THE PATENTS ACT, 1970
The Patents Rules, 2003

(SECTION 25(1) and RULE 55)

In the matter of the application for Patent 339/MUMNP/2006

And

In the matter of representation by way of opposition u/s 25(1) to the grant of patent thereon by I-MAK, Cipla Ltd., Okasa Pvt. Ltd. and Matrix Lab Ltd.

M/s Abbott Laboratories Ltd		Applicant
I-MAK, Delhi	....	Opponent-1
M/s Cipla Ltd.	....	Opponent-2
M/s. Okasa Pvt. Ltd.	....	Opponent-3
M/s. Matrix Lab Ltd.	....	Opponent-4

Present:

Archana Shanker	.....	Agent for Applicant
S. Majumdar	.....	Agent for Opponents 1, 2 and 3
Feroz Ali	.....	Agent for Opponent 4

HEARING HELD
BEFORE DR RUCHI TIWARI, DEPUTY CONTROLLER
OF PATENTS & DESIGNS

DECISION

1. The applicant M/s **Abbott Laboratories, USA** filed a national phase application No. 339/MUMNP/2006 on 24th March, 2006 in pursuance of their PCT application No PCT/US2004/027401 for granting of a patent for their invention entitled "SOLID PHARMACEUTICAL DOSAGE FORM" having the conventional priority of US application No. 10/650,178 dated 28th August, 2003. The complete specification had 37 claims out of which claims 1-18 and 22-36 claimed for ' A solid pharmaceutical dosage

form', claims 19-20 for 'A method of preparing a solid pharmaceutical dosage form', claims 21 and 37 claimed for 'A method of treating an HIV infection'. A request for examination was filed by the applicants on 24th March, 2006 and the first examination report was issued on 9th October, 2007.The applicant's agent replied to the FER vide their letter dated 7th July, 2008 and filed a revised set of claims. An opposition to the grant of a Patent thereto in the meanwhile was filed by I-MAK on 16th Aug 2008 followed by three more oppositions which are summarized below:

1.1 **Opponent-1: I-MAK (Initiative for Medicines, Access & Knowledge), Delhi** [herein after referred as Opponent-1] filed a representation by way of opposition under section 25(1) of the Act to the grant of patent thereto on 16th August, 2007. The reply statement with evidence in support of the application by the applicant to the representation was filed on 8th January, 2008 along with amended claims 1-25. The Opponent-1 has filed Reply to the Applicant's response with their letter dated 16th February, 2009. The Applicant has filed a Interlocutory Petition with their letter dated 9th April, 2009 against the Reply of Opponent-1. The petition interalia stated that the Reply of the Opponent-1 filed on 19th February, 2009 cannot be taken on record as it is a rejoinder with additional documents. The hearing of Interlocutory petition and main matter was appointed on 15th April, 2009.

1.2 **Opponent-2: CIPLA Ltd., Mumbai** [herein after referred as Opponent-2] filed a representation by way of opposition under section 25(1) of the Act to the grant of patent thereto on 23rd November, 2007. The reply statement with evidence in support of the application by the applicant to the representation was filed on 7th March, 2008 along with amended claims 1-25. The matter was heard on 15th April, 2009 along with Opponent-1.

1.3 **Opponent-3: OKASA Pvt. Ltd., Mumbai** [herein after referred as Opponent-3] filed a representation by way of opposition under section 25(1) of the Act to the grant of patent thereto on 4th March, 2009. The reply statement with evidence in support of the application by the applicant to the representation was filed on 25th June, 2009 and asking for the disregard of the reply statement submitted on 24th

June, 2009. The Applicant has filed two Interlocutory Petitions on 13th April, 2009. The petitions interalia stated that the pre-grant opposition filed by Okasa cannot be taken on record as it is an abuse of the Patents Act and system; further in another Interlocutory Petition requesting for an order denying the Opponent (Okasa) the right to challenge the revised set of claims made either during the prosecution of the application or otherwise before the grant of a patent that do not for a part of the published documents under section 11(A). The hearing of Interlocutory petition was appointed 29th May, 2009 and after disposing off the Interlocutory Petitions a hearing of the main matter was appointed on 30th March, 2010.

1.4 **Opponent-4: Matrix Laboratories Ltd., Hyderabad** [herein after referred as Opponent-4] filed a representation by way of opposition under section 25(1) of the Act to the grant of patent thereto on 14th May, 2009. The reply statement with evidence in support of the application by the applicant to the representation was filed on 25th January, 2010. The hearing was appointed on 10th June, 2010.

The revised set of claims on record filed on 15th April, 2009 is as below:

1. A pharmaceutical composition which comprises a solid dispersion of ritonavir and lopinavir in one or more pharmaceutically acceptable water-soluble polymers and one or more pharmaceutically acceptable surfactants, and said one or more pharmaceutically acceptable water-soluble polymers have a Tg of at least about 50°C, and said composition comprises from about 50 to about 85 % by weight of the total composition of said one or more pharmaceutically acceptable water-soluble polymers, and at least one of said one or more pharmaceutically acceptable surfactants has an HLB value of from about 4 to 10.

2. The pharmaceutical composition as claimed in claim 1, wherein said solid dispersion is a glassy or solid solution.

3. The pharmaceutical composition as claimed in claim 1, wherein said one or more pharmaceutically acceptable surfactants comprise a combination of at least one pharmaceutically acceptable surfactant having an HLB value of from about 4 to about 10 and at least one further pharmaceutically acceptable surfactant.

4. The pharmaceutical composition as claimed in claim 1, wherein said one or more pharmaceutically acceptable surfactants comprise a sorbitan fatty acid ester.

5. The pharmaceutical composition as claimed in claim 1 which comprises, relative to the weight of the composition, from about S to about 30 % by weight of said ritonavir and

lopinavir, from about 2 to about 20 % by weight of said one or more pharmaceutically acceptable surfactants, and from about 0 to about 15 % by weight of additives.

6. The pharmaceutical composition as claimed in claim 1, wherein at least one of said one or more pharmaceutically acceptable water-soluble polymers has a Tg of from about 80 to about 180 °C.

7. The pharmaceutical composition as claimed in claim 1, wherein said one or more water-soluble polymers comprise a homopolymer or copolymer of N-vinylpyrrolidone.

8. The pharmaceutical composition as claimed in claim 1, wherein said one or more water-soluble polymers comprise a copolymer of N-vinyl pyrrolidone and vinyl acetate.

9. The pharmaceutical composition as claimed in claim 1 containing at least one additive selected from flow regulators, disintegrants, bulking agents and lubricants.

10. The pharmaceutical composition as claimed in claim 1 which comprises, relative to the weight of the composition, from about 5 to about 30 % by weight of ritonavir and lopinavir, from about 2 to about 20% by weight of said one or more pharmaceutically acceptable surfactants, and from about 0 to about 15 % by weight of additives.

11. The pharmaceutical composition as claimed in claim 1, wherein said one or more pharmaceutically acceptable water-soluble polymers are selected from the group consisting of homopolymer of N-vinyl lactam, copolymer of N-vinyl lactam, cellulose ester, cellulose ether, polyalkylene oxide, polyacrylate, polymethacrylate, polyacrylamide, polyvinyl alcohol, vinyl acetate polymer, oligosaccharide, and polysaccharide; and wherein said at least one surfactant is selected from the group consisting of polyoxyethylene alkyl ether, polyoxyethylene alkylaryl ether, polyethylene glycol fatty acid ester, alkclene glycol fatty acid mono ester, sucrose fatty acid ester, and sorbitan fatty acid mono ester.

12. The pharmaceutical composition as claimed in claim 1, wherein said one or more pharmaceutically acceptable water-soluble polymers are selected from the group consisting of homopolymer of N-vinyl pyrrolidone, copolymer of N-vinylpyrrolidone, copolymer of N-vinyl pyrrolidone and vinyl acetate, copolymer of N-vinylpyrrolidone and vinyl propionate, polyvinylpyrrolidone, methylcellulose, ethylcellulose, hydroxyalkylcelluloses, hydroxypropylcellulose, hydroxyalkylallylcellulose, hydroxypropylmethylcellulose, cellulose phthalate, cellulose succinate, cellulose acetate phthalate, hydroxypropylmethylcellulose phthalate, hydroxypropylmethylcellulose succinate, hydroxypropylmethylcellulose acetate succinate, polyethylene oxide, polypropylene oxide, copolymer of ethylene oxide and propylene oxide, methacrylic acid/ethyl acrylate copolymer, methacrylic acid/methyl methacrylate copolymer, butyl methacrylate/2-dimethylaminoethy] methacrylate copolymer, poly(hydroxyalkyl acrylate), poly(hydroxyalkyl methacrylate), copolymer of vinyl acetate and crotoruc acid, partially hydrolyzed polyvinyl acetate, carrageenan, galactomannan, and xarithan gum, and wherein said at least one surfactant is selected from the group consisting of polyoxyethylene (3) lauryl ether, polyoxyethylene (5) cetyl ether, polyoi,-Yethylene (2) stearyl ether,

polyoxyethylene (5) stearyl ether, polyoxyethylene (2) nonylphenyl ether, polyoxyethylene (3) nonylphenyl ether, polyoxyethylene (4) nonylphenyl ether, polyoxyethylene (3) octylphenyl ether, PEG-200 monolaurate, PEG-200 dilaurate, PEG-300 dilaurate, PEG-400 dilaurate, PEG-300 distearate, PEG-300 dioleate, propylene glycol monolaurate, sucrose monostearate, sucrose distearate, sucrose monolaurate, sucrose dilaurate, sorbitan mono laurate, sorbitan monooleate, sorbitan monopalrnitate, and sorbitan stearate.

13. The pharmaceutical composition as claimed in claim 11, wherein said one or more pharmaceutically acceptable water-soluble polymers comprise a homopolymer or copolymer of N-vinyl pyrrolidone, and said at least one surfactant is a sorbitan fatty acid mono ester.

14. The pharmaceutical composition as claimed in claim 12, wherein said one or more pharmaceutically acceptable water-soluble polymers comprise copovidone, and said at least one surfactant is sorbitan mono laurate.

15. The pharmaceutical composition as claimed in claim 11, wherein said one or more pharmaceutically acceptable water-soluble polymers comprise a homopolymer orcopolymer of N-vinyl pyrrolidone, and said at least one surfactant is a sorbitan fatty acid mono ester, and wherein said ritonavir and lopinavir are present in an amount of from about 5 to about 30 % by weight of the composition , and said at least one surfactant is present in an amount of from about 2 % to about 20 % by weight of the composition.

16. The pharmaceutical composition as claimed in claim 15, wherein said solid dispersion is a glassy or solid solution.

17. The pharmaceutical composition as claimed in claim 15, wherein said one or more pharmaceutically acceptable water-soluble polymers comprise a copolymer of N-vinyl pyrrolidone and vinyl acetate.

18. The pharmaceutical composition as claimed in claim 15, wherein said one or more pharmaceutically acceptable water-soluble polymers are copovidone, and said at least one surfactant is sorbitan monolaurate.

19. The method of preparing a pharmaceutical composition as claimed in claim 1, comprising: preparing a homogeneous 'melt comprising said ritonavir and lopinavir, said one or more pharmaceutically acceptable water-soluble polymers and said one or more pharmaceutically acceptable surfactants; and allowing the melt to solidify to obtain a solid dispersion product.

21. The method as claimed in claim 19 additionally comprising grinding said solid dispersion product and compressing said ground solid dispersion product into a tablet.

22. A pharmaceutical composition comprising a solid dispersion of ritonavir and lopinavir in one or more pharmaceutically acceptable water-soluble polymers and one or more pharmaceutically acceptable surfactants when prepared by a process as claimed in claim 19.

2. Summary of the Representations & arguments of the Opponents:

2.1 Opponent 1:

The impugned patent application has been opposed on the following grounds:

Ground a) - Not patentable under section 3(d) of the Act [S.25 (1)(f)]

Ground b) - Lack of Inventive Step [S. 25(1) (e)]

Ground c) - Failed to disclose Information u/s 8 [S. 25(1) (h)]

2.1.1 Ground a) - Not patentable under section 3(d) of the Act [S.25 (1) (f)]:

The Opponent in support of this ground of non-patentability as per provisions of sec. 3(d) of the Act has referred the following documents:

Exhibit 2: Draft Manual of Patent Practice and Procedure, Patent Office, India, 2005

Exhibit 3: WO 2000/74677

Exhibit 4: The text book of Pharmaceutical Medicine, Fourth edition 2002, Edited by John P griffin and John O'Grady. Chapter 6: Clinical trails and good Clinical practice by Nigel Baber and John Sweatman, page 283.

Exhibit 5: Novartis Ag v Union of India, In the High Court of Judicature at Madras dated 6/8/2007, pages 51-53

Exhibit 6: J. Breitenbach, Melt Extrusion can bring new benefits to HIV therapy, the example of Kaletra® Tablets, American Journal of Drug Delivery, 2006, 4(2):61-64

Exhibit 7: Zhu et al, New Tablet Formulation of Lopinavir/Ritonavir is Bioequivalent to the Capsule at a Dose of 800/200 mg, Abbott Laboratories, Poster presented at 45th Interscience Conference on Antimicrobial agents and Chemotherapy (ICAAC), Washington Dc, December 16-19,2005.

2.1.2 Ground b) - Lack of Inventive Step [S. 25(1) (e)]:

The claims of the impugned application lack inventive step and are obvious in view of the disclosures in following documents:

Exhibit 8: WO01/34119

Exhibit 9: US 4769236

Exhibit 10: Applicant's Letter to EPO of 1 March, 2004 with respect to the prosecution of WO01/34119.

Exhibit 11: International Search Report for WO01/34119.

Exhibit 12: BASF, ExAct-Excipients and Actives for Pharma, No.2, July 1999

Exhibit 13: Jorg Breitenbach, Melt Extrusion: from process to drug delivery technology, European Journal of Pharmaceutics and Biopharmaceutics, 54, 2002,107-117

Exhibit 14: Abu T.M. Serajuddin, Solid Dispersion of Poorly water-soluble drugs: Early promises, subsequent problems and recent breakthroughs, Journal of Pharmaceutical Sciences, Vol. 88 (10), October 1999

Exhibit 15: Owen Corrigan et al., Surfactants in pharmaceutical products and systems, Encyclopedia of Pharmaceutical Technology, vol. 14, 2002, at page 2649.

2.1.3 Ground c) - Failed to disclose Information u/s 8 [S. 25(1) (h)]:

Opponent states that "whether the Applicant has provided the information and particulars of the equivalent foreign applications particularly of application at EPO".

Opponent further submitted the statement of the Opposition in reply to the Applicant's Response and cited the following documents:

Exhibit A: A comparison of the Single dose Bioavailability of a Ritonavir Tablet Formulation relative to the Ritonavir soft gelatin Capsule in Healthy adult subjects, J Ng et. al., Abbott laboratories, XVII International AIDS Conference, 3-8 August 2008, Mexico City.

Exhibit B: Press Release: Abbott study shows investigational; Heat-stable Norvir® Tablet provides similar drug levels to current Norvir capsule, Abbott Laboratories, 7 August 2008

Exhibit C: US Food and Drug Administration's (US FDA) Application Number: 21-906 Clinical Pharmacology/Biopharmaceutics Review (s)

Exhibit D: US Food and Drug Administration's (US FDA) Application Numbes 21-226 and 21-251, Clinical Pharmacology/Biopharmaceutics Review (s)

Exhibit E: Soliq's All time History

Exhibit F: J. Breitenbach et. al., Two concepts, one technology: Controlled-Relesee solid dispersions using melt extrusion (Meltrex), in modified-release drug delivery technology, vol. 1, chapter 16, 2008.

Exhibit G: Soliq's Meltrex Technology

Exhibit H: Devalina Law et. al.., Ritonavir-Peg 8000 Amorphous solid dispersions: In vitro and In vivo evaluations, Journal of Pharmaceutical Sciences vol. 93(3), March 2004.

Exhibit I: US 6197781

Exhibit J: US 4801460

Exhibit K: A Forster et. al., Selection of excipients for melt extrusion with two poorly water soluble drugs by solubility parameter calculation and thermal analysis, International Journal of Pharmaceutics, 226 (2001), 147-161.

Exhibit L: A Forster et. al.,Characterization of glass solution of poorly water soluble drugs produced by melt extrusion with hydrophilic amorphous polymers, Journal of Pharmacy and Pharmacology 2001, 53, 303-315.

Exhibit M: Howard C. Ansel et. al., Pharmaceutical Dosage forms and drug delivery systems, seventh edition (1999), pages 367-369.

Exhibit N: Biopharmaceutics Classification system (BCS) search of Ritonavir and Lopinavir by TSRL Inc

Exhibit O: US 2006/0068012 A1

Exhibit P: V. Buhler, Polyvinylpyrrolidine Excipients for Pharmaceuticals-Povidone, Crospovidone and Copovidone, Springer (2005)

Exhibit Q: WO 2006/091529 A2

Exhibit R: European Patent Office examination report for EP application no. 0673552.9

2.2 Opponent-2:

The impugned patent application has been opposed on the following grounds:

Ground 1- Lack of Novelty [S. 25(1) (b)]

Ground 2- Lack of Inventive Step [S. 25(1) (e)]

Ground 3- Non-patentable subject matter [S.25 (1) (f)]

Ground 4- Application not made within 12 months from the date of first disclosure in convention country [S.25 (1) (i)]

2.2.1 Ground 1- Lack of Novelty [S. 25(1) (b)]:

The Opponent in substantiating this ground of opposition has cited the following document:

Exhibit IV: WO 2004/032903

The claims 1-7, 10, 16-17, 19, 23-26, 27, 31-34 and 36 are not novel in view of the disclosures in Exhibit IV.

2.2.2 Ground 2- Lack of Inventive Step [S. 25(1) (e)]:

The Opponent in substantiating this ground of opposition has cited the following documents:

Exhibit I: H. Witteler and M. Gotsche "Chemistry and Physicochemical properties of Povidone" BASF ExAct Excipients & Actives for Pharma, No.2, July 1999.

Exhibit II: WO 97/44014 A1

Exhibit III: WO 01/22938 A1

Exhibit IV: WO 2004/032903 **[Exhibit IV-A:** US 2006/0257470 A1]

2.2.3 Ground 3- Non-patentable subject matter [S.25 (1) (f)]:

The Opponent in substantiating this ground of opposition of non-patentability of the combination of Lopinavir and Ritonavir has referred the following documents:

Exhibit V: WO 00/74677

Exhibit VI: Zhu et al, New Tablet Formulation of Lopinavir/Ritonavir is Bioequivalent to the Capsule at a Dose of 800/200 mg, Abbott Laboratories, Poster presented at 45th Interscience Conference on Antimicrobial agents and Chemotherapy (ICAAC), Washington Dc, December 16-19,2005.

2.2.4 Ground 4- Application not made within 12 months from the date of first disclosure in convention country [S.25 (1) (i)]:

Opponent states that the subject matter of application is already disclosed in earlier PCT application WO 2004/032903 (D1) published on 22nd April 2004 claims the priority date of 9th October 2002. The present application claiming the priority of US application No. 10/650,178 dated 28th august 2003 is not the first application in the sense of Article 8 of

PCT, therefore the priority claim is invalid for the subject matter already disclosed in the still earliier application D1.

Opponent has submitted the evidence in support of the opposition by Dr. Sudhakar G. Deshpande, Mumbai.

2.3 Opponent-3:

The impugned patent application has been opposed on the following grounds:

Ground 1) – OBVIOUSNESS AND LACK OF INVENTIVE STEP [S. 25(1) (e)]

Ground 2) - NOT AN INVENTION/ NOT PATENTABLE [S.25 (1) (f)]

Ground3) – INSUFFICIENCY [S.25 (1) (g)]

Ground 4) - SECTION 8 [S. 25(1) (h)]

2.3.1 Ground 1) – OBVIOUSNESS AND LACK OF INVENTIVE STEP [S. 25(1) (e)]:

The opponent relied on the following prior art in support of this ground of opposition:

Exhibit 1: US 6599528

Exhibit 1A: US 5834472

Exhibit 2: US 5776495

Exhibit 2A: Abu T.M. Serajuddin "Solid dispersion of poorly water soluble drugs: Early promises, subsequent problems and recent breakthroughs" Journal of Pharmaceutical Sciences, Vol. 88(10), October 1999.

Exhibit 3: WO 01/034119

Exhibit 4: US 2003/021840

2.3.2 Ground 2) - NOT AN INVENTION/ NOT PATENTABLE [S.25 (1) (f)]:

The Opponent states that the claimed invention is devoid of inventive step and also not patentable as per section 3(e) of the Patents Act, 1970 as it is a mere admixture resulting only in the aggregation of properties of components.

2.3.3 Ground 3) – INSUFFICIENCY [S.25 (1) (g)]:

The opponent states that the claims of the impugned application are not fairly based on the disclosures of the impugned application.

2.3.4 Ground 4) – SECTION 8 [S. 25(1) (h)]:

The opponent states that the applicant has failed to furnish statement and undertaking under section 8.

2.4 Opponent-4:

The impugned patent application has been opposed on the following grounds:

Ground 1- Prior Publication (Anticipation) [S. 25(1) (b)]
Ground 2- Lack of Inventive Step/ Obviousness [S. 25(1) (e)]
Ground 3- Not an Invention [S.25 (1) (f)]
Ground 4 – Non intimation of information under section 8 to the Controller [S. 25(1) (h)]

2.4.1 Ground 1- Prior Publication (Anticipation) [S. 25(1) (b)]:

The Opponent in discussing this ground of opposition has cited the following documents:

Exhibit 2: L. Dias et. al., (1996) Pharmaceutical Research Supplement 13(9); page S-351 PDD 7475

Exhibit 3: Win Loung Chiou, Journal of Pharmaceutical Sciences, Vol.60; page 1283 [1971]
Exhibit 4: US 5073379
Exhibit 5: Merck Index Details

2.4.2 Ground 2- Lack of Inventive Step/ Obviousness [S. 25(1) (e)]:

The Opponent in discussing this ground of opposition has stated the following documents:

Exhibit 6: WO 01/034119

Exhibit 7: Surfactants in Pharmaceutical products and systems, Encyclopedia of Pharmaceutical Technology [2002], page 2649.

Exhibit 8: Rejection of WO 01/034119 in EPO

2.4.3 Ground 3- Not an Invention [S.25 (1) (f)]:

Opponent states that the claims 21 and 37 claiming for the method of treatment are not patentable u/s 3(i) of the Act and also states that the combination of known substances is not patentable as per section 3(d) of the Act if enhanced efficacy is not shown. The instant application claims are not patentable in S.25 (1)(f) read in conjunction with section 3(d) of the Act.

2.4.4 Ground 4 – Non intimation of information under section 8 to the Controller [S. 25(1) (h)]:

The opponent states that the applicant has filed the same application in various countries through national phase entry but not informed the details to Controller as per section 8 of the Act.

3. Summary of Reply & arguments of the Applicant:

Applicant's have replied to all the oppositions individually and also submitted the combined submissions to all the oppositions on 4th August 2010 along with affidavits by Dr. Jorg Rosenberg, Dr. Jorg Breitenbach, Dr. John Morris and Dr. Yi Lin Chiu in support of their invention with 46 annexures.

In their submissions applicants have highlighted the Opponents' patent applications filed for the identical inventions mainly WO08/029417 with Indian Priority 1597/Che/2006 (Annexure 1),WO09/084036 with Indian Priority 3070/Che/2007 (Annexure 2), and 1730/Che/2007 (Annexure 3) by Matrix Laboratories; and 1269/MUM/2006 (Annexure 4) by Cipla. The above patent applications filed by Opponents for the identical invention show their admission that the invention is novel, inventive and patentable.

3.1 NOVEL AND INVENTIVE FEATURES OF THE PRESENT INVENTION:

Solid dispersion of Ritonavir (a BCS class IV compound) and lopinavir with adequate bioavailability.

a. Ritonavir class IV- difficult to formulate

i. variability in formulation is expected for different Class IV compounds,

ii.Cannot be reasonably predicted, without actually testing, if a given formulation would work for ritonavir.

iii. Extensive research needed to identify formulations that can provide adequate bioavailability for a Class IV compound

iv. Traditional trial-and-error process does not guarantee the identification of a suitable formulation for a Class IV compound

b. Co-formulating ritonavir and lopinavir was further complicated by the unexpected, yet-not-understood in vivo interaction between ritonavir and lopinavir.

Documents cited in the four oppositions:

1. WO 2004/032903 and its Equivalent US 2006/0257470
2. L Dias el al. (1996) Pharmaceutical Research Supplement 13(9): page S-351 PDD 7475
3. Win Loung Chiou, Journal of Pharmaceutical Sciences, Vol. 60, Page 1283 (1971)
4. US 5073379

Novelty over WO 2004/032903 (hereinafter referred to as '903) or US 2006/0257470:

This document is not relevant prior art as it was published after the priority date of the present invention. The cross linked polymer present at a concentration of at least 50% in the cited art is water swellable but not water soluble in contrast to the water soluble polymer recited in the present claims and used at a concentration of 50-85%. To support the contention of crosslinked PVP being water insoluble, the Applicant relies on the following documents:

i. US 2006/0257470, paragraph [0019] (Annexure 31A)
ii. page 4 of "Insoluble Kollidon grades, BASF, 2006" (Annexure 32);
iii. pages 3-4 of "Polyvinylpyrrolidone Excipients for Pharmaceuticals, by V. Buhler ; Springer-Verlag, Berlin, Germany, 2005" (Annexure 33);
iv. page 2 of "Ac-Di-Sol, FMC, 1996"(Annexure 34)

The function of the polymer in `903 is different from that of the present invention. Cross linked PVP of `903 aids in disintegration while the polymer in the present invention provides a matrix in which ritonavir is dispersed. The dispersion converts ritonavir to a high-energy state thereby facilitating the dissolution of the drug. Said citation does not disclose a solid dispersion of ritonavir - a BCS class IV drug. Yellow white extrudate produced in Example 6 is not a single phase system with uniformly dispersed drug and surfactant. Color signifies turbidity and phase separation. The citation does not disclose any solid dispersion containing both ritonavir and lopinavir. The citation does not teach or suggest the unexpected effect of surfactants with HLB 4-10 on the bioavailability of co-formulated ritonavir and lopinavir. Nor does the citation use such a surfactant to co-formulate ritonavir and lopinavir. Example 3 teaches away from the present invention. The example uses copovidone and Cremophor RH-40 to formulate lopinavir. However, the formulated solid form does not even dissolve in water until after several hours.

Novelty over L Dias et aL (1996) Pharmaceutical Research Supplement 13(9): page S-351 PDD 7475 (Exhibit 2):

Does not teach solid formulation of lopinavir, not to mention a co-formulation of ritonavir and lopinavir. Therefore, Dias et al. does not teach each and every element of the claimed invention - not anticipatory. If ritonavir and lopinavir were formulated according to Dias et at, it would likely have poor bioavailability, like the Comparative Example, due to lack of proper surfactants. Dias et al. fails to teach which kind of surfactants will work effectively with solid formulations that contain ritonavir and lopinavir. The citation does not teach or suggest the unexpected effect of surfactants with HLB 4-10 on the bioavailability of co-formulated ritonavir and lopinavir. Significance of the right surfactant is demonstrated by Comparative Example and Examples 1-3 of the present invention. Examples 2 and 3 use span 20 (HLB 7.6-9.6) as a surfactant and show an 18 fold higher bioavailability of ritonavir and 6.8 fold higher bioavailability of lopinavir as compared to example 1 (Cremophor RI-I 40 surfactant HLB 12-14), and a 21 fold higher bioavailability of ritonavir and 11 fold higher bioavailability of lopinavir as compared to the comparative example (no surfactant). Prior to the present invention the effect of a surfactant with HLB 4-10 might have on the bioavailability of a Class IV compound in an amorphous polymer matrix could not have been predicted as also the reasonable expectation of success by using surfactants with HLB 4-10. Thus the present invention is novel over Dias ei al

Novelty over Win Loung Chiou, Journal of Pharmaceutical Sciences, Vol. 60, Page 1283 (1971) and US 5073379:

CONTENTION: Chiou renders the process to make pharmaceutical compositions of the present invention lacking in novelty

1. Chiou refers to solid dispersion process.
2. Opponent has missed out on the novelty of the invention which resides in the novel pharmaceutical composition of ritonavir and lopinavir, which Chiou fails to teach or suggest. In addition, the citation does not teach or suggest the unexpected effect of surfactants with HLB 4-10 on the bioavailability of coformulated ritonavir and lopinavir.
3. Infact, Chiou on page 1282 clearly states: new field of pharmaceutical technique and

principles will play an important role in increasing dissolution, absorption, and therapeutic efficacy of drags in f rtrrre dosage forms. Therefore a thorough understanding of its fast release principles, methods of preparation, selection of suitable carriers, determination of physical properties, limitations and disadvantages will be essential in the practical and effective application of this approach" " .... solid dispersion technique may have numerous pharmaceutical applications which remain to be further explored".

4. US 5073379 merely refers to solid dispersion technique and melt extrusion technology.
5. US 5073379 is irrelevant as the novelty of the process claims lies in the application of solid dispersion technology to the production of a novel formulation of ritonavir and lopinavir, which Exhibit 4 fails to teach or suggest (Para 7-8 of Dr. Rosenberg's II Declaration- in reply statement to Matrix Opposition).
6. None of the aforementioned prior art teaches the addition of surfactants with HLB 4-10 to a solid pharmaceutical composition containing ritonavir and lopinavir to improve the bioavailability of ritonavir and lopinavir (unexpected effect of proper surfactants on the bioavailability of ritonavir and lopinavir).

3.2 The Applicant's submission for the second ground of opposition i.e Lack of Inventive

Step and Obviousness as under section [25(1)(e)] of the Act:

Citations in the four oppositions:

1. BASF, ExAct - Excipients and Actives for Pbarma, No. 2, July 1999 (BASF)
2. WO 97/44014
3. WO 01 /22938
4. WO 00/74677
5. WO 01 /34119
6. US 4769236
7. Applicant's letter to EPO of 15th March 2004 with respect to the prosecution of WO 01 /34119 (Exhibit 10)
8. ISR for WO 01 /34119
9. Jorg Breitenbach, Melt Extrusion : From Process To Drug Delivery Technology, European Journal Of Pharmaceutics And Biopharmaceutics, 54, 2002, 107-117
10. Abu. T.M. Serajuddin, Solid Dispersion Of Poorly Water-Soluble Drugs: Early Promises, Subsequent Problems, And Recent Breakthroughs, Journal Of Pharmaceutical Sciences, Vol 88, No. 10, October 1999 (Published On Web 27/8/1999)

11. Owen Corrigan et. al., Surfactants in Pharmaceutical Products And Systems, Encyclopedia Of Pharmaceutical Technology, Vol 14, 2002, At Page 2649
12. US 6599528
13. US 5834472
14. US 5776495
15. US 2003/0021840
16. CA 2408915
17. Journal of Pharmaceutical Sciences, September 1971, Volume 60 Number 9
18. Encylopedia of pharmaceuticaltechnology [2002) by Martel Dekker page 2649

The ground of obviousness is denied in its entirety as none of the cited documents obviates the present invention due to following reasons:

- None of the references teaches or suggests the unexpected effect of surfactants, having HLB 4-10 on the bioavailability of ritonavir and lopinavir in solid dispersion. It was against common sense to use a less soluble surfactant (e.g., surfactants having HLB of below 10) to improve the bioavailability of a poorly soluble drug in solid dosage forms.
- None of the references teaches or suggests the use of surfactants having HLB 4-10 to improve the bioavailability of co-formulated ritonavir and lopinavir.
- None of the references teaches or suggests the unexpected in vivo interaction between ritonavir and lopinavir that make co-formulation of the two drugs exceedingly difficult. None of the references even recognizes the difficulty of co-formulating ritonavir and lopinavir in an amorphous solid dispersion.
- None of the references teaches or suggests how to co-formulate ritonavair and lopinavir in an amorphous solid dispersion.
- Class IV compounds are among the most difficult to be formulated into solid dosage forms, partly because membrane permeability, as compared to solubility, is less likely to be improved by formulation.
- Ritonavir, is a Class IV compound having low aqueous solubility and low membrane permeability.
- There is no general formulation for Class IV compounds, and extensive research must be conducted for each Class IV compound in order to identify formulations that can provide adequate bioavailability.
- Present invention is the result of years of intensive research as the first attempts to

use solid dispersion technologies to improve ritonavir/lopinavir bioavailability had failed, as exemplified in the comparative examples of the present application.

- Further, even the traditional trial-and-error technique is time-consuming and labour-intensive for a class-IV compound and often fails to provide a desired formulation.
- Originally solid dispersion technology was designed to improve solubility and/or dissolution rates but not membrane permeability according to the Noyes-Whitney equation, one of ordinary skilled in the art would not have expected that further modifications of the solid dispersion technology would lead to improved bioavailability of co-formulated ritonavir and lopinavir in light of the failure demonstrated by the comparative example.
- Though the use of PVP in pharmaceutical formulations are disclosed but the use of PVP as the principle carrier to form a drug-supporting matrix for the enhancement of bioavailability of co-formulated ritonavir and lopinavir is neither disclosed nor is suggestive, in any of the cited document.
- Further, as demonstrated in the Comparative Example of the present application, a PVP matrix would not work for ritonavir and lopinavir due to lack of proper surfactants.
- Further, those skilled in the art would have avoided using surfactant-containing solid dispersions as it would impose a stability risk to the product.
- Particularly, it was totally unexpected that surfactants with HLB values of from about 4 to about 10 can significantly improve the bioavailability of ritonavir and lopinavir in an amorphous polymer matrix.

3.3 The Applicant's submission for the third ground of opposition i.e. Not an invention within the meaning of the Act as under section [25(1)(f)] of the act:

3.3.1 Section 3(d):

The applicant submits that the present invention is NOT A MERE DISCOVERY, NOT A KNOWN SUBSTANCE and NOT A NEW FORM OF SOFT GEL FORMULATION. With respect to the Opponent's allegation of lack of data on efficacy in the application it is respectfully submitted that the law does not require that data on efficacy be included in the specification itself and that such data can be presented to the Controller during the course of

prosecution of the application. The Applicant has provided sufficient evidence and data to support their contention on efficacy. For all the reasons stated above it is submitted that the present invention clearly falls outside the purview of section 3(d).

3.3.1 Section 3(e):

The Applicant submits as follows with respect to the objections raised on the ground of section 3(e). The present invention provides a synergistic combination of different elements (namely Ritonavir, lopinavir; water soluble polymer and surfactant with HLB 4-10), which results in a product possessing significantly different properties.

3.4 The Applicant's submission for the fourth ground of Inability to submit information foreign filing under section 8 as under section 25(1)(h) of the Patents Act is as follows:

The Opponent contended that the Applicant has failed to keep the Patent Office updated regarding the status of corresponding applications filed in countries outside India. It is submitted that the Applicant has kept the Patent Office informed regarding the foreign filing information from time to time. The Applicant has filed with the Patent Office the search and examination reports issued by the US and EP patent offices and has also submitted information in Form 3 vide' their letters dated 1st February 2008, 7th July 2008 and 22nd January 2010.

3.5 The Applicant's submission for the fifth ground of insufficiency as under section 25(1)(g)] of the Act:

The Applicant submits that a patent application does not necessarily require examples though examples can often assist in showing patentability. A broad range cannot become a limitation to patentability as long as the invention can be worked within that range. It is submitted that examples that examples are merely illustrative of the invention. There is no restriction as to the type of examples that can be included in a specification. Examples can also be comparative in nature. Therefore it is baseless to argue that the present invention entails examples which cover surfactants having a higher HLB value that the surfactants claimed.

3.6 The applicants submission for the sixth ground of opposition i.e. Application Not Made With In 12 Months From The Date Of Disclosure In Convention Country as under section [25(1)(i)] of the Act (in view of application number WO 2004/032903):

The arguments presented by the Opponent on this ground are vague and are vehemently denied as has been stated earlier WO 2004/032903 does not describe solid dispersion of Ritonavir and lopinavir and the inclusion of 50 -85% water soluble polymer. Therefore the disclosure made by said application is completely different from the present invention. Hence, WO 2004/032903 should not be considered the first disclosure of the present invention. Accordingly section 25 (1) (i) does not apply.

4. Findings of the proceedings:

Considering all the four representations by way of Opposition u/s 25(1) and Applicant's reply statements with affidavits and after dealing with interlocutory petitions in different matters the summary of my findings are as following:

4.1 NOVELTY:

The claim 1 is for a pharmaceutical composition which comprises a solid dispersion of ritonavir and lopinavir in one or more pharmaceutically acceptable water-soluble polymers and one or more pharmaceutically acceptable surfactants, and said one or more pharmaceutically acceptable water-soluble polymers have a Tg of at least about 50°C, and said composition comprises from about 50 to about 85 % by weight of the total composition of said one or more pharmaceutically acceptable water-soluble polymers, and at least one of said one or more pharmaceutically acceptable surfactants has an HLB value of from about 4 to 10.

The independent claim 19 claiming for the method of preparing a pharmaceutical composition as claimed in claim 1, comprising: preparing a homogeneous 'melt comprising said ritonavir and lopinavir, said one or more pharmaceutically acceptable water-soluble polymers and said one or more pharmaceutically acceptable surfactants; and allowing the melt to solidify to obtain a solid dispersion product..

The independent product-by-process claim 22 claiming for a pharmaceutical composition comprising a solid dispersion of ritonavir and lopinavir in one or more pharmaceutically acceptable water-soluble polymers and one or more pharmaceutically acceptable surfactants when prepared by a process as claimed in claim 19. .

None of the prior art documents cited specifically disclose the pharmaceutical composition with ritonavir, lopinavir, 50-85% water soluble polymer having Tg above 50°C and surfactant of HLB value 4-10, **therefore claim 1 is held novel over the cited prior art. The independent claim 19 for preparing a pharmaceutical composition of claim 1 is held novel in view of preparing a novel product.**

The claim 22 is for a product by a process claimed in claim 19 (which specifically claims a process for preparing a pharmaceutical composition as claimed in claim 1), then again claiming for a composition of ritonavir, lopinavir, and water-soluble polymer and surfactant appears to be redundant in view of claim 1, however in the absence of the limitations of HLB values given in claim 1, the subject matter of claim 22 is already disclosed in the cited prior art **WO 01/34119 A2 ('119)** [Exhibit 8 of Opposition-1, Exhibit 3 of Opposition-3 and Exhibit 6 of Opposition-4] as following:

> *A pharmaceutical composition comprising a solid dispersion of a pharmaceutical compound, a water soluble carrier, and a crystallization inhibitor selected from the group consisting of* ***polyvinylpyrrolidone (PVP)*** *and hydroxypropylcellulose (HPMC)* [Claim 1].
>
> *The composition of Claim 1 wherein said pharmaceutical compound is an HIV protease inhibitor dissolved in an organic solvent* [Claim 3].
>
> *The composition of Claim 3 wherein said HIV protease inhibitor is a combination of 2S, 3S, 5S)5 (N. (N ((NmethylN ((2isopropyl4 thiazolyl) methyl) amino) carbonyl) Lvalinyl) amino2 (N ((5 thiazolyl) methoxycarbonyl)amino)amino1, 6diphenyl3 hydroxyhexane* ***(ritonavir)*** *and (2S, 3S, 5S)2 (2, 6 Dimethylphenoxyacetyl) amino3hydroxy5 [2S (ltetrahydro pyrimid2onyl)3methyl butanoyl amino1, 6diphenylhexane* ***(ABT-378)*** [Claim 7].
>
> *The composition of Claim 1 further comprising an additive or a mixture of additives independently selected from the group consisting of* ***pharmaceutically acceptable surfactants*** *and antioxidants* [claim 10].

Therefore, the product claimed in **claim 22 is not new in view of above disclosures in '119.**

4.2 INVENTIVE STEP:

The cited prior art **WO 01/34119 A2 ('119)** [Exhibit 8 of Opposition-1, Exhibit 3 of Opposition-3 and Exhibit 6 of Opposition-4] teaches and discloses the following:

For a variety of reasons, including patient compliance and taste masking, a solid dosage form, such as a capsule or tablet, is usually preferred over a liquid dosage form. However, oral solid dosage forms of a drug generally provide a lower bioavailability than oral solutions of the drug. One goal of the development of a suitable ***solid dosage form is to obtain a bioavailability of the drug*** *that is as close as possible to the ideal bioavailability demonstrated by the oral aqueous solution formulation of the drug* [Lines 8-17, page2].

An alternative ***dosage form is a solid dispersion.*** *The term solid dispersion refers to the dispersion of one or more active ingredients in an inert carrier or matrix at solid state prepared by the melting (or fusion), solvent, or melting-solvent methods. (Chiou and Riegelman, Journal of Pharmaceutical Sciences, 60,1281 (1971)). The dispersion of a drug or drugs in a solid diluent by mechanical mixing is not included in this category. Solid dispersions may also be called solid-state dispersions* [Lines 18-24, page 2 and Lines 1-2, page 3].

A range of ***1%-95% (w/w) of PVP*** *can be employed, with a range of 1W-15k (w/w) being preferred* [Lines 5 and 6, Page 11].

A pharmaceutical composition comprising a solid dispersion of a pharmaceutical compound, a water soluble carrier, and a crystallization inhibitor selected from the group consisting of ***polyvinylpyrrolidone (PVP)*** *and hydroxypropylcellulose (HPMC)* [Claim 1].

The composition of Claim 1 wherein said pharmaceutical compound is an HIV protease inhibitor dissolved in an organic solvent [Claim 3].

The composition of Claim 3 wherein said HIV protease inhibitor is a combination of 2S, 3S, 5S)5 (N (N ((NmethylN ((2isopropyl4 thiazolyl) methyl) amino) carbonyl) Lvalinyl) amino2 (N ((5 thiazolyl) methoxycarbonyl)amino)amino1, 6diphenyl3

hydroxyhexane ***(ritonavir)*** *and (2S, 3S, 5S)2 (2, 6 Dimethylphenoxyacetyl) amino3hydroxy5 [2S (ltetrahydro pyrimid2onyl)3methyl butanoyl amino1, 6diphenylhexane* ***(ABT3-78)*** [Claim 7].

The composition of Claim 1 further comprising an additive or a mixture of additives independently selected from the group consisting of ***pharmaceutically acceptable surfactants*** *and antioxidants* [claim 10].

It is clear from the above teachings that the object of the '119 is same as that of the present invention and the three essential components of a pharmaceutical composition of instant invention namely HIV inhibitors such as ritonavir, lopinavir (ABT-378) and water soluble polymer having Tg of at least about 50°C in a solid dispersion is disclosed. Although there is a disclosure in '119 that the composition can further comprise additives such as pharmaceutically acceptable surfactants but it does not specifically teach the surfactant. Thus the main difference of the instant invention from the prior art lies in the selection of surfactants with HLB value from 4-10. In view of above, the alleged invention resides in the selection of a suitable surfactant. Now for determining the inventive step, the question to be answered is whether the selection of surfactants of HLB values from 4-10, with ritonavir, lopinavir and 50-85% water soluble polymer in a solid dispersion is obvious to a person skilled in the art in view of the disclosures and teachings in cited prior art.

The cited document **US 6599528 B1 ('528)** [exhibit 1 of Opposition-3] teaches and discloses the following:

The present invention relates to mechanically stable pharmaceutical presentations for oral administration, comprising in addition to one or more active ingredients and at least one melt-processable matrix-forming excipient more than 10 and up to 40% by weight of a surface-active substance with an ***HLB of from 2 to 18,*** *which is liquid at 20° C. or has a drop point in the range from 20 to 50° C* [Lines 9-15, Column 1].

It is an object of the present invention to find mechanically stable ***solid formulations for oral use*** *which can be used in particular for rapid and nevertheless long-lasting solubilization of active ingredients of low solubility after they have been liberated from the drug form* [Lines 30-34, Column 2].

Particularly suitable active ingredients are immunosuppressants, ***protease inhibitors,*** *reverse transcriptase inhibitors, cytostatics or antimycotics, in addition to CNS-active substances or dihydropyrimidine derivatives* [Lines 47-50, Column 2].

Suitable and preferred surface-active substances are low molecular weight substances which have an HLB (HLB—hydrophilic lipophilic balance) and are liquid at 20° C. or have a drop point in the range from 20° C. to 50° C., preferably up to 40° C. Preferred substances have an ***HLB of from 7 to 18,*** *particularly preferably* ***10 to 15*** [Lines 60-65, Column 2].

Pharmaceutically acceptable polymers are, in particular, homo- and copolymers of N-vinylpyrrolidone such as polyvinylpyrrolidone with Fikentscher K values of from 12 to 100, in particular K 17 to K 30, or copolymers with vinyl carboxylates such as vinyl acetate or vinyl propionate, for example ***copovidone*** *(VP/VAc-60/40)* [Lines 29-34, Column 3].

The resulting drug forms comprise the active ingredient embedded amorphously. The preferred result is solid ***dispersions in which the active ingredient is in the form of a molecular dispersion****. The drug forms according to the invention make it possible for even active ingredients of low solubility to be sufficiently solubilized and stably dispersed in aqueous medium* [Lines 52-58, Column 4].

The teachings in '528 highlight the importance of selection of surfactant for preparation of solid formulations of protease inhibitors for oral use based on HLB value. There is a disclosure in '528 that the solid formulation can be prepared with suitable active ingredients such as protease inhibitors and water soluble polymer such as copovidone along with surfactant having HLB value from 2 to 18. Thus it is clear that the person skilled in the art can derive the motivation for the selection of suitable HLB value surfactant for preparing the solid formulations with protease inhibitor. Therefore, it appears that the selection of surfactant of particular HLB value 4 to 10 for preparing the solid dispersion formulations can be achieved through routine experimentation by combining the disclosures of cited document '528 with the disclosure of cited document '119.

The other cited prior art documents also provide some insight into the formulations comprising solid dispersion of different therapeutic agents with water soluble polymers and surfactants.

During hearing the Applicant's agent has mainly argued that the inventiveness of the composition lies in selection of surfactant with HLB value 4 to 10. The Applicant argued that "None of the references teaches or suggests the unexpected effect of surfactants, having HLB 4-10 on the bioavailability of ritonavir and lopinavir in solid dispersion. It was against common sense to use a less soluble surfactant (e.g., surfactants having HLB of below 10) to improve the bioavailability of a poorly soluble drug in solid dosage forms". As discussed above, the prior art '528 clearly teaches the selection of surfactant with HLB values from 2 to 18 for stable solid formulations for oral use and person skilled in the art can easily select the suitable surfactant for preparing solid formulations by routine experimentation.

The Applicant also argued that "the co-formulation of class IV compound i.e ritonavir with lopinavir in an amorphous solid dispersion is exceedingly difficult". However, the combination of ritonavir and lopinavir in solid dispersion formulation is not new as the prior art document '119 discloses that in solid dispersion formulations.

Now on considering the Applicant's argument that "particularly, it was totally unexpected that, surfactants with HLB values of from about 4 to about 10 can significantly improve the bioavailability of ritonavir and lopinavir in an amorphous polymer matrix"; and upon perusal of comparative example and example 1 given in the specification, it is clear that the use of surfactant improves the bioavailability of ritonavir and lopinavir (also supported by prior art),however when example 1 is compared with the subsequent example 2, where Cremophor RH40 (HLB value 14 - 16) and Span 20 (HLB value 7.6- 9.6) have been used respectively, the effect of HLB values on bioavailability is not clearly reflected as the compositions are not prepared by the same method and the amounts of ritonavir and lopinavir used are also different. Comparison of the examples 2 and 3 which differ only in their method of preparation show difference in bioavailability particularly for ritonavir. The example 4 which uses a mixture of Cremophor RH40 (HLB value 14-16) and Span 20 (HLB value 7.6-9.6) shows bioavailability similar to example 2. Thus the examples do not

clearly show the unexpected or surprising results with selected surfactants of HLB value from 4 to 10. Therefore, the applicant's argument fails to overcome the ground of obviousness relied upon by the opponents.

In view of the above disclosures in cited prior art documents and considering all the arguments of Applicant along with affidavits and all the Opponents, it is held that the pharmaceutical composition as claimed in claim 1 of the instant invention does not clearly involve inventive step and is obvious to a person skilled in the art. The dependent claims 2-18 further characterize the pharmaceutical compositions which do not have any feature that involves inventive step. The independent claim 19 and dependent claim 21 claiming for the method of preparing a pharmaceutical composition as claimed in claim 1 is also obvious and clearly do not involve inventive step in view of the teachings particularly in cited document '528 and also in the absence of demonstrated advantages over the prior art methods. The claim 22 is not novel and hence it is also not involving inventive step.

4.3 NOT AN INVENTION [S.25 (1) (f)]:

The subject matter of claim 22 is not new and claims 1-21do not involve inventive step as discussed in above paragraphs hence they do not constitute an invention as per section 2(1)(j) of the Act.

4.3.1 Section 3(d):

The product claimed in the instant application is a pharmaceutical composition which has been arrived at after selecting its constituents, and not a mere discovery of a new form of a known substance, hence they cannot be held as not patentable as per provisions of section 3(d) of the Act. Therefore, the Opponents ground of opposition u/s 3(d) of the Act is not tenable.

4.3.2 Section 3(e):

The product claimed in instant invention is a pharmaceutical composition and the invention lies in the selection of suitable surfactants, therefore it cannot be a mere admixture, hence the claims cannot be held as not patentable as per provisions of section 3(e) of the Act. Thus the Opponents ground of opposition u/s 3(e) of the Act is not tenable.

4.4 INSUFFICIENCY [S.25 (1) (g)]:

The complete specification sufficiently and clearly describes the pharmaceutical composition and its process of preparation with examples 1 to 7. Hence, it cannot be said that it not sufficiently and clearly describing invention. Therefore, Opponents fail to establish this ground of opposition.

4.5 NON INTIMATION OF INFORMATION UNDER SECTION 8 TO THE CONTROLLER [S. 25(1) (h)]:

The Applicant's have filed updated foreign filing details as per Section 8 of Patents Act, 1970 on 8th July 2008, 15th April 2009, 27th January 2010 and 1st July 2010 along with a petition under Rule 137 of the Patents Rules, 2003. Therefore, the Opponents opposition on this ground is not tenable.

4.6 APPLICATION NOT MADE WITHIN 12 MONTHS [25(1) (i)]:

The application is filed through national phase of PCT and it carries the valid priority from the US application as stated above and hence it cannot be said that the application is not made within 12 months. Therefore, the Opponent's ground of opposition is not tenable.

In view of my findings as above in paragraphs 4.1 to 4.3, I refuse to proceed with the application for grant of a patent.

Dated this 30th day of December 2010

(DR. RUCHI TIWARI)
D.Y. CONTROLLER OF PATENTS AND DESIGNS

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