The Patents Act, 1970 (as amended)
And
The Patents Rules, 2003 (as amended)
SECTION 15 and 25(1)

In the matter of an Application No. 1746/MUM/2008

And

In the matter of representation u/s 25(1)

Patents Act, 1970 as amended by

The Patents (amendment) Act, 2005

And

In the matter of rule 55 of

The Patents Rule, 2003 (as amended)

LINCOLN PHARMACEUTICALS LIMITEDof

LINCOLN House, B/h. Satyam Complex,

Science City Road, Sola, Ahmedabad – 380060, Gujarat, India …….. Applicant

TROIKAA PHARMACEUTICALS LTD of

Commerce House 1, SatyaMargBodakdev

Ahemdabad, 380054, Gujarat, India…….. Opponent

Representative:

None attended the hearing ……for Applicant

S. Majumdar(INPA-126)

Vilas Shetty(2006)

Darshiv Bhatt.....for Opponent

The Pre-grant Opposition filed by above named Opponent in the alleged patent application and the proceedings in the subject Patent Application bearing no. 1746/MUM/2008 is disposed under Section 25(1) of the Patents Act read with Section 15 of The Patents Acts, 1970 (as amended) and corresponding Rule 55 of The Patents Rule, 2003 (as amended).

Decision U/s. 15

1. Facts of the Application:

Date of application	18/08/2008
Publication Date	26/02/2010
Request for Examination Date	17/03/2010
FER date	25/05/2012
Reply to FER Date	21/11/2012
Hearing Date[u/s 14 and 25(1)]	06/01/2020
Response to Hearing Date	20/01/2020

2. *All the prior scheduled Hearing was* adjourned as it was sought by both the parties over a period of time *and finally hearing, after due process, was held on January 6, 2020.* However, Applicant failed to attend the said hearing at the scheduled date & time and therefore, after waiting for some time on hearing date thereupon the hearing was held ex-parte, and the Opponent was allowed to make their oral submissions at scheduled date and time relating to the captioned opposition. The opponent submitted post hearing submission timely. *Since, applicant did not attend the scheduled hearing therefore, this opposition has been decided based on records available in the file.*
3. Present application was filed on 18/08/2008 as a complete specification by LINCOLNPHARMACEUTICALS LIMITED, Ahmadabad, and Gujarat and same was published in the official journal on 26/02/2010.
4. A representation u/s 25(1) was received in this application by Troikaa Pharmaceuticals Ltd through their agent S Majumdar& Co. on 08/04/2011.

The said representation was communicated to the applicant through official communication dated June 14, 2012 and applicant filed their reply on September 12, 2012.

5. The representation u/s 25(1) was filed with following grounds –

a) Section 25(1) (d)-Prior Public Known/Prior Public Use-
-that the invention so far as claimed in any claim of compete specification was publiclyknown or publicly used in India before the priority date of that claim*;*
b) Section 25(1) (e)-Obviousness/lack of inventive step-
-that the invention so far as claimed in any claim of the complete specification isobvious and clearly does not involve any inventive step, having regard to thematter published as mentioned in Section 25(1) (b) or having regard to what wasused in India before the priority date of the applicant's claim.
c)Section 25(1) (f)-Not an invention-
-that the subject of any claim of the complete specification is not an invention within the meaning of this Act, or is not patentable under this Act;
d) Section 25{1) {g)-insufficiency-
-that the complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed*;*
e) Section 25(1)(h)-Failure to disclose information or furnishing false information relating to foreign filing-
-that the applicant has failed to disclose to the Controller the information required by Section 8 or has furnished the information which in any material particular was false to his knowledge.

6. At the time of hearing Opponent withdraned his grounds a) and e) (see; point 6, above) relating to Section *25(1) (d)-Prior Public Known/ Prior Public Use* and *Section 25(1)(h)-Failure to disclose information or furnishing false information relating to foreign filing. Therefore, theses grounds will not be discussedanymore in this decision.Accordingly, Opponent argued/ explained and made their submission* with respect to lack of inventive step and being obvious [under Sec 25(1)(e)], not an Invention/Not patentable [under sec 25 (1) (f)] and Insufficiency [under sec 25 (1) (g)].

7. ***Ground u/s 25(1) (e)-Obviousness/lack of inventive step-***

Opponent relied on following documents/exhibit in their argument-

Exhibit 1: US2004/0247627

Exhibit 2: US2003/0170296

Exhibit 3: Abstract of Research paper entitled "Effect of solvents on rectal absorption rate of paracetamol in man: an in vitro approach" published by H.

Vormans et al. in the International Journal of Pharmaceutics Volume 26, Issues 1-2, September 1985.

Exhibit *4:* WO03/051398

Exhibit 5: EP0916347

Exhibit 6: EP1889607

Exhibit 7 to Exhibit 15 (additional documents submitted through e-filing dated 01/06/2020 and also provided a copy of the same to the applicant via email).

Opponent argument on *25(1) (e)-Obviousness/lack of inventive step-*

9.1 Opponent has made a detailed submission in support of ground 25(1) (e)-Obviousness/lack of inventive step, some important part of their arguments is reproduced/summarized below.

9.2 Opponent submitted that paracetamol in injectable form is known from D1, D4, D5 and D6.

9.3 Use of glycofurol as solvent in paracetamol injection formulation is known fromD2, D3 and few pharmaceutical handbooks as cited.

9.4 Document D2 discloses combination of paracetamol with water miscible tetraglycol and water for dissolving the drug. The table under paragraph [0037] discloses preparation procedure for Pac-3 and PAC-4 formulation. D2 refers to complete dissolution of 0.7 g (700 mg) paracetamol in 1.4 ml of solubilizing solvent (glycofurol). So, in accordance with the teachings of D2, complete dissolution of 150 mg, 100 mg and 60 mg paracetamol can be achieved only in 0.3 ml, 0.2 ml and 0.12 ml of glycofurol respectively. However, the impugned application refers to usage of (0.44 ml of glycofurol for 150 mgParacetamol, 0.36 ml of glycofurol to dissolve 100 mg paracetamol and 0.22 ml of glycofurol to dissolve 60 mg paracetamol) excess solvent. Thus D2 teaches dissolution of higher concentration of paracetamol in lower amount of solvent (glycofurol).

9.5 Opponent submitted that D2 discloses paracetamol injectable solutions with high concentration of paracetamol in the range of up to 50% w/v which can be easily prepared by utilizing glycofurol as solvent wherein complete dissolution of paracetamol up to 50% w/v (500 mg/ml) is achievable and if need be and depending on delivery system, alcohol can also be incorporated into solvent system.

9.6 Opponent submitted that D3 discloses that in the case of poorly water-soluble drugs (such as- paracetamol) the solubility can be improved by the addition of certain solvents, such as propylene glycol, glycofurol orpolyethylene glycols, resulting in an increase of the concentration gradient ΔC.Table 1B of D3 indicates that better results may be expected with a lower concentration of glycofurol: 30% resulted in asaturation concentration just high enough to dissolve all the drug used. Therefore, D3 provides clear motivation to improve solubility of paracetamol by using solubilizing agent namely glycofurol in lesser quantity of paracetamol. Skilled person will note from D3 that complete dissolution of paracetamol up to 214 mg can be easily achieved in 50% glycofurol solution and thus preparation of high concentration of paracetamol solution was feasible and was known since 1985.

9.7: D4 provides for preparation of injectable solutions of Paracetamol, it also teaches preparation of injectable solutions comprising combinations of Paracetamol with other active substances. Since Paracetamol is practically insoluble in water, efforts made for its dissolution into organic-solvents or mixtures of them suitable for parenteral use. Paracetamol is soluble in Methanol, Ethanol, DMF, Ethylene chlorine, Benzylethanol and other organic solvents, but none of them can be used alone or in amixture, because of their toxicity.

-D4 further discloses that the qualified solvent in the case of Paracetamol is Glycerol formal. Page 5 of D4 further states: Glycerol formal is an almost atoxic solvent (LD50 I. V. to rats, 3,5mg/kg bodyweight) possesses the advantage of mixing with Water, Alcohol and PropyleneGlycol and has been proved to be the most favourable and qualified solvent for Paracetamol's injectable parenteral solutions, which can be used alone or in mixtures with water, Ethanol, Benzyl ethanol and Propylene glycol. Further pages 6-8 of D4 provide paracetamol formulations with different concentration of paracetamol in the range of 60-150 mg/ml(example 1-8).

Thus, a skilled person aware of the teachings of D4 will be well aware that paracetamol injectable solutions with high concentration of paracetamol in the range of 60-150 mg/ml (6-15% w/v) is routinely prepared as also will be aware

of usage of alcohol such as ethanol as solvents for complete dissolution of high concentration of paracetamol.

9.8; D6 discloses paracetamol parenteral formulations comprising paracetamol in concentration of 150 mg/ml. Under paragraph [0012-0015] of D6 it is disclosed that Paracetamol is soluble in many organic solvents, however solutions of Paracetamol with such solvents are unfit for therapeutical use, because of the produced toxicity when parenterally administered therefore any selected solvent or solvents system must be pharmacologically inactive(i.e. to not interfere with Paracetamol's or other's substance therapeutical properties), to not form complexes with the active substance, to be blood conventional, free of sensitization or irritating activity, chemically stable, clear and not influenced by pH declinations and must have the full ability of mixing with water not only because this way it or they will facilitate the manufacturing process but will also reduce the manufacturing cost.

D6 also discloses paracetamol injectable solutions with high concentration of paracetamol in the range of 15% w/v (paracetamol is in the range of 600 mg in 4 mlampoule i.e. 150 mg/ml i.e. 15% w/v) with the usage of alcohol such as ethanol as solvents for preparing formulations pertaining to parenteral administration of paracetamol.

9.9; opponent submitted that Claim 1 of the impugned application claims-

-a pharmaceutical formulation for paracetamol injection comprising Paracetamol (known from D1, D4, D5 and D6 discloses injectable formulation of paracetamol), glycofurol (Glycofurol acts as solubilizing- D2 and D3 provide that dissolution of higher concentration of paracetamol [at least up to 50% w/v] can be achieved through lesser amount of glycofurol. Further the extracts from Martindale-The Extra Pharmacopeia-31st Edition and "Handbook of Pharmaceutical Excipients" and the CAS database as cited also clearly indicate the routine use ofglycofurol as solvent in preparation of parenteral formulations ofparacetamol), co-solvent (i.e. alcohol, D4 and D6 exemplify paracetamol injection formulations with 10% v/v of Ethanol along with water and other solubilizing agent for dissolving/solubilizing paracetamol in the range of 60 mg-150 mg/ml.FurtherD2, D4 and D6 specifically disclose that paracetamol is soluble in ethanol (alcohol) and are routinely used in preparation of

paracetamol solutions), Water(D4 and D6 specifically indicate that though paracetamol is poorly soluble in water, usage of water along with other solubilizing agent helps inreducing manufacturing cost) and Preservative (i.e. benzyl alcohol, D6 and D4).

-Claim 2 claims the concentration of paracetamol to be in the range of 6-15% w/v. D4 and D6 disclose paracetamol formulations wherein concentration of the range of 6-15% w/v.As per D2 around 50%w/v dissolution of paracetomol is feasible and can be prepared as per process disclosed in D2.similalry D3 disclose preparation of paracetamol solutions wherein complete dissolution of up to 214 mg in 1 ml of 50% glycofurol is exemplified which implies paracetamol concentration in solution up to 214 mg i.e. around 21%w/v.

9.10: The Opponent submitted that if a skilled person is aware that complete dissolution of paracetamol can be achieved through glycofurol as well as isaware that ethanol is being routinely used for dissolving paracetamol,then it is but obvious that combination of both the aforesaid solventsshould also achieve complete dissolution of paracetamol.

9.11: The Opponent therefore submitted that the solvent system of glycofurol and alcohol as referred to in claim 1 and claim 10 for achieving dissolution of higher concentration of paracetamol can be deduced from theindividual teachings of D2 as well as combined teachings of D2/D3 withD4/D6.

9.12: The opponent also submitted that the impugned specification in general refers to providing of following advantages through the claimed formulation:

- Ease of administration to the patient;
- Less pain to the Patient;
- High effectiveness;
- Less viscous injectable formulation;
- Ready-to-use solution.
- WITH RESPEDCT to ease of administration and ready to use opponent submitted that injection formulations of paracetamol in small ampoules (ml capacity) have been known much prior to the claimed invention as can be noted form D1 D4 and D6.
- With regard to less pain to the Patient opponent submitted that present specification does not disclose the manner in which the injection is

administered and is also completely silent on the manner as to how the claimed formulation lessens the pain of the patient.

- With respect to High effectiveness andless viscous injectable formulation present speciation fails to disclose any enhanced therapeutic effect and less viscosity data vis-à-vis formulation known in the prior art.
- The Opponent submitted that in the absence of such data in the impugned specification, no inventive step can be attributed to the alleged formulation claimed in the impugned application.
- The opponent also cited some case laws in support of their arguments which have not reproduced here.

Applicant argument on *25(1) (e)-Obviousness/lack of inventive step-*

9.13: Since applicant, or any duly authorized representative thereof, has neither attended the hearing nor made any response to the hearing scheduled on January 6, 2020, thus the ground on which opponent relied upon are considered true and valid.

9.13*; notwithstanding to observation made under point 9.13, Applicant reply dated 18/09/2012 as "reply to statement of pre-grant opposition" are already in record and applicant has argued therein that* document US2004/0247627 (as exhibit 1 or D1)discloses "Ready-to-use Paracetamol injection solutions containing propylene glycol as the only co-solvent" and refers to ready-to-use highly stable paracetamol injectable solutions, prepared by mixing paracetamol, water, propylene glycol, and a citrate buffer (pH 4.5 to 6.5), and by heating said solution under preset conditions which may be stored for an extended period of time within a wide range of temperatures, with no paracetamol precipitation and/or its chemical modification. The prior art relates to a rectal drug administration. *The paracetamol used in the prior art is 4% while the application claims 6- 15% paracetamol. The opponent himself agrees with the fact that the amount of paracetamol used by the applicant is more than that claimed by the prior art (see Para 7.2 Page 8).*

9.14; Also the prior art claims use of propylene glycol as a solvent for dissolving paracetamol in water and nowhere in the prior art the glycofurol is claimed. The applicant has used glycofurol as solvent and has received an enhanced solubility of the paracetamol in the water. The contestations of opponent saying

that the invention is obvious over the prior art are false. Moreover, the prior art claims the formulations for 100 ml for which they use 4% paracetamol, while the invention uses 6-15% for the volume of 2, 3 and 5 ml.

9.15; Applicant submitted that US2003/0170296 (as exhibit 2 or D2) entitled "Transdermal Drug Delivery System" relates to a transdermal delivery system for analgesic, anti-pyretic and/or anti-inflammatory drugs such as acetaminophen, aspirin, capsaicin, diclofenac salts or any analgesic-anti-pyreticagent that may be selected from the group consisting of non-steroidal anti-inflammatorydrugs (NSAIDs) in a transdermal delivery system (TDDS). The applicant also submitted that paracetamol used in present formulation in an amount of 6-15% w/v. There has been no indication that paracetamol is used in amount of 6-15% w/v in prior art. Also the prior art claims a transdermal drug delivery system wherein the Non steroidal anti-inflammatory drugs (NSAIDs) are dissolved in variety of solvents. The selection of solvent system for transdermal drug delivery system and parenteral drug delivery system is completely different. Further the applicant has clearly claimed alcohol as a co-solvent in the example 1 and the original claims 1 and 10 of the specification. This means that alcohol is a part of the formulation and not an optional step. The applicant would clarify that only glycofurol is not used as a solvent in the invention. A combination of glycofurol in an amount of 22-44% v/v and alcohol in an amount of 10% v/v as solvents is not obvious over the prior art and the opposition is not admitted and hereby denied.

9.16; The applicant also submitted that the amount of paracetamol used in the exhibit 1(or D1) is 4% which is much less than the invention where the paracetamol is used in the amount of 6-15% w/v. Also the solvent system used to dissolve paracetamol into water completely is 22-44% of glycofurol and 10% of alcohol. Moreover, there is no indication of using paracetamol in 6-15% w/v or above and the formulation is made upto 100 ml which is quite a large dose when compared to parenteral drug administration. The invention claims the 2, 3 and 5 ml of injectable formulation of paracetamol. Thus the opposition is not admitted and hereby denied.

9.17; With regard to exhibit 3(or D3) applicant made their observation that nowhere in those documents is it disclosed that use of glycofurol as a solvent

would help achieve a dissolution profile of 15 mg/ml. The applicant has provided the invention in which by use of glycofurol and alcohol the paracetamol is dissolved easily and a high dissolution profile of 15 mg/ml is achieved. Therefore, the invention is not obvious when compared to exhibit 1, 2 and 3 combined.

With respect to exhibit 4, 5 and 6 applicant made their observation that exhibits 4-6 are not similar to the invention because the desired dissolution profile is achieved by the use of solvents and additives, viz. glycerol formal, ethanol, nipagin A and nipagin M (see example 1 to 8 on Page 50-53 of exhibit 4 and Page 77 Paragraph [00023] of exhibit 6) and further the exhibit 6 talks about "solubility of paracetamol in aqueous medium in order of 12 mg/ml" wherein the applicant has claimed an invention with 6-15% w/v paracetamol formulation which is very high concentration than that claimed in exhibit 6. In exhibit 5 the paracetamol is made up into a solution by use of glucose and other sugars. The use of glycerol formal is completely different than that of glycofurol and thus the invention is not obvious when compared to exhibit 4 to 6. Hence, this opposition is not admitted and hereby denied.

Decision on section *25(1) (e)-Obviousness/lack of inventive step-*

9.18: Since applicant, or any duly authorized representative thereof, has neither attended the hearing nor made any response to the hearing scheduled on January 6, 2020, thus ground on which opponent relied upon are considered true and valid.

Therefore, based on above alone the ground u/s 25(1)(f) of the opposition is maintained..

9.19: I observe that document D4 discloses a formulation of paracetamol with concentration in the range of 60-150 mg/ml but solvent system of D4 (e.g. glycerol formal, ethanol, nipagin A and nipagin M) is different. It does not disclose the specific combination of “glycoferol and alcohol” solvent system. From disclosure of Documents D2 and D3 an essence can easily be drawn that glycofurol is an additional/alternative solvent for dissolution of paracetamol and it also increase the dissolution of paracetamol in water. Further, it also well know that Paracetamol perse is soluble in alcohol like Methanol, Ethanol etc. (e.g. see; D4) further it is also well know that the preparations of injectable

solutions of Paracetamol or any other pharmaceutical active substances require the choice of the suitable solvent or combination of solvents with or without water shall contain certain requirements of suitability such as pharmacologically inertness, to not form complexes with the active substance, to be blood conventional, free of sensitization or irritating activity(e.g. see; D4) etc. Since the glycofurol is non-toxic, increase the solubility of paracetamol in water, used as solvent in parenteral products for intravenous or intramuscular injection (see; CAS database provided by opponent) therefore, skilled person may combine alcohol with that of glycofurol with that of the formulation as disclosed in D4.

9.20; Further, applicant has mentioned in the description that the present formulation is prepared with an objective of "Ease of administration to the patient, less pain to the Patient, High effectiveness, less viscous injectable formulation, Ready-to-use solution. But description of the application completely lacking any data related to above, thus it is considered that the object of the invention has not been met and therefore alleged invention is considered obvious over the prior art disclosure as mentioned above.

9.21: Even though there is no explicit or implicit disclosure in any of the prior art cited by the opponent that a solvent combination "glycofurol and alcohol" can be used to prepare the parental formulation of paracetamol in the amount of 6-15% w/v.But, as said above glycofurol was already in use as a solvent for parental formulation, it is non-toxic and it increases the solubility of paracetamol in water. Also applicant has neither provided any data (and/or comparative data) with regard to the relevant physical property of the formulation (like, stability, solubility, viscosity etc.) nor anything related to ease of administration to the patient, less pain to the patient and high effectiveness (object of the invention as mentioned at page 2 of the as filed complete specification) or enhanced technical effect vis-a-vis prior art. Therefore, alleged invention is considered obvious in view of clear disclosure of D2 in combination to D3 and D4.

Therefore, in view of above explanation the ground of opposition u/s. 25(1)(e)-Obviousness/lack of inventive step is validly established by the opponent.

10: Ground u/s section 25(1) (f)-claims are Not patentable under Section 3(d) and 3(e):

Opponent argument on 25(1) (f)-3(d) and 3(e):

10.1: The opponent submitted that the claimed invention falls under the mischief of Section 3 (d) because of lack of therapeutic efficacy of paracetamol injectable formulation vis-à-vis the closest prior art.

10.2: Opponent submitted that the object of the impugned application refers to high effectiveness of claimed formulation which impliedly refers to high effectiveness of the active Paracetamol. The impugned patent application has not shown how the compositions disclosed therein provide enhanced efficacy as compared to preparations disclosed in prior art.

10.3: The Opponent submitted that in citations it is clear that the paracetamol injection formulations as claimed in the impugned patent application fall under the purview of "combination" provided under the Explanation part of Section 3(d) of Patents Act and hence it was imperative upon the Applicant to provide efficacy data for the claimed dosage forms as also comparative enhanced efficacy data. Since no such data has been provided in the impugned specification, the claims of the present application are not patentable under Section 3(d).

10.4 opponent also submitted that the claimed invention falls under the mischief of section 3(e) which clearly states "a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance" as not patentable under this Act.

10.5 The Opponent submitted that Glycofurol and alcohol are individually known to solubilize paracetamol, so it was imperative upon the Applicant to provide comparative data to show the synergistic effect (enhanced solubility) achieved through the combination of solvents. Since applicant has failed to provide any synergistic data achieved through the usage of solvent system comprising of glycofurol and alcohol, the invention claimed in the impugned application fails to satisfy the provisions of Section 3(e) of the Act.

10.6 Applicant submitted that the impugned application nowhere in the specification demonstrate by means of appropriate experimental data any

synergy achieved in dissolution of paracetamol through the solvent system comprising of glycofurol and alcohol. Applicant has failed to demonstrate any satisfactory synergy between the solvent glycofurol and alcohol. In absence of any data on synergy, the claimed formulation would amount to mere admixture.
10.7; The Opponent further relied on the submissions made in the representation and in the preceding paragraphs and stated that the alleged invention falls under the mischief of Section 3(d) and 3(e) and hence is not patentable and hence needs to be refused in to under section 25(1)(f).
10.8; The opponent also cited some case laws in support of their arguments which have not reproduced here.

Applicant submission on *25(1) (f)-3(d) and 3(e):*

10.9: Applicant in their reply has submitted that as per “Draft Manual of Patent Practice and Procedure 2011” (Page 85 Paragraph 08.03.05.04) it can be calculated that Section 3 (d) is only concerned about "substance". And Substance is defined as "Matter; particularly solid matter"(See; annexure 2) and composition is defined as "A mixture of ingredients" (See; Annexure 3).
10.10: Applicant made submission that composition and substance is different thing in the Pharmaceutical Industry. Therefore opponent’sstatement that "Section 3(d) read with its explanation state that the known combination shall be considered to be the same substance" is totally vague because substance and combination both are different things. Thus, present invention does not fall under section 3 (d) of non-patentable invention.
10.11: Applicant made submission that the combination of glycofurol and alcohol result in the enhanced solubility of paracetamol in water in the invention is not just mere aggregation of known substance.
Decision on section *25(1):*

10.12: Since applicant, or any duly authorized representative thereof, has neither attended the hearing nor made any response to the hearing scheduled on January 6, 2020, thus ground on which opponent relied upon are considered true and valid.

Therefore, based on above alone the ground u/s 25(1)(f) of the opposition is maintained.

10.13: Notwithstanding above, I is noticed that the paracetamol in their injectable form is known in the art (e.g. D1) and the objects of the present invention is to obtain a formulation with high effectiveness but present application has not provided any data (like, stability, solubility, viscosity or ease of administration to the patient, less pain to the patient and/or high effectiveness) or enhanced technical effect vis-a-vis prior art resultant of the present injectable form of paracetamol formulation to establish its therapeutic effect or effectiveness.

10.14: I observe that present application has not provided any comparative data with regard to any unforeseen effect. The specification neither indicates any data (as mentioned above) related to present injectable form of pharmaceutical formulation nor demonstrated any enhanced therapeutic efficacy vis-à-vis prior art injectable pharmaceutical formulation.

Thus, the ground raised by the opponent u/s 25(1)(f) is maintained.

11: Ground (U/S 25 (1) (g): INSUFFICIENCY:

Opponent argument on 25(1)(g):

11.01; Opponent submitted that the impugned application claims a pharmaceutical formulation for paracetamol injection comprises paracetamol, glycofurol, co-solvent, water and preservative whereas the Applicant has alleged that one of the inventive step resides in providing paracetamol formulation wherein paracetamol concentration is in the range of 6-15% w/v. The Opponent submits that claim 1 merely refers to paracetamol injectable formulation and does not provide any reference to

the high concentration of paracetamol which it claims to have achieved. Thus, as per plain reading of claim 1 of the impugned application, paracetamol injectable formulation with less than 6-15% (60-150 mg/ml) will also fall within the scope of claimed invention, though the specification fails to provide any embodiments in this regard.

11.02 The Opponent submitted that the term claim 1 is too broad in the sense that claim 1 mentions the use of co-solvent which is further narrowed down to alcohol in claim 10 but applicant has not specified any specific alcohol neither in the specification nor in the embodiments as to which alcohol it refers to.

11.03 The opponent further states that claim 10 claim the use of co solvents only with respect to 2 ml injectable formulations and not for 3 ml and 5 ml ((example 3 and 4) injectable formulations it is not clear as to whether alcohol is an essential component or an optional component.

11.04 Opponent submitted that present specification provides examples of paracetamol injectable formulation with (Example 1) and without (Example 2) alcohol as a co-solvent and not provided any solubility data with regards to the claimed formulation thereby raising serious doubts as to what are the essential components of the claimed invention. If complete dissolution is achieved even in the absence of alcohol, the Applicant needs to justify the use of alcohol in example 1 and the impugned specification is completely silent in that aspect.

11.05 The opponent submitted that the impugned specification in the "Summary" refers to the essential use of alcohol whereas on page 5, states, "if required, then alcohol is used", thereby lacking clarity as to need for co-solvent in the claimed formulation.

11.06: The Opponent submitted that the impugned specification exemplifies 1-4 as embodiments of claimed invention, but does not provide any resultant and/or comparative data to show the viscosity, crystallization data, effects provided by each of those formulations and

efficacy of the claimed formulation. Thus, the impugned specification is not sufficiently enabled.

Applicant argument on 25(1)(g):

11.07: Applicant in their reply to the opposition has submitted that the invention is for preparation of high concentration (6-15% v/v) paracetamol injection by use of solvents glycofurol (22-44% v/v) and alcohol (1 0% v/v) in water to prepare 2 ml, 3 ml and 5 ml formulation for parenteral administration. Benzyl alcohol is added to the formulation as a preservative. The paracetamol injection of the invention provides a high efficacy and low viscosity formulation.

Decision on section *25(1)(g):*

11.08: Since applicant, or any duly authorized representative thereof, has neither attended the hearing nor made any response to the hearing scheduled on January 6, 2020, thus ground on which opponent relied upon are considered true and valid.

Therefore, based on above alone the ground u/s 25(1)(f) of the opposition is maintained.

11.09: Notwithstanding to above, I observed that, as per page 4 of the specification, the object of the invention is to "*prepare a pharmaceutical formulation of paracetamol that provide ease of administration to the patient, less pain to the patient and high effectiveness. Another object of the present invention is to prepare less viscous injectable formulation of paracetamol. Further object of the present invention is to prepare ready to use solution due to which there is no need of dilution.* Further, on page 4 and 5 of the specification it is disclosed that"*Paracetamol is used in a concentration of 6-15 % w/v (% mg/ml). 15%, 10% and 6% of paracetamol is used for 2 ml, 3 ml and 5 ml of injection respectively. Glycofurol is used in a concentration of 22-44% v/v (% ml/ml). 44%, 36% and 22% of glycofurol is used for 2 ml, 3 ml and 5 ml of injection respectively. If required then alcohol is used as a co-solvent in a concentration of 10% v/v (% ml/ml).*

11.10*; I observe that specification contain total four examples and out of four examples only example 1 contain alcohol as a co-solvent. Further, there is no disclosure of any specific alcohol in said example 1.*

11.11: I also observe that the specification exemplifies 1-4 as embodiments of claimed invention, but does not provide any resultant and/or comparative data to show the viscosity, crystallization data, effects provided by each of those formulations and efficacy of the claimed formulation.

Therefore, based on above finding ground of opposition raised u/s 25 (1) (g) is maintained.

Order:

Since applicant, or any duly authorized representative thereof, has neither attended the hearing nor made any response to the hearing scheduled on January 6, 2020, thus ground on which opponent relied upon are considered true and valid. Further, the reply of the opposition submitted by the applicant is also insufficient to overcome the objection of the opponent as raised U/S 25 (1) (e), U/S 25 (1) (f) and U/S 25 (1) (g).Therefore, instant applicant is refused to grant of patent under section 15 of the Act.

Dated: June 18, 2020

(Emaduddin)

AC of Patents & Designs

Copy to:

1. RAJESHKUMAR H.ACHARYA,
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2. ABHISEK SEN of,
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