hence, for applicability of the section the mere discovery of new form of the new substance is to be proven first. In the

instant case, the respondent has failed to prove that the claimed compound is a discovery of new form of known substance or relate to a new property

or a new use of known substance; hence the objection in not tenable.

Ã, We are of the view that the claimed compound is neither a known substance nor it is the new form of any known substance, the applicability of

section 3(d) in the instant application is not warranted.

Ã, It is once again observed that the respondent while dealing with these issues left the other issues raised in hearing notice unattended. She holds in

her order that in the present scenario I am skipping the discussion related to rest objection as raised by hearing letter dtd. 25/08/2015 as the said

discussion does not have meaningful and significant contribution to the same over the above mentioned paragraphs. This is not a fair practice and is

against the tenet of natural justice.

6. The respondent is therefore, directed to be careful and address all the relevant issues in her all future orders. Giving benefit of doubt to the

appellant, we waive off all such unaddressed issues of the respondents.

7. Considering the above facts, we set aside the order of the Respondent dated 04/11/2015 and direct the respondent to grant the patent on existing set

of claims 1-7 within 3 weeks from the issuance of this order.

8. Keeping in view the above, the instant appeal is allowed. No cost.