SECTION 25 (2)

In the matter of the Patents (amendment) Act, 2005 and
In the matter of the Patents (amendment) Rules, 2006.
and
In the matter of the Patent Application No. (1119/MUMNP/2003) and
In the matter of the Patent No. 202297 and
In the matter of opposition u/s 25(2) on the grant of Patent thereon.

Richter Gedeon Vegyeszeit Gyar NYRT, Hungery … Patentee
Cipla Limited, India … Opponent

HEARING HELD ON 03rd May, 2010
BEFORE

DR. AMARENDRRA SAMAL
ASSISTANT CONTROLLER OF PATENTS & DESIGNS

Present:

1. Mr. H. Subramaniam Opponent’s Attorneys
2. Mr. F. S. Groser & Swarup Kumar Patentee’s Agent
3. Dr. Ruchi Tiwari Dy. Controller of Patents & Designs

DECISION

This is a post-grant opposition under section 25(2) of Patents (amendment) Act, 2005 and the corresponding Rules 55-A to 62 of Patents (amendment) Rules, 2006 by Cipla Limited, India (herein after referred to as opponent) after grant of a patent to Richter Gedeon Vegyeszeit Gyar NYRT, Hungery (herein after referred to as patentee) on their
patent IN 202297 (Application No. 1119/MUMNP/2003) for an invention relating to “Dosage Regimen and Pharmaceutical Composition for Emergency Contraception”. The said patent application was filed as a PCT national phase application on 09\textsuperscript{th} December, 2003 and was published on 21\textsuperscript{st} October, 2005 under section 11-A of Patents (amendment) Act, 2005. As a matter of prosecution of the patent application under the provisions of the Act, as well as in view of applicant’s request for examination, the said application was examined under section 12 and 13 of the Act and later on was granted a patent IN 202297. Notification of such grant of the patent was published on 13\textsuperscript{th} April, 2007 under Section 43(2) of the Act. The claims of the granted patent (only one claim) which is exclusively for protection of a process is as follows:

1. Process for preparation of single application dose pharmaceutical composition for emergency contraception, characterized by mixing with $1.5 \pm 0.2$ mg of levonorgestrel as active ingredient in each application dose in admixture with known excipients, diluents, flavouring or aromatizing, stabilizers, as well as formulation-promoting or formulation providing additives, commonly used in pharmaceutical practice.

An opposition under section 25(2) of Patents (amendment) Act, 2005, and corresponding Rule 55-A of Patents Rule was filed on 05\textsuperscript{th} February, 2008 by the opponent, accompanied by full written statement and expert’s evidence by Dr. Sudhakar Gajanan Deshpande as expert relying upon various grounds of opposition on grant of a patent (i.e. post-grant opposition) and requested the Controller to grant a hearing in due course. The patentee filed reply statement under Rule 58 of Patents Rule on 25\textsuperscript{th} April, 2008 and served a copy to the opponent. It is evident from the record that the opponent did not filed reply evidence as required under Rule 59 of Patents Rule and expressed that they would rely upon the evidence already on record.

**Various grounds of opposition as relied upon by the opponent are as follows:**

(a) Under Section 25 (2)(b), i.e anticipation by prior publication;
(b) Under Section 25 (2)(d), i.e. prior public knowledge and use in India;
(c) Under Section 25 (2)(e), i.e. obviousness and lack of inventive step;
(d) Under Section 25 (2)(f), i.e. not an invention or patentable invention;
(e) Under Section 25 (2)(g), i.e. lack of clarity and insufficiency of description;
(f) Under Section 25(2)(h), i.e. failure to disclose details of corresponding foreign applications;

Hearing under Rule 62 of Patents Rule, 2003 (as amended), was fixed on 3rd May, 2010 at 11.00 A.M. vide office letter dated 07th April, 2010 and both the opponent and patentee were intimated to attend the hearing and address their contention already on record.

The opponent vide their letter dated 26th April, 2010 which was received in Patent Office on 27th April, 2010 have filed three additional documents which they would like to further rely upon at the time of hearing are as follows:

1. Dominique Tremblay wt al., The Pharmacokinetics of 750 µg levonorgestrel following administration of one single dose or two doses at 12 or 24 hr interval (2001) Contraception, volume 64, pages 327-331.


Further the opponent vide their letter dated 28th April, 2010 which was received in Patent Office on 28th April, 2010 have filed three more additional documents which they would like to rely upon at the time of hearing are as follows:

1. Pharmaceutical Dosage Forms; Edited by Herbert A. Lieberman, Leon Lachman and Joseph B. Schwartz; (1990); pages 27-29.

2. Encyclopedia of Pharmaceutical Technology; Edited by James Swarbrick and James C. Boylan; Volume 14 (1996); page no. 392.

Upon submission of additional documents by the opponent after fixation of hearing, the patentee objected to it vide their letter dated 28\textsuperscript{th} April, 2010 expressing that these further documents filed under Rule 60 of Patents Rule should not be a part of opposition proceedings. The opponent vide their letter dated 29\textsuperscript{th} April, 2010 contested on the objection raised by the patentee and submitted that they have filed the further documents under Rule 62 (4) after hearing under Rule 62 is fixed and well within prescribed time period and should be taken on record. They also stated that the said issue will be addressed in the main hearing fixed on 03\textsuperscript{rd} May, 2010.

In the hearing the opponent at the outset argued that the additional documents filed vide their letters dated 26\textsuperscript{th} April, 2010 and 28\textsuperscript{th} April, 2010 was filed under Rule 62(4) of Patents Rule, 2003 and are well within the prescribed time period. Rule 62 (4) of Patents Rule says that “If either party intends to rely on any publication at the hearing not mentioned in the notice, statement or evidence, he shall give to other party and to the controller not less than five days notice of his intention, together with details of such publication”. The opponent stated that as these documents are submitted five days before hearing under Rule 62 and are well within time as stipulated in Rule 62 (4).

The patentee on this issue referred to Rule 60 of Patents Rule, and argued that the further documents filed by the opponent has not been made with the leave or direction of controller and such submissions should not be taken on record in the opposition proceedings. On the specific issue, I find merit in opponent’s submission and say that the opponent has filed these further documents availing the provision contained in Rule 62 (4) of Patents Rule and the documents filed by them on 27\textsuperscript{th} April, 2010 is taken on record and admitted as a part of the opposition proceedings. However, the further documents vide the their letter dated 28\textsuperscript{th} April, 2010 which the patentee stated was received by them on 29\textsuperscript{th} April, 2010 is not within the prescribed time period (i.e. not within five days excluding the date of hearing) and hence not taken on record and can not be a part in the opposition proceedings. In the hearing both parties were asked to argue only on the documents filed in opposition and the documents vide the opponent’s letter dated 26\textsuperscript{th} April, 2010 (as further documents) after fixation of hearing under Rule 62 of Patents Rule, 2003.
Now I would like to make a complete overview on the arguments and submission by both the parties in the hearing taking into account separately various grounds of opposition and various documents relied upon by them.

1. **Invention claimed in any of the claims of the patentee’s invention is not novel in view of prior publication under section 25(2)(b) of the Act.**

   The opponent has relied upon the following documents to establish that invention so far as claimed in any claim of the complete specification has been published before the priority date of the claim and argued that the claim is lacking in novelty.


**D2:** A prospective randomized comparison of levonogestrel with Yzupe regimen in post-coital contraceptive; Ho P.C. and Kwan M. S. W.; Human reproduction; vol. 8, no. 3; pp 389-392; 1993.

**D3:** Dominique Tremblay wt al., The Pharmacokinetics of 750 μg levonorgestrel following administration of one single dose or two doses at 12 or 24 hr interval (2001) Contraception, volume 64, pages 327-331.


On the disclosure of **D1** as a prior art, the opponent says that the said document provides a summary of different emergency contraceptives including Levonorgestrel 0.75 mg double dosage administered 12 hours apart up to 72 hours after intercourse as disclosed in Table 1 in page no. 1059. This disclosure **D1** establishes that Levonorgestrel is a known substance and is known to possess post coital emergency contraceptive property. The scheme of administration (up to 72 hours of coitus) and the amount of active ingredient administered (0.75 + 0.75 = 1.5 mg) is also anticipated by the cited document. The opposed patent is not novel in view of the disclosure of the cited document. The only novelty part claimed by the patentee is the possibility of applying two dosages at the same time. Hence, merely increasing the amount of the active ingredient can’t render the
process of mixing novel. In order to render a process patentable, its novelty must reside in a process step or the ingredients and the final product including its use as well. The double dosage scheme of Levonorgestrel i.e. \(0.75 + 0.75 = 1.5\) mg described in D1 is well within the range of \(1.5 \pm 0.2\) mg of Levonorgestrel used as a single application dosage in the opposed Patent No. 202297. Both the regimens (i.e. claimed invention and disclosure in D1) require that for effective contraception, Levonorgestrel be administered within 72 hours of coitus.

However, the patentee argued that their invention discloses and claims a process for the preparation of a pharmaceutical composition for emergency contraception containing levonorgestrel as active ingredient in the range of 1.3 mg to 1.7 mg in combination with excipients, diluents, flavouring agents etc. the inclusion of such a broad range of levonorgestrel \((1.5 \pm 0.2\) mg) in the composition resulting from the process of preparation as claimed was never known in the past and hence is novel.

On the disclosure of D2 as a prior art, the opponent states that the said document teaches the use of a composition containing Levonorgestrel for post coital contraception to be administered within 72 hours of coitus in a dosage of 0.75 mg each (i.e. 1.5 mg) over a period of 12 hour. Hence, the subject matter of the claims of the impugned patent 202297 is comprehensively anticipated by D2. The features of excipients, flavouring agents and other additives mentioned in claim 1 of the impugned patent are all admittedly known and commonly used in pharmaceutical practice and therefore, can’t/do not impart novelty for a known compound for its known use.

The patentee on this issue contends that such a document which has been acknowledged in the descriptive part was known to them which exclusively teaches a regimen for using levonorgestrel to prevent post-coital conception which is different from the instant patent.

On the disclosure of D3 as a relied prior art, the opponent states that there has been a suggestion in the said document administration of two tablets of 750 µg levonorgestrel at a 12 to 24h interval has been shown to be a safe and effective means of
emergency contraception which was an open, observer-blind, randomized study with three parallel groups. Three groups of eight participants, each receiving one of the following treatments: Group A, one tablet of 750 µg levonorgestrel at time 12 h and one tablet at time 0; Group B, one tablet of 750 µg levonorgestrel at time 0; Group C, one tablet of 750 µg levonorgestrel at time 24 h and one tablet at time 0. The results showed that single or two administrations of a tablet containing 750 µg levonorgestrel is rapidly absorbed. This suggestion of D3 destroys the novelty of the invention claimed in the complete specification.

The patentee strongly opposed to such a document as anticipating the novelty of the invention and stated that the said document is not relevant to the invention claimed by them which discloses the pharmacokinetic of administration of 750 µg levonorgestrel of one single dose or two doses at 24 hours interval. They submitted that their invention is entirely different from the disclosure of D3.

On the disclosure of D4 as a prior art, the opponent states that there has been a teaching in the said document on administration of two doses of 0.75mg levonorgestrel in 12h interval which is same as the claimed invention and anticipates the novelty of the invention claimed.

The patentee opposed the statement of the opponent and argued that the teachings of D4 is related to a comparative study of the efficacy of levonorgestrel and mifepristone on emergency contraception and not related to the opposed invention wherein a process has been devised for preparation of a single application dose of pharmaceutical by mixing with 1.5 ± 0.2 mg of levonorgestrel as active ingredient with known excipients, diluents, flavouring or aromatizing stabilizers etc. hence, D4 can’t be a novelty destroying document.

On the disclosure of D5 the opponent states that there has been disclosed a comparison of mifepristone and levonorgestrel on emergency contraception in page 7, para 3 which is as follows:
A multinational randomized double-blind study is under way to compare the efficacy and side effects of 10 mg of mifepristone and two treatments of levonorgestrel (i.e. two doses of 0.75 mg of levonorgestrel administered at 12-hour interval, or as one single dose of 1.5 mg) for emergency contraception up to 120 hours after unprotected intercourse. The study is being carried out in 15 centres and the target is to recruit a total of 4200 women. The clinical phase is expected to be completed by the first half of the year 2000. The opponent further argued that D5 discloses one single dose of 1.5 mg levonorgestrel which the patentee claimed as a process for preparation of single dose pharmaceutical by mixing with 1.5 ± 0.2 mg of levonorgestrel as active ingredient with known excipients, diluents, flavouring or aromatizing stabilizers etc. They also stated that a process for preparation of a composition of the kind as claimed by the patentee wherein the active ingredient levonorgestrel is present in an amount of 1.5 ± 0.2 mg by mixing with known excipients, diluents, flavouring or aromatizing stabilizers etc. is not novel since the active levonorgestrel of the amount 1.5 mg in a pharmaceutical dose is known from D5.

The patentee on this issue replied that even though D5 discloses a dose containing 1.5 mg levonorgestrel, its effect is not realized and the opponent have failed to address whether such a dose works or not. This submission by the opponent is speculation and should not be relied upon. The instant invention claimed by the patentee is proven to be potential and supporting data are disclosed in pages 4-6 of the complete specification.

Further in rebuttal the opponent express the concern that the applicant has not followed any protocol/guidelines while conducting the trials to establish the working of the invention and only randomized trials have been made.

2. Invention so far as claimed in any claim of the complete specification was publicly known or publicly used in India before the priority date of that claim;

The opponent relied upon and argued on such a ground of opposition which as they state is linked to the ground of opposition under Sec. 25(2)(b) (i.e. prior publication). As per their argument, they state that since the said invention claimed is not novel, and is
available in prior art, it is publicly known or publicly used in India before the priority date of that claim.

The patentee however argued that their invention discloses and claims a process for the preparation of a pharmaceutical composition for emergency contraception containing levonorgestrel as active ingredient in the range of 1.3 mg to 1.7 mg in combination with excipients, diluents, flavouring agents etc. the inclusion of such a broad range of levonorgestrel (1.5 ± 0.2 mg) in the composition resulting from the process of preparation as claimed was never known in the past and is novel. Thus this ground of opposition as relied upon by the opponent is baseless. The claimed invention in the complete specification was not publicly known or was not publicly used in India before the priority date of that claim.

3. **Invention so far as claimed in any claim of the complete specification is obvious and clearly does not involve any inventive step under section 25(2)(e) of the Act.**

The opponent has relied upon the following documents to establish that invention so far as claimed in any claim of the complete specification is obvious and clearly does not involve any inventive step.


**D2:** A prospective randomized comparison of levonogestrel with Yzupe regimen in post-coital contraceptive; Ho P.C. and Kwan M. S. W.; Human reproduction; vol. 8, no. 3; pp 389-392; 1993.

**D3:** Dominique Tremblay wt al., The Pharmacokinetics of 750 µg levonorgestrel following administration of one single dose or two doses at 12 or 24 hr interval (2001) Contraception, volume 64, pages 327-331.


D7: A multicenter clinical investigation employing ethinyl estradiol combined with dl-norgestrel as a post coital contraceptive agent; Fertility and Sterility, Volume 37, No. 4, pages: 508-513, published on April, 1982.

The contents of each of the documents from D1 to D5 and the submission and argument made by the opponent and patentee in respect of these documents have already been discussed under the ground of opposition under section 25(2)(b) of the Act and need not require further comments.

However, on the disclosure of the prior art D6, the opponent says that the said annexure reports the availability of Levonorgestrel-alone for emergency contraceptions. The said annexure at column 1, paragraph 2 and column 2 at paragraph 1 also establishes that Levonorgestrel as an emergency contraceptive has a higher success rate and lesser effects compared to the other combination contraceptives available in the market. The opponent further says that patentee has merely tried to avoid prior art and acquire monopoly over a known substance for a known use by illegally claiming the invention as novel and inventive. With the available prior art which has tested and established the competency of Levonorgestrel as an emergency contraceptive, it is only obvious for the patentee to modify the dosage-regimen and also the process for preparation thereof. Such a modification is obvious and lacks an inventive merit.

The patentee referred to the exhibit “A” “Pharmacokinetic study of different dosing regimens of Levonorgestrel for emergency contraception in healthy women” by Elof Johansson et. al published in the European Society of Human Reproduction and Embryology, Vol. 17, No. 6, 2002 in pages 1472 and 1473 furnished in their reply statement which establishes that the pharmacokinetic studies of different dosing regimens of Levonorgestrel for emergency contraception that 2 x 0.75 mg of Levonorgestrel is not equal to 1 x 1.5 mg of Levonorgestrel. Hence the opponent contention that it could be cumbersome to take a dosage twice over within a twelve-hour period, it would be obvious for a person skilled in the art to combine the two dosages into a single dose is not valid and the claimed invention is inventive over the prior art teachings.
On relying upon the disclosure of the prior art D7, the opponent says that (as admitted by the patentee in the impugned specification in page 3, paragraph 2) first reported a pharmaceutical composition as post coital contraceptive in a single-dose (containing 100µg of ethinyl-estradiol and 1.0 mg of norgestrel) but later modified to a double-dose regimen. Since it would be cumbersome to take a dosage twice over a twelve hour period, it would be obvious for a person skilled in the art who reads the prior art cited herein to combine the dosages of twelve hour regimen into a single regimen. The shift from the double to single dose has nothing to do with the contraceptive properties at all but merely a matter of convenience which can’t constitute an invention.

The patentee strongly denied such contention of the opponent and says that the said document which is relied upon by the opponent is already discussed by the patentee in the prior art disclosure and they are aware of such prior published document. This document specifically teaches a trial to prove the efficacy of a combination of ethinyl-estradiol 0.2 mg with 2.0 mg of norgestrel or 1.0 gm of Levonorgestrel on contraception. From the teachings of the said document a person skilled in the art would not be able to prepare a dosage containing 1.5 mg of Levonorgestrel for emergency contraception. The opponent has no basis in arguing on this document.

4. **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 under section 25(2)(f) of patents Act.**

   The opponent has relied upon Section 3(d) and Section 3(e) of patents Act and stated that 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.

   Under section 3(d) of Patents Act, the opponent says that even new uses of a known substance or new forms of known substances are not patentable unless there is a significant increase in efficacy. In the present case, what is claimed is not even a new use of known substance or new form of a known substance but known use of a known substance in a known form prepared by a known method. They submitted that the shift from double to
single dose has nothing to do with the contraceptive properties at all but merely a matter of convenience which does not and can not constitute an invention. The method of making a single application dosage regimen by a single mixing step claimed by the patentee is therefore, only a mere known use of a known substance in known form in known amount in known way for known level of efficacy.

The patentee contended that they have claimed a process for preparation of a composition i.e. an admixture wherein section 3(d) has nothing to do with compositions.

Under section 3(e) of Patents Act, the opponent says that Section 3(e) of the Act precludes from patentability a substance which is a mere admixture resulting in only a mere aggregation of the properties of the components thereof as well as processes for preparing such admixtures. The opposed patent No. 202297 claims a pharmaceutical composition containing 1.5 ± 0.2 mg of Levonorgestrel as active ingredient in admixture with known and commonly used pharmaceutical excipients, diluents, stabilizers, flavouring or aromatizing as well as formulation promoting or formulation providing additives. In order to overcome rejection under Section 3(e) the composition claimed must be a synergistic composition having improved and unexpected properties. The increase in dosage of Levonorgestrel does not result in any synergy or new or unexpected property. So there is no synergy between the constituents of the alleged composition as claimed in opposed Patent No. 202297.

The patentee expresses that the invention claimed relates to the preparation of a pharmaceutical composition and, unlike any physical manifestation of synergism or interaction, any special effects can only be evinced when the composition is actually administered. The very fact that there is marked increase in prevention of contraception in terms of percentage (81.9%) in those women treated with a single dose of the composition prepared by their invention and those (77.3%) treated with two doses of 0.75 mg of Levonorgestrel at twelve-hour intervals.

5. The complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed under section 25(2)(g) of patents Act.

The opponent argues that the patentee has failed to disclose the invention as stipulated under Section 10(4) of Patents Act, which states that every complete
specification filed with an application for a patent shall fully and particularly describe the invention, its operation or use and the method by which it is performed, and shall also disclose the best method of performing the invention. The patentee’s composition containing Levonorgestrel in the range of 1.3 to 1.7 mg as an active ingredient was claimed and only a method of making a composition containing 1.5 mg Levonorgestrel was disclosed. There are no examples provided in the description for the other amounts claimed. Also the patentee’s statistical data pertaining to efficacy on the claimed composition is not meaningful, biasing and unscientific.

The patentee in their defense expressed that the corresponding patent application with identical disclosure has been proceeding to grant in European Patent Office wherein the test of clarity and sufficiency is very rigid. Had the disclosure been unclear and insufficient, it would not have been granted in EPO.

6. The applicant has failed to disclose to the Controller the information required by section 8 or has furnished the information in which any material particular was false to his knowledge;

The opponent contends that the patentee has failed to comply with the requirements of Section 8 of the Act. They have suppressed the material information wherein certain foreign filings corresponding to the opposed Patent No. 202297 have not been communicated to the Indian Patent office.

Contrary to the Opponent’s allegation, the patentee says that they have complied with the requirement of Section 8 of Patents Act during the prosecution of Patent application as evident from the Form 3 filed on dated 8th October, 2004 wherein they have mentioned the Japanese patent application and United States patent application. However, the voluntary abandonment of the Japanese and US patent applications by them were not conveyed through the filing of form 3 for the reason that these abandonment took place after the application form which their Patent No. 202297 matured had been placed in order.

After hearing the opponent and the patentee, their arguments, the documents they have relied upon, and the report and joint recommendation of the Opposition Board, I am drawing the following conclusions parawise on each and every grounds of opposition.
1. **Referring to the ground of opposition that invention claimed in any of the claims of the applicant’s invention is not novel in view of prior publication**, I find that all documents relied upon by the opponent except D5, are not relevant prior art for anticipating the novelty of the claimed invention. The impugned patent claims a process for preparation of single application dose pharmaceutical composition for emergency contraception, characterized by mixing with 1.5 ± 0.2 mg of levonorgestrel as active ingredient in each application dose in admixture with known excipients, diluents, flavouring or aromatizing, stabilizers, as well as formulation-promoting or formulation providing additives, commonly used in the pharmaceutical practice. I don’t find in prior art documents D1 to D4 which discloses a process of for the preparation of single application dose pharmaceutical composition containing 1.5 ± 0.2 mg of levonorgestrel as active ingredient. Even a teaching comprising a dosage containing levonorgestrel as active agent in an amount of 1.5 ± 0.2 mg as contraceptive is not derivable from the disclosures of D1 to D4.

While discussing on prior art document D5, I find that there is a disclosure of use of one single dose 1.5 mg levonorgestrel for emergency contraception up to 120 hours after unprotected intercourse. Even though the said document does not explicitly discloses a method of preparation of the said dose, a single dosage containing 1.5 mg levonorgestrel is used and known from this document. I do not find any novel features in the claimed process by the patentee, except the fact that the active ingredient levonorgestrel is mixed with known excipients, diluents, flavouring or aromatizing, stabilizers etc. in an amount of 1.5 ± 0.2 mg which is also known from D5. Thus, the novelty of the invention claimed in the patent is anticipated from the disclosure of D5. I conclude that the invention claimed by the patentee is not novel and the opponents ground of opposition is validly established.

2. **Referring to the ground of opposition that the invention so far as claimed in any claim of the complete specification was publicly known or publicly used in India before the priority date of that claim**, I do not find a merit in the opponent’s contention. The opponent has not been able to convince me that
the patentee’s claimed invention was publicly known or publicly used in India before the priority date of that claim. **The opponent has failed to establish such a ground of opposition in absence of any evidence.**

3. **Referring to the ground of opposition that the invention so far as claimed in any claim of the complete specification is obvious and clearly does not involve any inventive step,** I would like to emphasize that the patentee’s claimed invention is not novel in view of the prior art published document D5 as concluded in preceding paragraph. The patentee has not made any amendment to the claimed invention to overcome the opponent’s objection on novelty. The criteria of adjudicating inventiveness of the claimed invention would be arising, had the claims been novel. I conclude that the patentee’s claimed invention is not novel and hence not inventive as well. **I also conclude that the invention claimed by the patentee is obvious and hence does not involve an inventive step.**

4. **Referring to the grounds of opposition 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;** I agree that the applicant has not provided any data to substantiate enhancement of efficacy of the claimed invention. I don’t agree with the patentee’s contention that they have claimed a process for preparation of a composition i.e. an admixture wherein section 3(d) has nothing to do with compositions. A patent can’t be granted for an invention which as per the definition of Section 3(d) is “the mere use of a known process unless such known process results in a new product or employs at least one new reactant”. I do not find that the instant process claimed either results in a new product or employs at least new reactant. The product which is obtained by the claimed process is not novel since disclosed in D5, and the reactants are known reactants for preparation of a pharmaceutical dosage form for emergency contraception. **I conclude that the subject of any claim of the complete specification is not patentable under Section 3(d) of Patents Act and the opponent’s ground of opposition is validly established.**
On the opponent’s argument that the patentee’s claim is not patentable u/s 3(e) of Patents Act in absence of any valid disclosure/data demonstrating synergy of the composition claimed, I don’t find this a valid ground of opposition. The claimed invention is a process for preparation of single application dose pharmaceutical composition for emergency contraception, characterized by mixing with 1.5 ± 0.2 mg of levonorgestrel as active ingredient in each application dose in admixture with known excipients, diluents, flavouring or aromatizing, stabilizers, as well as formulation-promoting or formulation providing additives, commonly used in the pharmaceutical practice wherein the composition employs a single active agent, the question of evaluating synergistic action does not arise. **I conclude that the claimed invention does not attract Section 3(e) of Patents Act. Hence, the opponent has failed to establish this ground of opposition.**

5. **Referring to the ground of opposition that the complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed,** I see that the complete specification is clear and sufficiently describe the invention as claimed and the method by which it is to be performed. From the disclosure of the invention a person skilled in the art would be able to perform the invention without any ambiguity. I appreciate the opponent’s contention that the higher and lower values of the active agent in the claimed process for preparation of the pharmaceutical composition is not exemplified, but such broader aspect of the invention can be claimed if disclosed in the specification. **I conclude that such a ground of opposition is not validly established by the opponent.**

6. **Referring to the ground of opposition that the applicant has failed to disclose to the Controller the information required by section 8 or has furnished the information in which any material particular was false to his knowledge;** my findings are as follows:

The patentee filed the PCT application through national phase entry on 09th December, 2003 providing the statement and undertaking in Form 3 on the priority data only. Their next submission (updated information in Form 3) in this context was filed only
on 25th October, 2004 mentioning its entry into several countries. Intimation of grant of such an application was send to patentee on 20th June, 2006. Even though substantial updated information on the corresponding application filed in foreign countries were expected to be available like the information in JP and USA, the same was not informed to the Indian Patent Office. I view this irregularity by patentee as violation of provision as required under Section 8 of Patents Act. **I conclude that such a ground of opposition is validly established by the opponent.**

Considering the post-grant opposition, report and recommendation of Opposition Board, pleadings of both parties and in view of my above findings, I hereby order **to revoke** the patent IN 202297 granted on Patent Application No. 1119/MUMNP/2003. **There is no award of costs to either party.**

Dated this 04th Day of August, 2010.

**(DR. AMARENDRA SAMAL)**  
Asst. Controller of Patents & Designs  

Copy to :  

2. Mr. F. S. Groser of Grocer & Grocer, D – 1/5, DLF Qutab Enclave, Phase – I, Gurgaon – 122 002, India  
3. The concerned post grant opposition file and register of Patent.