THE PATENTS ACT, 1970

SECTION 25(1)

In the matter of:

Application No.308/DEL/2005

In the matter of a representation under section 25(1) of the Patents Act, 1970 as amended by the Patents (Amendment) Act, 2005

And

In the matter of:

The Patents Rules, 2003

Venus Remedies Limited, Chandigarh - Applicant

Akums Drugs & Pharmaceuticals, New Delhi - Opponent

Hearing held on 28th January,2014

Present:

Sh.Tuhin Subhra Singharoy	- Applicant
Sh. Rajan Ailavadi	- Agent for Opponent
Dr.Lipika Patnaik	- Examiner of Patents &Designs

ORDER

1. Venus Remedies Limited S.C.O. 39, Sector 26, Madhya Marg, Chandigarh - 160019, India filed a provisional application no. 308/DEL/2005 dated the 14th February, 2005 followed by complete specification on 7th February, 2006 through their agent M/S Dubey & Partners, New Delhi for their invention entitled "Parenteral Composition Comprising Ceftriaxone and Vancomycin for Bacterial Resistance and Process of Preparation Thereof" containing 26 claims. A request for examination of the said application was filed by their agent on 14th July,2006.This application was published under the provisions of Section 11(A) of the Patents Act,1970 as amended in 2005 (hereinafter referred as 'Act') in the Patent Journal No. 7/2006 dated 17th February,2006.

2. This application was examined by the Office and First Examination Report (FER) thereof issued on 4th June, 2010 and applicant responded to FER on 3rd August, 2010. A second Examination report was issued on 6th December, 2010 and applicant again responded on 15th February, 2011. Before proceeding to dispose of the application in accordance with the provisions hereinafter appearing and on request from applicant on 15th February, 2011 for being given an opportunity to be officially heard before any adverse order on the application is passed. Accordingly, a hearing under Section 14 of the Act was fixed on 1st July, 2011 under section 14 of the Act and this matter was heard.

3. The opponent Akums Drugs & Pharmaceuticals, 304, Mohan Place, L.S.C., Block C, Saraswati Vihar, New Delhi filed an opposition under Section 25(1) of the Act on 17th August, 2011 along with representation and written statement of opposition. The representation of opposition under Section 25(1) of the Act forwarded to the applicant on 27th January, 2012 under Rule 55(3) of the Patents Rule, 2003 as amended in 2006 (hereinafter referred as 'Rule'). Accordingly Applicant has filed the reply statement under Rule 55(4) on 23rd April, 2012.

The application has been opposed by the Opponent on the following grounds:

1.Patent application lacks inventive step as required under section 2(1)j, 2(1)ja,2(1)(I);

2. It falls within the ambit of section 3(d) and 3(e) of the Act.

The opponent mentioned that the patent application under consideration does not involve any inventive step or new product or new process or new invention. The various studies relating to the concomitant use of vancomycin and ceftriaxone are already make the part of the prior art and are also been mentioned in the specification of the impugned patent application. The same applicant has filed two applications bearing number 2411/DEL/2004 and 2510/DEU2004, for which the applicant gets the patent bearing number 236996 and 235775. Application bearing number 2411/DEL/2004 was filed on 02/12/2004 i.e. prior to the filing date of the impugned application. In

this patent application the applicant discloses the use of EDTA for stabilizing the injectable solution of ceftriaxone and sulbactam in the form of Particulate formation/precipitation inhibitor. Application bearing number 2510/DEL/2004 was filed on 17/12/2004 i.e. prior to the filing date of the impugned application. In this patent application the applicant discloses the use of L-arginine for stabilizing the injectable solution of Cefepime and Amikacin. The opponent further mentioned that the combination of Vancomycin and Ceftriaxone is clearly mentioned in the prior art and Use of either EDTA or L-arginine for stabilizing the antibiotic formulation was already mentioned in the prior art. The opponents does not supported the grounds of opposition with any prior art in the representation of Opposition under Section 25(1).

4. Applicant responded to the opponent's representation that Contention made in this representation is misleading. There is no specific ground in the representation that could be made out for a valid pre-grant representation. The applicant responded that the subject patent application has the date of filing as 14/02/2005 and the mentioned references 2411/DEL/2004 and 2510/DEL/2004 were published on 3/3/2006 and 30/12/2005 after the filing of the subject patent application. The subject invention claimed relates to a synergistic pharmaceutical composition for treatment of non-ocular infective conditions with drug resistant bacterium (MRSA- Methicillin resistant Staphylococcus aureus, some known as SUPER BUG) and for parenteral administration, comprising: i) Ceftriaxone and ii) Vancomycin in particular weight ratio and iii) a chemical vector , wherein the chemical vector is L- arginine, EDTA , sodium bicarbonate or combination and the chemical vector is preferably L-arginine, sodium bicarbonate. The claimed invention has made the incompatible antibiotics Ceftriaxone and Vancomycin compatible by use of the said one or more chemical vector along with additional therapeutic benefit of overcoming problem of MRSA infection and cure. The applicant further added that the composition of the current invention is essentially directed to overcome resistance caused by Methicillin resistant Staphylococcus aureus bacterial strains (para 3, page 12). The invention claims a composition that uses Ceftriaxone , Vancomycin , chemical vector in the form of L-arginine and EDTA disodium all in the form of a single unit dose in dry powder form for use upon reconstitution with a suitable solvent. Before the date of this application, the state of the art described only the concomitant use of the antibiotics used in the present invention. This concomitant use was the problem of the prior art and the claimed invention solves that problem by providing the two antibiotic in a single fixed unit dose which goes strongly against the teaching of the state of the art. Applicant has found that the claimed composition, which includes two antibiotic agents, advantageously overcomes the bacterial

resistance experienced by monotherapy with individual antibiotic agents. As claimed, one of the antibiotic agents is a glycopeptide, vancomycin and glycopeptides provide a bactericidal action against a variety of gram positive bacteria. The other antibiotic agent is a cephalosporin, and cephalosporins exhibit a high degree of stability in the presence of beta-lactamases of both gram positive and gram negative bacteria, but both are incompatible with each other & degrade. In current invention, the inventor has innovatively selected chemical vectors that bring compatibility to the otherwise incompatible antibiotics. The applicant also submitted that there is not a single prior art that could anticipate use of Ceftriaxone & Vancomycin in combination with other antibiotics in a single injection resulting from a single unit dosage form including the combination of antibiotics. While the claimed invention relates to bow to overcome resistance caused by Methicillin resistant Staphylococcus aureus bacterial strains, the invention goes not just against conventional wisdom as to combined use of Ceftriaxone, Vancomycin, but also against the clear warning of the innovator of the Ceftriaxone (Roche-Rocephin®) in their prescribing information that Ceftriaxone should not be co-administered with Vancomycin. The use of mentioned chemical vector makes the two otherwise chemically incompatible antibiotics compatible, and hence allows them to be administered in a single injection rather than as two separate injections (i.e., a separate injection for each antibiotic). The agent also helps to form a single dry powder ready to reconstitute before injection, where the resulting solution is free of precipitates, and thus can be administered intravenously. The claimed combination therapy is directed to a treatment regimen wherein the two antibacterial agents are administered together in a single injection in such a way as to provide a beneficial effect from co-action of these therapeutic agents. Such beneficial effects include pharmacokinetic or pharmacodynamic co-action of the therapeutic agents. Combination therapy, for example, results in lowering the dosage of one or both agents than would normally be administered during monotherapy, thus decreasing risk or incidence of adverse effects associated with higher doses. Combination therapy also results in increased therapeutic effect at the normal dose of each agent in monotherapy. Furthermore, combination therapy maximizes the therapeutic effect, efficacy and safety of the antibiotic used (paragraph 2, page 17). The claimed composition prevents the conjugation of the microbes and thus prevent spread of infection. When administered intravenously, the claimed combination therapy provides enhanced treatment options as compared to administration of either antibacterial agent alone. Combination therapy according to the invention provides effective treatment of an infective condition caused by bacteria, and reduces the time required to resolve the infective condition, particularly multi-drug-resistant varieties such

as MRSA and Staphylococcal species. Administration of the claimed compositions also reduces the risk of developing such infective conditions. The combination therapy can be administered prior to or following surgery or hospital admission to prevent or reduce the risk of a subject developing an infection, such as those caused by MRSA and Staphylococcal species (paragraph 3-5, page 17).

5. Before proceeding to dispose of the application in accordance with the provisions hereinafter appearing, and on request from applicant and opponent for being given an opportunity to be officially heard by the Controller before any order on the application is passed .Accordingly, a hearing was fixed on 4th December, 2012 but the opponent requested for the adjournment of the hearing on 30th November, 2012. The hearing was again re-fixed on 28th January, 2014 and this matter was heard.

6. The Opponent submitted during hearing and written submissions on 14/2/2014 that the applicants themselves in their description, at various pages, admittedly state the already known use and synergistic effect of the combination of ceftriaxone and vancomycin in treatment of antibacterial ailments. There exists no terms such as a "chemical vector" in pharmaceutical chemistry. In fact a deeper analysis of the complete specification, leads to the fact that L-arginine was being used as the solublizing agent which the applicant term as chemical vector. L-arginine or cheleating agents are known for and already in use as solublizing agents to stabilize the turbidity. More particularly in dry powder form of medicine which have to be reconstituted for administration be it oral administration or in the form of injections. Cefepime, is already known to be administered with the solublizing agent - L-arginine. The chemical vector disclosed by the applicant in complete specification which includes L- Arginine, EDTA or its salts thereof, sodium bicarbonate or combination thereof are mere excipients. It is submitted by the opponent that the L- Arginine was already use as solublizer during intravenous use of ceftazidime. It is also submitted that sodium bicarbonate was also being used as buffer in intravenous use of Cephalotin.

The opponent reproduce a paragraph from article "Product development issues of Powders for injection" by Arvind K. Bansal published in Pharmaceutical Technology, March 2002, which shows that L- Arginine and sodium bicarbonate are being used as excipients for powder for injections. The corresponding US Patent [US 7960337], claiming priority from the Indian Application 308/DEL/2005, there is no reference to any such term as "Chemical Vector" in the claims. It is further submitted that the applicants have opined that the composition advantageously overcomes the bacteria resistance that is experienced by the monotherapy (page 13 of complete

specification). But the synergistic effect of multiple antibacterial agents for prevention and treatment of a variety of infectious diseases and that an additive effect is observed when combinations of ceftriaxone plus vancomycin were studied at sub inhibitory concentrations are admittedly known as described by the Applicants in the background art of the description. The combination therapy as being proclaimed by them has synergistic effect over and above the conventional treatment therapy. The results of the study conducted and reported by Desbiolles et. al. in 2001 where they very categorically mention that the synergistic parameter i.e. Fractional maximal effect (FME) for the combination of VAN-CRO was 1.35 with VAN. The complete specification does not provide the details of the study, which resulted in the findings of the so-called chemical vector. The applicant has nowhere mentioned in the specification as to how the chemical vector enhances the compatibility of two non- compatible antibiotics. The applicant has mentioned about the combination therapy in the specification stating that it helps the dosage and time reduction.

The claimed composition lacks efficacy and is mere affirmation of background art that vancomycin and ceftriaoxine when taken together show synergism and superior to individual mono-therapy. The chemical vector does not enhance the efficacy and does nowhere contribute to synergism.

It is submitted that of the claimed invention i.e. the pharmaceutical composition as combination of ceftriaxone and vancomycin – the use of combination therapy of ceftriaxone and vancomycin is well known, being practiced and also documented as matter of fact. The applicants have time and again emphasised that the combination being produced by them results in lower dosage and time reduction for treatment. However, the point of fact is that all this is being proclaimed on very hypothetical terms and there has been no evidence as to the efficacy of dosage vis-a-vis the combinational therapy already known. It is not surprising to note that in the tests submitted to the CTRI, the applicants have stated that the tests were conducted on their combined dosage vis-a-vis the monotherapy of vancomycin. Now it is well known that combinational treatment of CRO and VCO is better, synergistic and effective over the monotherapy. It is also known to use L-arginine and EDTA as solubilising agents for reducing turbidity of powder form injections which require reconstitution before for being used.

The applicants in their reply statement have asserted that their prior applications 2411/DEL/2004 and 2510/DEL/2004 though being filed prior but where published later than the filing date of the present application 308/DEL/2005. It is to be noted that the said prior applications do disclose the use of EDTA and L-arginine as solublizing agents in 2411/DEL/2004 and

2510/DEL/2004. These two patent applications clearly state the use of the EDTA and L-arginine as solubizing and stabilizing agent which other-wise is also well documented in the many other prior published research papers.

Paragraph 17 of the Novartis Judgement, Hon'ble Supreme Court refers to the IPAB statement that India is having higher standard of inventive Step by introducing Section 3(d).

7. The applicant submitted before the hearing and explained the first independent claim Claim 1 to which all other claims either depends directly or incorporate the limitation of Claim 1 as:

1. A pharmaceutical composition for non-ocular infective conditions with drug resistant bacterium for parenteral administration, said pharmaceutical composition comprising:

a first antibacterial agent, wherein said first anti bacterial agent is Vancomycin or pharmaceutically acceptable salt thereof, preferably Vancomycin hydrochloride;

a second antibacterial agent, wherein said second antibacterial agent is Ceftriaxone or pharmaceutically acceptable salt thereof, preferably Ceftriaxone Sodium;

a chemical vector ;wherein said chemical vector is L- arginine, EDTA or its salts thereof, sodium bicarbonate or combination thereof ;and

wherein said chemical vector is preferably L-arginine, sodium bicarbonate present in a weight range of 35% to 75% of combined weight of said first and said second antibacterial agent and wherein with EDTA in the range of 10% to 40% of combined weight of the said composition;

wherein said first antibacterial agent and said second antibacterial agents are present in a weight ratio of any of 1:4 to 4:1, preferably 1:3 to 3:1 more preferably 1:2 to 2:1;

wherein said first antibacterial agent and said second antibacterial agent are present in sterile dry powder form;

wherein said pharmaceutical composition is reconstituted with a compatible pharmaceutically acceptable solvent prior to parenteral administration; and

wherein pH of said pharmaceutical composition after reconstitution is in the range of 7-9.

The claims are directed to a single unit combinations of two incompatible antibiotics with suitable chemical vectors, in a composition suitable for injection or in a dry powder form, that can be reconstituted for injection without precipitation or degradation of any of the antibiotics. Applicant has found that the claimed composition, which includes two antibiotic agents, surprisingly overcomes the bacterial resistance experienced by monotherapy (individual antibiotic agent). One of the antibiotic agents is a glycopeptide (vancomycin) which provides a bactericidal action against a variety of gram positive bacteria. The other antibiotic agent is a

cephalosporin, and cephalosporins exhibit a high degree of stability in the presence of beta- lactamases of both gram positive and gram negative bacteria (Reference: page 13, last para of the specification and page 14, first para). The claimed single unit formulation is directed to a treatment regimen wherein the two mutually incompatible antibacterial agents are made compatible and can be administered together in a single injection into provide a surprising synergistic effect that was not possible from the from co-administration of these antibiotic agents . The single unit combination therapy efficaciously fights microbial resistance problems such as multi-drug resistant varieties including MRSA, VRSA and Staphylococcal species (Reference: Table 1, page 19 of the specification) which is not possible with individual administration of these antibiotics alone or one after the other. Administration of the claimed compositions also reduce the risk of developing such infective conditions particularly caused by multi drug resistant bacteria such as MRSA. The surprising beneficial effects do not end with the above mentioned pharmacokinetic or pharmacodynamic co-action of the therapeutic agents, rather the combination therapy results in lowering of the dosage of one or both of the individual drugs than would normally be administered during monotherapy, thus decreasing risk or incidence of adverse effects associated with higher doses and thus makes the claimed single unit combination more economically significant and cost effective. The single unit combination therapy is made possible by including compatibility stabilizing agents, such as L-arginine, EDTA and Na2C03. The agents make the two otherwise chemically incompatible antibiotics compatible, and hence allow them to be administered in a single injection rather than as two separate injections. The compatibility of stabilizing agent also help to form a ready to use injection, which is free of precipitates, and thus can be administered intravenously. The single injection of instantly claimed invention having two known antibacterial agents and compatibility of stabilizing agents jointly make formulation active against multiple drug resistant bacteria which is not possible by any of the individual component of invention alone.

The single unit combination therapy as claimed instantly is entirely different from the prior art wherein combined use of the two antibiotic was possible only through contralateral forearms as separate injections administered sequentially or simultaneously, owing to their incompatibility. This sequential or simultaneous administration of the two drugs Ceftriaxone and Vancomycin in separate arms was practiced in the art for the fact that both the antibiotics forms precipitation and/ or degrade each other when combined and thus can not be used as parenteral formulation either as a single unit dose or be administered in a single arm one after

another. Single unit use of Vancomycin and Ceftriaxone together in an injection was not known and single unit use as instantly claimed is not same as combined use reported in the art. The opponent mentioned at page 3 of the representation that "concomitant use of vancomycin and ceftriaxone are already make the prior art''. The applicant mentioned the same in the background section of the specification. However, what the opponent failed to differentiate between is that concomitant use of the Ceftriaxone, Vancomycin as reported in the prior art and single unit as parenteral dosage form of Ceftriaxone, Vancomycin along with compatibility / stabilizing agents as claimed instantly are completely different. The prior art mentions combined use of the two antibiotic because it was required medically but owing to incompatibility, the antibiotics could not be combined together and hence concomitant use represent administration of two antibiotics in contralateral forearms as separate injections administered sequentially or simultaneously. Thus single unit use of Ceftriaxone and ,Vancomycin in a compatible manner without resulting a degradation of either of the drug or precipitation of the drug as claimed instantly was completely unknown to the prior art.

Secondly-Single unit use of Ceftriaxone and Vancomycin was not known for effectiveness in microbial resistance - Combined use was done to get additive effect of combination to the extent possible, owing to degradation of antibiotics when combined, in routine infections and does not speak about treatment of drug resistance bacteria unlike the presently claimed invention that surprisingly breaks bacterial resistance. Single unit use of the Ceftriaxone and Vancomycin for treatment of microbial resistance was unknown completely in the art and represents surprising synergy of not only two antibiotics but the combination of all components of the formulation as a whole, as instantly claimed.

The opponent allegedly mentions at page 3 of the per-grant representation that EDTA was known from publication of 2411/DEL/2004 for stabilization of Ceftriaxone and Sulbactam (a betalactamase inhibitor class, entirely different from Vancomycin of class glycopeptide antibiotics). However, the opponent failed to recognize that this document became prior art only on 03/03/2006 much after filing of the presently claimed invention (14/12/2005). Furthermore, this prior art failed to contemplate the problem of incompatibility between Ceftriaxone and Vancomycin as identified in the presently claimed invention, let alone solving it. Therefore, EDTA was not known for the purpose of arriving at the presently claimed invention at the date when present application was filed. L-arginine was not known as chemical vector from the cited art before filing of the instantly claimed invention, let alone as stabilizer of Ceftriaoxone and

Vancomycin solution, the opponent allegedly mentions at original page 3 per-grant representation that L-arginine was known to stabilize solution of cefepime and amikacin (aminoglycoside antibiotic , entirely different from Vancomycin class) after the publication of 2510/DEL/2004. However, the opponent failed to recognize that this document became prior art only on 30/12/2005 much after filing of the presently claimed invention (14/ 12/2005). Furthermore, this prior art failed to contemplate the problem of incompatibility between Ceftriaxone and Vancomycin as identified in the presently claimed invention, let alone solving it. L-arginine was not known for the purpose of arriving at the presently claimed invention at the date when present invention was filed. The opponent failed to recognize the fact that Na2C03 is one of the claimed feature of the instantly claimed invention and thus failed to give any basis and thus admitted that Na2C03 was not known as chemical vector that can stabilize Ceftriaxone and Vancomycin in solution.

Roche (the company marketing ceftriaxone) provides prescribing information which states, in no uncertain terms, that Ceftriaxone is incompatible with Vancomycin and cannot be present in admixture with vancomycin. Ceftriaxone is marketed by Roche(innovator of ceftriaxone) under the name Rocephin®. The prescribing information for Rocephin®. Page 20 of the prescribing information states that "*Vancomycin, amsacrine, aminoglycosides, and fluconazole are physically incompatible with ceftriaxone in admixtures. When any of these drugs are to be administered concomitantly with ceftriaxone by intermittent intravenous infusion, it is recommended that they be given sequentially, with thorough flushing of the intravenous lines (with one of the compatible fluids) between the administrations. Do not use diluents containing calcium, such as Ringer's solution or Hartmann's solution, to reconstitute Rocephin vials or to further dilute a reconstituted vial for IV administration. Particulate formation can result. Rocephin solutions should not be physically mixed with or piggybacked into solutions containing other antimicrobial drugs or into diluent solutions other than those listed above, due to possible incompatibility (see WARNINGS)".*

Applicant further submitted that opponents failed to recognize the huge cost which is involved in treating multidrug resistant bacteria such as MRSA. As per World Health Organization, the world is moving to pre antibiotic era because currently available drugs fail to treat resistant strains. In such scenario the instantly claimed invention is a boon for ailing humanity and cannot be achieved by mere combining of one or more components of instantly claimed invention because it results from synergy of all the constituents.

The presently claimed invention is not a mere aggregation of property/feature since Ceftriaxone and Vancomycin forms precipitate or degrade each other when combined as per prior art (technical prejudice from prior art) which is not the case for the present invention. The applicant submitted a HPLC study of degradation of Ceftriaxone and Vancomycin in presence of each other in solution without chemical vector as claimed instantly. The present invention has made a compatibility between incompatible Ceftriaxone and Vancomycin by employing chemical vector of adjuvants such as L-arginine, EDTA and Na2 C03.

8. During the hearing ,I considered the arguments of opponents and defense of the applicants and the papers, proceedings presented by them. The Opponent filed a representation under Section 25(1) on 2(1)j,2(1)ja,2(1)l,3(d) and 3€ of the Act without any documentary evidences. The opponent during the hearing restricted the arguemnts only on Section 3(d) and 3(e) of the Act and other ground of opposition withdrawn due to lack of documentary support. The prior applications 2411/DEL/2004 and 2510/DEL/2004 do not stand even as anticipatory documents under section -13, Subsection of 25(1) (c) of the Act because the date of publication of both applications after the filing date of this application.Therefore, both the cited references 2411/DEL/2004 and 2510/DEL/2004 do not stand as prior art/ anticipatory document. It becomes clear from the submissions made herein before that no individual feature of the claimed composition was known for the purpose of arriving at the presently claimed invention. No teaching, suggestion or motivation could ever be found in the prior art . The features, particularly use of selected chemical vectors, of the claimed inventions makes it surprisingly effective in curing microbial resistance as compared to monotherapy or individual administration of the antibiotics and bring significant cost effectiveness as discussed in the specification.

No hind sight bias should drive the formulation of the claimed inventions vis- a-vis the prior art and nothing in the prior art qualify as "known substance" for the purpose of the presently claimed invention and section 3(d) rejection. The opponent again failed to provide any documents in support of their arguments on the ground under Section 3(d) of the Act.

I agreed with arguments of the applicant submited that Section 3(d) should not be taken as extension to novelty and inventive step analysis, rather Section 3(d) be taken only as subject matter eligibility test to which the presently claimed invention does not get barred by this section given the nature of the claimed invention as discussed herein before. In this regard, the applicant submits that the Hon'ble Supreme Court in the Novartis Judgment and as a part of ratio decidendi opined in para 104 that:

"We have so far seen section 3(d) as representing "patentability", a concept distinct and separate from "invention". But if clause (d) is isolated from the rest of section 3, and the legislative history behind the incorporation of Chapter II in the Patents act, 1970, is disregarded, then it is possible to see section 3(d) as an extension of the definition of "invention" and to link section 3(d) with clauses {j) and {ja) of section 2(1). In that case, on reading clauses {j) and (ja) of section 2(1) with section 3(d) it would appear that the Act sets different standards for qualifying as "inventions" things belonging to different classes, and for medicines and drugs and other chemical substances, the Act sets the invention threshold further higher, by virtue of the amendments made in section 3(d) in the year 2005 Since section 3(d) can not be separated or disintegrated from other parts of section 3, section 3(d) can not become extension of clauses (j) and (ja) of section 2(1) ie. Section 3(d) is not extension either or both of Novelty and Inventive-stepanalysis. To put it differently, court interpreted that S- 3(d) is not an extension novelty or inventive step criteria and thus should not be attracted to attack inventive merit of the presently claimed invention."

the applicant also provided some of the significant efficacy test results and unexpected results, showing claimed invention-Vancoplus has broad spectrum activity and suprisingly effective in MRSA and surprising efficacy on breaking MRSA resistance by the product-Vancoplus falling under the claimed invention on the effectiveness of the instanly claimed invention in breaking microbial resitance. The claimed invention is economically significant. Thus feature of the claimed invention makes both technical advance as well as economic significance to enable it qualify the inventive step under section 3(d). My view is supported by the case before EPO, Board of Appeal, T 2564/86 SUMITOMO/Yellowdyes O.J.EPO 1989,115,(1989) E.P.O.R. 257 "An invention which relates on substantial and surprising improvement of a particular property need not also show advantages over the prior art with regard to other properties relevant to its, use, provided, the latter are maintained at a reasonable level so that the improvement is not completely offset by disadvantage in other respect....."

The invention disclosed in this application is essentially as synergistic fixed dose combination of antibiotics and the opposition has failed to mention as to why this application would attract provision Section 3 (d) and 3 (e) of the Act.

9. In view of all the above mentioned detailed discussion in the light of all the submissions of the opponent and applicant and arguments before hearing by the applicant and opponent, the facts

given in the documents submitted by both the parties, the representation is dismissed and the instant application is allowed to proceed for grant of patent with amended claims 1 to 8.

10. There is no order as to the costs.

Dated this 30th September, 2014

(DR. RAJESH DIXIT)

Assistant Controller of patents and Designs

Copy to:

(1) Venus Remedies Limited S.C.O. 39, Sector 26, Madhya Marg, Chandigarh - 160019, India (Applicant)

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