The Patents Act, 1970

Section 25(1)

IN THE MATTER OF the application for patent No. IN/PCT/2002/507/DEL filed on 14th May,2002

And

THE MATTER OF representation under section 25(1) of the Patent Act, 1970 as amended by Patent 1971 (Amendment) Act, 2005.

And

IN THE MATTER OF rule 55 of the Patent Rules, 2003, as amended by the Patent (Amendment) Act, 2005.

M/s OSI Pharmaceuticals Inc, USA ……. The Applicant

M/s CIPLA Ltd., India ……. The Opponent

Hearing held on August 25,2008

Represented by

Mr. D.J. Soloman — Agent for the Applicant
From De Penning & De Penning

M/s S. Majumdar — Agent for the opponent
From S. Majumdar & co.

DEC ISION

A representation by way of opposition under section 25(1) of the Patent Act, 1970, as amended by Patent (Amendment) Act, 2005, was filed by M/s S. Majumdar & Co on behalf of M/s CIPLA Limited on 30thJanuary,2008 with a request for hearing under rule 55 of the Patent Rules, 2003 as amended by Patent (Amendment) Act, 2005. The applicant submitted their reply statement and evidence on 2nd June,2008. The hearing was fixed on 20th July 2008 was refixed on request of the party to 25th August ,2008 and both the parties to the opposition attended the hearing on the scheduled date.

The present application is filed by M/s Kumaran & sagar on behalf of applicant M/S OSI Pharmaceutical Inc. having priority of USA application dated 11th November,1999 for an invention claiming “a crystalline polymorph of N-(3-ethynylphenyl)-6,7-bis(2-methoxyethoxy)-4-quinazolinamine,its preparation process and pharmaceutical composition thereof.”

The opponent raised following grounds in their written submission. (1) Prior Publication (2) Publicly known and used in India (3) Obvious and lack in inventiveness (4) Not an invention / not patentable (5) Failure to disclose information under section 8. But during the subsequent prosecution of the application in the patent office , objections were raised by the examiner & consequently the applicant amended their claims and submitted six claims comprising two product claims, three process claims and one composition claim. The amended claims submitted by the applicant was also sent to the opponent to facilitate the opponent to confine their argument to the extent of outstanding grounds of opposition with respect to the amended claims.

During the hearing opponent dropped the grounds of anticipation and inventive step in view of the amended claims. Only certain factual submission necessary were maintained for appreciation of the pleading under other grounds. Before the argument the applicant also argued that the clarification letter sent by the applicant on 18th Aug., 2008 and the reply statement made earlier are quite contradictory statement , submitted by the applicant .The opponent compared the contradictory statement of the applicant's reply statement and the letter dated 18th Aug. 2008

(a) In the reply statement vide para 9-3, the applicant replied that the US 5747498 (Equivalent Indian Patent No. 196774) Patent certainly does not contain a direct and unambiguous disclosure of polymorph B free of polymorph A as claimed in revised claim 1. In the letter of clarification dated 18th Aug., 2008 it submitted that the said US Patent No. 5747498 (Ind .Patent 196774) is for the main compound " Erlotinib hydrochloride" which includes all possible polymorphs of the main compound known or unknown . Therefore these two statements 'are in total contradiction to each other.

(b)In the reply statement applicant did not refer the present invention to be a selection invention but in the clarification letter it has pleaded that the polymorph B which is substantially free of polymorph A is a selection invention. The opponent argued these two statements are contradictory and the pleading of selection has no basis as in the case of selection it is imperative that the subject matter of the selection has to be contained in the prior art itself and the applicant is required to show some remarkable unexpected benefits in respect of the selection ,with in the prior art. In the reply statement the applicant has rather pleaded that in the prior art 4757498 polymorph is not taught. Therefore applicant has themselves defeated their own plea without any basis. In paragraph 3 of the reply statement the applicant mentions about the corresponding patent of selection invention of polymorph B, which was applied in the year 2000 and granted as US 6900221 in 2005. In USA it is possible & routinely granted ,

the patent for incremental invention eg polymorph B of the main compound in addition to the main/umbrella compound but under Indian Law the same is possible provided the section 3(d) is satisfied , ie requirement of establishing the improvement relating to the efficacy is satisfied. The opponent objected to this statement during hearing, that in the Patent Act there is nothing known about main/dominating/umbrella patent . Therefore the reply statement and the clarification given vide letter dated 18th Aug. 2008 is quite contradictory.

During the hearing opponent argued that on page 17 of the specification of the present application vide second para indicated the hydrochloride compound disclosed in US Patent 4757498 actually comprises a mixture of polymorph A and B which because of its partially reduce stability (i.e. from polymorph A component) was not preferred for tablet form than the mesylate salt form which is rather more effective in solution form . Opponent argued that vide para 4 of the classification letter dated 18th Aug., 2008 in which applicant have themselves stated that "polymorph B is claimed to be thermodynamically more stable and it helps in providing improved oral dosage in solid form. However it does not mean that either the main/dominating/umbrella compound or any other possible polymorphs, whether singly or in mixture combination, thereof were not useful and could not be used in solid oral dosage form. It is categorically submitted that all the known, so far, polymorphic forms of the main compound Erlotinib Hydrochloride were (in 1996) and are (today), Capable of being put into a tablet form," This statement of the applicant defeat their own specification & the entire basis of the impugned invention.

The opponent further argued vide para 5 of opponent clarification letter ,the applicant stated. "All publication relied upon to prove superior efficacy in respect of US 4757498 (Indian Patent 196774) are based on clinical trials conducted on Erlotinib Hydrochloride (an EPGR inhibitor) irrespective of its polymorphic form i.e. polymorphA+polymorphB, Polymorph B, Polymorph C, Polymorph E or any other polymorph since a

polymorph is not a different compound and not even a different molecular form thereof, but only a different spatial orientation of two or more molecules forming a particular crystalline shape of the compound." In this context the opponent referred to the prosecution history of the corresponding US Patent 6900221 vide para 2, at page 14, the applicant themselves have stated , in their response to US Patent office that the word "Polymorph" does not appear in US Patent 4757498. The same applicant in the present proceeding stated that US Patent '498 includes all known and unknown polymorph , which is in contradiction to its reply statement and its response to USPTO . The applicant also stated in their reply statement that ----"Polymorph can be deemed within the prior art is totally false & baseless." Is totally contradicting with the statement made by them in the clarification letter dated 18th Aug., 2008. At one point it was the case of applicant that the polymorph are not included in US/'498 and the present stand is that all polymorphs known or unknown are included in US/'498. The applicant cannot stand on the face of self defeating pleading & is liable to be rejected.

The opponent also apposed to the plea of the applicant for 'selection invention. In this regard they referred to a case Law, E.I DU PONT DE NEMOURS AND CO.

"----------The cases speaks of selection from a class consisting of homologous compound i.e related to our homologous with a specific product or process already patented or within the public domain….."

Therefore it is clear form the above that in case of a selection patent, the selection has to be from the prior art and the applicant's admission that their invention is a 'selection invention' themselves have admitted that the impugned application is a part of the prior art. While in the reply statement & in the US prosecution, the defence of the applicant is wholly different where it states "no polymorph is disclosed in US/'498. Therefore the plea of selection is bad and unsupported. Hence

the application is liable to be rejected. The opponent also opposed to the lines 21 &22 of page 6 of the specification i.e “The polymorph designated the B polymorph may be substantially in pure form, relative to the polymorph A” and referred in this respect the following passage of the judgment *Evorshed J. in Dreyfus & others Application* [1945] 62 RPC 125 at 133 ***“invention of selection there be, must involve, at least the discovery that the selected member posses qualities hitherto undiscovered, peculiar to themselves and not attributable to them by virtue merely of the fact of their belonging to a class specified be the earlier inventor”*** further it referred ***----”. You can not obtain a valid patent generally for the discovery of the new quality in or use of a known product or process. But as Lord Wilberforce pointed out, this does not apply when the new quality or use is discovered in or for a product or process which is merely a member of a class (in the sense used in Selection Patent Law). The subject of the Selection Patent is the inventive step as described by Lord Diplock. I am not convinced that the necessarily involves that the different inventive step the subject matter or the earlier patent is subsumed. But, if it were, that would be something inherent in the very concept of selection patent which inevitably involve the taking over by a later patent of part of an area previously claimed in an earlier one for a class. “***

It is submitted that the applicant having argued that there is no reference to polymorph in ‘498 cannot take opposite stand in the said clarification letter and claim a selection in polymorph B. Even if selection is argued that applicant has not shown any unexpected surprised benefits or efficacies related to the polymorph of the impugned invention. Further the applicant has submitted in its specification, that polymorph designated polymorph B is substantially in pure form relative to the polymorph A and mixture of A & B are present and the application has failed to provide any comparative date related to efficacy and improvement / technical advantage arising out of the B polymorph of the impugned

invention other than stability and capability of being formed into tablets. Therefore the impugned invention can not qualify the selection invention.'

The opponent argued that in the specification on page 7 it is apparent that A polymorph is also present along with B polymorph. During hearing applicant argued that polymorph B is free from A polymorph. Further the opponent argued that claim 1 & 2 do not qualify as invention under section 3(d) of the Patent Act. Amended claims 1 & 2 relates to a crystalline polymorph of the hydrochloride salt of N-(3-ethynylphenylamino) –6-7-bis [2-methoxyethoxy)-4-quinazolinamine designated the B polymorph which is free from A polymorph. During hearing it was argued that the claimed product claim 1 & 2 cover polymorphs of known compound and are not patentable subject matter under section 3(d). The applicant in the reply statement has not replied on the pleading of the opponent under section 3(d) which means applicant has admitted the content of the para 6-7 of the representation.

In respect of the clarification vide paragraph 4 , applicant has submitted that B polymorph of the present invention is thermodynamically stable. In respect of this opponent has relied upon the decision of controller in respect of application no. 1602/MAS/98 (Novanties AG Vs Cipla Ltd.) where the solubility was not considered to be a enhancement in therapeutic efficacy. Further nowhere in the specification any data is provided which shows there is an enhancement in the efficacy of the polymorph B compound to the compound mentioned in US/'498. Even in the clarification letter, applicant is silent about therapeutic efficacy which goes to prove that the polymorph of the impugned invention has not brought about any unexpected surprising effect as regard therapeutic efficacy. Therefore invention as claimed in claim 1 & 2 is not patenetable under section 3(d). Further the claimed product is a polymorph of a known compound and are not patentable under section 3(d), in this regard the opponent referred the judgment dated 6th Aug.,2007 in writ petition 24760/06 passed by the Hon'ble High Court of Judicature at Madras in the case of Novartis AG vs

Union of India & others. The court defined what is therapeutic efficacy & efficacy. ***"…….As we understand the amended section, it only declares that the very discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of the substance, will not be treated as invention. The position therefore is if the discovery of a new form of a known substance must be treated as invention, then the patent application should show that the substance so discovered has a better therapeutic effect. Darland's Medical dictionary define the expression 'efficacy' in the field of pharmacology as 'the ability of a drug to produce the desired therapeutic effect ' and efficacy is independent of potency of the drug. Dictionary meaning of 'therapeutic is healing of disease-having a good effect on the body. Going by the meaning for the word efficacy and therapeutic extracted above, what the patent applicant is expected to show is, how effective the new discovery made would be in healing a disease/having a good effect on the body. In other words, the patent applicant is aware as to what is the 'therapeutic effect of the drug for which he had already got a patent and what is the difference between the therapeutic effect of the patented drug and the drug in respect of which patent is asked for. Therefore it is a simple exercise of though preceded by research. We state for any patent application to place on record what is the therapeutic effect/efficacy of known substance and what is the enhancement in that known efficacy……."***

In the present application not even a single data in provided which would show the enhancement in the therapeutic efficacy of the polymorph B compared to the compound in the prior art '498. In the clarification letter the applicant is silent about the therapeutic efficacy which goes to prove that the polymorph of the impugned invention has not brought about any unexpected surprising effect in the therapeutic efficacy. The clinical studies provided on page 50 to 52 as pointed out by the opponent during hearing is devoid of any therapeutic efficacy. Therefore the invention

claimed in claim 1 & 2 are not patentable under section 3(d) and insufficiency of disclosure . Therefore liable to be rejected.

Regarding claim 6, the opponent argued that the pharmaceutical composition adapted for solid oral administration comprising polymorph of claim 1 and a pharmaceutically acceptable carrier. Since the composition does not provide any other ingredients therefore fails to qualify as composition claim. The composition claim is a mere repetition of the product claim are redundant and superfluous & ought to be rejected.

Regarding process claims vide claims 3 to 5 of the impugned application, the opponent argued, that no example was provided in the specification wherein crystallization was done with alcohol only. Both alcohol and water was used as mixture in the preparation of the crystalline polymorph in Example 4. This argument gets strength from the reply of the applicant against the rejection of the inventiveness in the selection of solvent combination against the background of prior art '498 document. Therefore the process with the specific combination of water & alcohol for crystallization should only be allowed by merging claim 4 in claims 3.

The applicant during hearing first contested against the objection raised by the opponent in respect of clarification letter dated 18 Aug.,2008 and stated that they do not agree that the content of the reply statement and the clarification letter of 18 Aug.,2008, are inconsistent. In fact paragraph 3,4&6 of our clarification letter provides additional information about polymorph & clarify how the present invention satisfy the requirement of section 3(d). Opponent argument that the submission made the applicant during the prosecution of the corresponding US Patent application with the submission made in the clarification letter are contradictory. This US patent has been granted as US Patent No. 6900221 with claims almost similar to the original claims filed in respect of present application.

The applicant argued that section 3(d) explanation particularly, provide …." For the purpose of this clause, salt, esters, ethers, polymorphs, metabolites pure form, particle size, isomers, mixture of isomers complexes, combinations and other derivatives of a known substance shall be considered to be the same substance; unless they differ significantly in properties with regard to efficacy." This means that known substance will be patentable provided that any one of the properties with regard to efficacy is significantly different. It is well recognized in Law and in science, that efficacy in a pharmaceutical substance is the result of several different factors and is best assesses through comprehensive clinical data, pharmaco-dynamic & pharmaco-kinetic studies and toxicity studies and submitted reference of different documents with few specific pages of each eg. Scoll. A waldman "does potency predict clinical efficacy ; strom et.al pharmacoepi dermatology, Goodman & Gilemans "The pharmaceutical basis of therapeutics," Muson et.al 'principal of pharmacology' etc. in support of their submission . That efficacy is to be assessed on the basis of several different parameters and not mere clinical efficacy. The applicant argued that above said literature reference clearly establish that efficacy of a molecule is a function of bio-availability, stability, activity, toxicity, drug interaction etc. The polymorph B claimed in the present invention in particular more stable than polymorph A. This enhanced stability of polymorph B enabled to provide stable solid oral doses form with proven safety & efficacy as evidence in example 6.

The opponent argued that revised claims 3 to 5 could be allowed if the feature of claim 4 is included in to claim 3. To that applicant said if the Learned Controller feels necessary, may consider it.

In respect of insufficiency the applicant argued that the specification provide clear guidance to a person skilled in the art to work the invention. In this regard the attention of controller is drawn to the para bridging page 6 & 7 of the specification which fully support the present claims.

After completing the argument in respect of clarification letter, the applicant reverted back to the main written statement of the opponent & argued that the opponent during the hearing informed that they are withdrawing the grounds of anticipation & obviousness in view of the revised claims filed by the applicant with reply statements, consequently the applicant has decided not to present any argument against these grounds.

Again in respect of objection under section 3(d) the applicant submitted that the application of section 3(d) would be inappropriate in the present case since the section was introduced into the Patent Act after the filing of the application. Nevertheless at the outset opposition in the present case under section 3(d) is not valid as section 3(d) makes it clear that efficacy is not mere clinical efficacy and that if a new form shows any improvement in any of the properties relating to efficacy it would be patentable. In the present case polymorph B is thermodynamically stable and in particular more stable than polymorph A or a mixture of polymorph B plus polymorph A and successfully used in human clinical trial as disclosed in example 6 of the specification. The enhanced stability of polymorph B enabled to provide a stable solid oral dosage with proven efficacy & safety as evidenced in example 6. Further they repeated their argument which they pleaded against the objection raised by the opponent in respect of clarification letter which I don't wish to repeat again.

In respect of insufficiency of disclosure applicant gave the same reply as given in respect of clarification letter of 1st Aug.,2008.

Now before I give my opinion in respect of these ground raised & contested by the parties, it is pertinent to mention that a week before the scheduled hearing, the applicant submitted a clarification letter dated 18th Aug.,2008. In a representation under section 25(1), the rule 55 does not provide any provision for any submission of documents once the written statement by opponent & reply statement by the applicants are submitted within the stipulated period. However in absence of any specific prohibition & in the interest of providing a fair opportunity to the applicant I have taken

the document on record and allowed for argument on that clarification letter. I also allowed the opponent to reply in their written argument on any matter raised in the clarification letter which they could not properly plead due to the lesser time available to them.

During hearing the opponent informed that they are dropping the grounds of anticipation and the inventive step in view of the amended claims filed by the applicant. However they submitted that the pleading under the said ground consist of factual submission which were maintained for the appreciation of the pleading under the other grounds.

The two grounds on which the opponent argued are" not an invention under section 3(d)" and "insufficiency of description." Because of the clarification letter submitted by the applicant, it appears that the applicant wanted to plead their invention to be a selection invention. In the reply statement vide para 9.3, stated that the prior art document US 5747498 (Indian Patent No. 196774) certainly does not contain a direct and unambiguous disclosure of polymorph B free from polymorph A as claimed in the present invention. While the US 51747498 patent teaches the synthesis and crystallization of N-(3-ethylphenyl) 6,7-Bis-(2-methoxyethoxy) –4-quenazolainine monohydrochloride,. There is no indication in the US'498 patent that there are different polymorph of the hydrochloride salt. But in the clarification letter of dated 18th Aug.,2008, the applicant submitted vide paragraph 1, that the US '498 is for the main compound Erlotinib hydrochloride which include all possible polymorphs of the main compound known or unknown. It appears that the applicant in their reply statement submitted the same argument which they put forwarded in USPTO during prosecution vide page 14 of annexure I Para 2 indicates "--------the word polymorph does not appear in the US'498 patent. The process of example 20 of the US'498 patent is not the same as the process described by the subject application for preparing claimed polymorph B". But in the clarification letter they have made a somersault sort of thing, and pleaded that the Patent '498 includes all polymorphs known or unknown. The

opponent inferred that the applicant is keen to take refuge under selection patent.

Although during the hearing applicant did not stress for selection patent and pleaded that applicant has tried to provide additional information vide para 3,4 & 6 of the clarification letter dated 18th Aug.,2008, about the polymorph and clarified how the present invention satisfy the requirement of section 3(d). It is pertinent to note that whether the applicant try to claim selection patent or prove that the requirement under section 3(d) is satisfied, in both cases the applicant is required to prove beyond doubt to show unexpected surprising benefits or efficacies related to the polymorph. Therefore point before me for consideration is whether the present invention provide sufficient proof that it contains unexpected or surprising benefit not conceived or motivated by the prior art and there is a substantial improvement in the known efficacy of the present invention of polymorph B compared to the prior art compound. Here it is essential to find out what is the known efficacy. In this regard I will rely upon the relevant passage of the judgment dated 6th Aug.,2007 in WP 24760/06 passed by the Hon'ble High Court of judicature at Madras in the case of Novartis AG Vs Union of India & others.Although the case is under appeal in the higher court the interpretation of the words 'therapeutic efficacy' ,arrived at by the Hon'ble court appears very reasonable. The relevant passage "-----***As we under stand the amended section, it only declares that the very discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of the substance, will not be treated as invention.***

The position therefore is, if the discovery of a new form of a known substance must be treated as invention, then the patent application should show that the substance so discovered has a better therapeutic effect. Dorland's medical dictionary define the expression 'efficacy in the field of pharmacology as 'the ability of a drug to

produce desired therapeutic effect and efficacy is independent of potency of drug.

Dictionary meaning of 'therapeutic' is healing the disease having a good effect on the body. Going by the meaning of the word 'efficacy' & therapeutic' extracted above, what the patent application is expected to show is, how effective the new discovery made would be in healing a disease/having a good effect on the body. In other word the patent applicant is definitely aware as to what is the therapeutic effect of the drug for which he had already got a patent and what is the difference between the therapeutic effect of the patented drug and the drug in respect of which patent is asked for .

Therefore it is a simple exercise of- though preceding by research. We state for any patent application to place on record what is the therapeutic effect/efficacy of a known substance and what is the enhancement in that known efficacy---------. In our opinion, the explanation (under section 3(d) would come in aid only to understand what is meant by the expression, "resulting in the enhancement of a known efficacy' in the amended section and therefore we have no doubt at all that the explanation would operate only when discovery is made in the pharmacological field."

From the above it is clear that the efficacy required under section 3(d) is therapeutic efficacy i.e. healing of disease/good effect on body. Applicant has submitted that under section 3(d) a new form of a known substance will be patentable provided that any one properly with regard to efficacy in significantly improved.The applicant further argued that in pharmaceutical substance the efficacy is the result of several different factors assessed through comprehensive clinical, pharmaco-dynamics & pharmaco-kinetic and toxicity studies. they referred to some document they relied upon and argued that, it establishes that efficacy of molecule is a function of bioavailablity, stability, activity, toxicity, drug interaction etc. I agree with the applicant's opinion that therapeutic efficacy includes many

parameters including some of these mentioned by the applicant but the law requires the significant enhancement in the therapeutic efficacy. Where is that efficacy shown in the body. In the context of the present invention the applicant pleaded that the polymorph B of claim 1 & 2 is thermodynamically stable & more stable than polymorph A , enabling preparation in a solid oral doses form and that is why it is more efficacious. First of all the stability may not lead to efficacy because bioavailability may not necessarily lead to achievement of desired effect. In the body of specification no such data has been provided or no expert opinion submitted during hearing etc. to prove more bioavailabilty & better desired effect compared to the prior art form. In other word whether the extra bioavailability due to the stability of the form alleged is able to influence the pharmacokinetics parameters such as absorption, distribution, metabolism & excretion without any undesired adverse effects and lead to clinical disease improvement or therapeutically efficacious or the stability of form is merely with respect to higher melting point which is desirable for manufacturer for the preparation of stable solid ordal doses form. The applicant has completely failed to provide any comparative data with respect to the prior art of any therapeutic efficacy either in the body of the specification or any other evidence & expert opinion thereon during the opposition prosecution period. Therefore the stability is for enabling manufacture of stable solid oral doses form providing a new form of drug administration in addition to the prevailing forms , the improvement brought about fails to qualify the enhanced therapeutic efficacy condition under section 3(d).

It is well recognized in the pharmaceutical field that many solids exhibits polymorphism which is frequently defined as the ability of the substance to exist as two or more crystalline phases that have different arrangement or conformation of the molecule in the crystal lattice (US pharmacopoeia). It is also well recognized in the art that the different polymorph will display different physical properties such as X-Ray diffraction, melting point, solubilites etc. The present invention are drawn to

the same pure substance as the prior art and that the only difference is the different arrangements and/or different conformations of the molecule. A mere difference in physical property is a well known conventional variation of the same pure substance not showing an unobvious properties. Therefore the changes alleged by the applicant is in the physical properties and not in the therapeutic efficacy. I therefore conclude that the instant invention claim 1&2 are not patentable under section 3(d) of the Patent (Amendment) Act.

Regarding insufficiency of description I agree to a large extent with the opponent that the applicant has failed to provide sufficient data to substantiate their claim for patent. There is no comparative data compared to prior art US'498 to show any enhancement in the therapeutic efficacy of the polymorph B. Even the stability etc. and bioavailability they claimed , no data is provided or compared their value with the prior art US'498 compound. The therapeutic effective amounts are without specific reference to the condition and the dosage form given is 0.001 to 100 mg/kg/day for various type of cancer as diverse as brain, squalors all, bladder, gastric, pangenetic, breast, head, neck etc, leaving the skilled person in the art to do extensive experimentation. The claim of applicant's invention could have been much stronger with those disclosure.

In respect of claim 6 i.e the pharmaceutical composition for solid oral administration containing the crystalline polymorph B as claimed in claim 1, is also not allowed as the compound used in the composition has not been allowed for reason mentioned above. The pharmaceutical composition comprises conventional carrier, excepient, dilerent etc. known in the art. There is nothing in the composition which is novel or inventive .

In respect of process patent, the claim 3 of the present invention provides for recrystallization of the M-(3-ethynlyphenyl) –6,7-bis(2-methoxyethoxy) - 4 - quinazolenamine hydrochloride using solvent alcohol. On page 22 of the specification vide para 3 provides a method of preparing polymorph B of the N-(3-ethynylphenyl) –6,7-bis(2-methoxyethoxy)-4-

quinazolinamine which comprises recrystallization with a solvent comprising water and alcohol . The example 4. of the present application uses the solvent as a mixture of water & alcohol . Therefore claim 3 and claim 4 has to be suitability merged in one claim. The applicant during the hearing agreed to merge the claim 3 & 4.

I therefore conclude that the claim 1 and 2 which is polymorph B free from polymorph A and the composition claim 6 the present invention are not allowed under section 3(d) of the Patent Act. 2005 and insufficiency of disclosure.

The process claim 4 of the present application is to be suitably merged with claim 3 to make it claim 1 and claim 5 to be renumbered as claim 2. The applicant is directed to submit the two amended claims as process claim, explained above, with in a period of one moth from the date of issue of this decision for its allowance.

The application stand disposed with no cost to either party.

Dated this 15th day of December, 2008.

S. K. ROY
Asstt. Controller of Patents & Design

Copy to:- (1)M/S De PENNING & De PENNING
120-Velachery Main Road
GUINDY, CHENNAIi-600 032
(2) M/S Majumdar & C0mpany
5,Harish Mukherjee Road
KOLKATA-700 025