IN THE HIGH COURT OF JUDICATURE AT MADRAS

(SPECIAL ORIGINAL JURISDICTION)

W.P. NO. OF 2006

Novartis AG
Schwarzwaldalle 215
4058 Basel, and
Lichstrasse 35,
4002 Basel,
Switzerland, rep by Mr. power of Attorney
Holder Ranjna Mehta Dutt ... Petitioner

Versus

1. Union of India
through the Secretary, Department of Industry,
Ministry of Industry and commerce
Udyog Bhavan, New Delhi
Rep. Asst. Controller of Patents & Designs, Through the Patent Office, Intellectual Property Rights Building, G.S.T. Road, Guindy, Chennai-32.

2. The Controller General of Patents & Designs
Through the Patent Office
Intellectual Property Rights Building
G.S.T. Road, Guindy
Chennai-600 032

3. M/s Cancer Patient Aid Association, India
5, Malhotra House, Opp. G.P.O.,
Mumbai
400 001

.....Respondents

AFFIDAVIT FILED ON BEHALF OF THE PETITIONER

I, Ranjna Mehta Dutt, W/o Mr. Dinesh Kumar Dutt, Hindu, aged about 36 years, working at Remfry House at the Millennium Plaza, Sector 27, Gurgaon 122 022/Haryana now temporarily come down to Chennai do hereby solemnly and sincerely affirm and state as follows:

1. I am the Power of Attorney holder for the Petitioner herein. I am authorised to swear to this Affidavit on behalf of the Petitioner herein. I am well acquainted with the facts and circumstances of the case stated hereunder. I know the facts of the case from the records maintained in the ordinary course of business by the Petitioner. The Petitioner has not filed any other Writ Petition seeking for the same relief.

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2. The Petitioner conducts its business in India through Novartis India Ltd. Sandoz House, Dr. Annie Besant Road, Worli, Mumbai - 400 018 which is responsible for carrying on the manufacture, importation, sale and distribution in India of the products of the Petitioner.

3. This writ is being filed against the impugned order dated January 25, 2006 passed by the Asst. Controller of Patents and Designs, Chennai Patent Office, in pre-grant opposition proceedings filed by Respondent No.3 against the Petitioner's patent application No.1602/MAS/1998 for the beta crystalline form of imatinib mesylate sold under the brandname Gleevec/Glivec. The patent application has been rejected, *inter alia*, on account of Section 3(d) of the Patents Act, 1970 as amended by the Patents (Amendment) Act, 2005. The Petitioner is advised that the said provision is unconstitutional and against the provisions of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organisation to which India is a signatory. The Petitioner has challenged the said provision in a separate writ before this Hon'ble Court. The present writ concerns itself with the merits of the case and other aspects of the impugned order.

4. The petitioner has approached this Hon'ble court under Article 226 of the Constitution since the statute (The Patents Act, 1970) gives no remedy at all like that of an appeal from the decision of the Assistant Controller of Patents rejecting the patent application. Only a review is provided to the same authority. In these circumstances, the Petitioner has no other remedy against the order dated January 25, 2006 except approaching this Hon'ble court under its writ jurisdiction under Article 226 of the Constitution of India.

5. The Asst. Controller, without taking into consideration all materials and submissions placed by the Petitioner on record erroneously refused to proceed with the application for the grant of patent filed by the Petitioner. The grounds on which the Asst. Controller has relied upon are as follows:

- Section 3(d) holding that the subject compound did not differ significantly in properties with regard to efficacy as compared to the known compound despite recording that there was a 30% increase in bio-availability of the subject compound over the known substance.

- Anticipation by prior publication- i.e. the subject compound is already disclosed in public documents thereby destroying the novelty of the invention.

- Obviousness- The Asst. Controller has held that the subject compound is obvious, 'the naturally occurring form' and that there is no inventive step.

- Priority- The Asst. Controller has also taken into account the fact that the subject application claims priority from a non-convention country at the relevant time (Switzerland). Without prejudice to the Petitioner's contentions in this regard, it is submitted that in the present case, claiming wrong priority is not fatal and cannot result in the rejection of the application, especially under a pre-grant representation under Section 25(1) of the Patents Act, as amended.

6. **BRIEF FACTUAL MATRIX**

1) The Petitioner is a leading Swiss pharmaceutical company engaged in the manufacture and sale of pharmaceutical and medicinal products including anti-cancer drugs. The name of the Petitioner, i.e., Novartis is derived from 'novaeartes', a latin word meaning "new skills". As the name suggests, the Petitioner is committed in its endeavour to research and develop innovative products. True to this commitment, the Petitioner invests substantial amount in research and development. In 2002, for example, the Novartis Group (to which the Petitioner belongs) spent over

US$ 2.8 billion (equal roughly to Rs. 12,500 crores) in research and development.

2) The Petitioner has to its credit several patented inventions including "the beta crystalline form of imatinib mesylate" (hereinafter referred to as "the subject compound") used in the treatment of myeloid leukaemia (blood cancer) and Gastro-Intestinal Stromal Tumours (GIST). This compound is the subject matter of the patent application in question which is entitled "Crystal Modification of a N-Phenyl-2-Pyrimidineamine Derivative, Processes for its manufacture and its use".

3) It is pertinent to mention that in the early 1990's, the Petitioner invented certain compounds known as "Pyrimidineamine Derivatives" and is the lawful owner of patents relating thereto which are valid and subsisting in many countries including Canada (Patent No. 2093203) filed on April 1, 1993 and granted on November 26, 2002 and the European Union (Patent No. EP0564409).

4) The Petitioner through its continued research and development was successful in inventing a particular form of methanesulfonic acid addition salt of a particular "Pyrimidineamine Derivative" ("imatinib Mesylate") in crystal form. The Petitioner invented two forms- Alpha and Beta- of which the Beta form stores better, is less hygroscopic, is easier to process and guarantees a constant quality of the final drug product. The Beta Crystalline form of Imatinib Mesylate also results in a higher bio-availability over the 1993 compound and, hence, differs significantly in properties with regard to efficacy.

5) The beta crystalline form of Imatinib Mesylate is being produced and sold on a commercial scale all over the world, including India, after conducting exhaustive clinical trials and obtaining all the requisite approvals in various countries. The exercise aforegoing involved a substantial investment of resources and time.

6) The Petitioner has been running a philanthropic programme known as Glivec International Patient Assistance Programme (GIPAP) in many countries related to the drug in question. GIPAP is one of the most generous and far reaching Patient Assistance Programme ever developed for a breakthrough cancer therapy. GIPAP was established in 2001 by the Petitioner's group to provide the subject drug at no cost to patients meeting certain criteria

7. Currently, Petitioner has its GIPAP in place in 83 countries of the world including India. It is pertinent to note that the total number of patients registered under GIPAP in India as on March 15, 2006 is 5151. In fact, the Petitioner gives 99% of Glivec free of cost under the GIPAP programme and sells only 1% of the drug.

8. The conditions for availing the GIPAP programme in India are: (i) the patient should have been properly diagnosed; (ii) the patient is earning less than Rs. 3,36,000/- per month; (iii) the patient does not have insurance cover; (iv) the patient is not being reimbursed by the employer or the Government and/or (v) the patient is otherwise not being compensated.

9. Having developed the new product from its own original invention of 1993, the Petitioner was naturally desirous of securing patent protection for it.

10. The Petitioner accordingly filed during the period 1997-2000 applications for a product patent for the said "beta crystalline form of Imatinib Mesylate" in over 50 countries and has already been granted patents in 35 of them.

11. It is further submitted that pending introduction of a full-fledged product patent regime, India was required to receive applications for product patents with respect to pharmaceuticals and agro-chemicals which were to be taken up for examination after December 31, 2004(Black/Mail Box Applications) and, in the interim, provide for protection by way of Exclusive Marketing Right (EMR)

in respect thereof to enable commercial exploitation of the product of the invention (Article 70(8) and (9) of the TRIPS Agreement). This was given effect to by the provisions of Chapter IVA (Exclusive Marketing Rights) of the Patents Act, 1970 (since repealed) brought in by the Patents (Amendment) Act, 1999 with retrospective effect from January 1, 1995.

12. The Petitioner after having complied with all the pre-conditions as mandated under chapter IV A of the Act filed an application with the Patent Office, Kolkata for the grant of an EMR for the subject compound.

13. The application for the grant of exclusive rights filed by the Petitioner was allowed by the Controller on receipt of a report by the Examiner mandated under section 24 A(1) of the Act.

14. After an exhaustive scrutiny and satisfying itself on all grounds, technical and legal, the Patent Office granted the Petitioner an EMR by a certificate EMR No. 2 dated November 10, 2003. The said certificate granted the Petitioner "an exclusive right to sell or distribute the beta-crystalline form of Imatinib Mesylate in its doses forms as approved by the appropriate authority in India". The EMR was intended to be in force for a maximum period of 5 years or until grant or rejection of Petitioner's product patent application (Black Box application) for the said drug whichever was earlier.

15. Pursuant to grant of the EMR and after the efforts of the Plaintiff to amicably resolve the matter with the infringing parties were not successful, in January 2004, the Petitioner filed suits for infringement (as provided by Section 24E read with Chapter XVIII of the Act) against nine entities in Madras and Bombay who were manufacturing, selling and distributing generic versions of the Petitioner's drug. The suits are pending adjudication.

16. In September, 2005 Respondent No.3 moved the Chennai Patent Office and filed a representation by way of pre-grant opposition under section 25(1) of the Act. In October, 2005 the Petitioner filed in the Chennai Patent Office a statement in reply along with evidence. The hearing was conducted on December 15, 2005 and the impugned order was passed on January 25, 2006. In view of the facts and circumstances of the case, the impugned order is vitiated on several factual and legal counts and is liable to be set aside by this Hon'ble Court in view of the grounds set out hereinafter.

17. Presuming, without admitting that Section 3(d) is valid, constitutional and does not contravene TRIPS, the Petitioner submits that it would be able to succeed on merits.

18. The order dated January 25, 2006 of the Asst. Controller is without any legal or factual basis/justification. The Asst. Controller has arrived at conclusions without citing the material relied upon or the reasoning adopted. The Asst. Controller has not followed the established principles of patent law or discussed the case law submitted by the Petitioner. The impugned order is vitiated on the ground of being cryptic and is against the principles of natural justice in that it has gravely prejudiced the rights of the Petitioner. The approach of the Asst. Controller goes against the principles of administrative law crystallised and reiterated by decisions of Hon'ble Supreme Court, in particular the Wednesbury principle that states as follows:

> Supreme Court Practice 1993 Volume, 1 Pages 849-850:
>
> "Wednesbury principle – A decision of a public authority will be liable to be quashed or otherwise dealt with by an appropriate order in judicial review proceedings where the Court concludes that the decision is such that no authority properly directing itself on the relevant law and acting reasonably could have reached it" (Associated Provincial Picture Houses Limited v. Wednesbury Corpn., (1948) 1 KB 223:(1947) 2 All ER 680 per Lord Greene M. R.)"

19. In other words, the Respondent No.2 has:

(a) exceeded its power;

(b) committed an error of law by not following the well laid-out principles of patent law and further by not justifying its conclusions through any factual or legal material;

(c) committed a breach of the rules of natural justice by not considering the submissions of the Petitioner;

(d) reached a decision which no reasonable Tribunal would have reached and

(e) abused its powers

20. The Petitioner submits that under the second proviso to Section 11(7) of the Patents Act, 1970, the rights of the patentee in respect of the applications made under sub-section 2 of Section 5 before the 1st day of January 2005 shall accrue from the date of grant of the patent. In the light of the above the Petitioner herein, has already lost 8 valuable years in the term of the patent. Any further delay is detrimental to the Petitioner's rights. It is therefore most urgent that the Petitioner approach this Hon'ble Court for the appropriate reliefs before the vacation court. Further the Petitioner was granted an Exclusive Marketing Right underlying the impugned patent application. The Petitioner also filed suits on the file of this Hon'ble Court to enforce the said EMR. The Petitioner had the benefit of interim orders in the said suits. On the rejection of the impugned patent application Cipla Limited has taken out an application to reject the suit. In the light of the said development, the Petitioner is in urgent need of interim orders before the vacation court.

Having no other equally effective and efficacious alternative legal remedy the petitioner has no other alternative but to approach this Hon'ble Court for appropriate reliefs under Article 226 of the Constitution of India on the following among other grounds

GROUNDS

A. Section 3(d)

(i) Because the Asst. Controller erred in concluding that the subject matter of the application was not patentable under Section 3(d) of the Act. It is humbly submitted that section 3(d), does not apply to the present case. The invention of beta crystalline form of imatinib mesylate is not a mere discovery of a new form of a known substance but a deliberate, inventive step involving human intervention. The subject compound is at two steps removed from the prior art, in effect, a two fold improvement over the prior art- (i) the imatinib free base has been chemically changed into a salt form (the methanesulfonic acid addition salt) and further (ii) to a particular crystal form of this salt i.e. the beta crystal form which has been made through ingenuity and human intervention.

(ii) Because the Asst. Controller failed to appreciate that the subject compound comes within the purview of the definition of 'invention' in Section 2(1)(j) of the Act which presupposes an element of human intervention and an informed/deliberate exercise to achieve an inventive end-result. In view of the above, it is submitted that since the subject compound fulfilled the criterion of being an 'invention', there was no occasion for the Asst. Controller to apply the provisions of Section 3(d) of the Act.

(iii) Assuming without admitting that that the subject compound is a mere discovery of a new form of a known substance, it is still patentable, as it has resulted in the enhancement of the known efficacy of the known substance i.e. imatinib free base, thereby making the subject compound more efficacious. It is submitted that the Asst. Controller ought to have appreciated the tests /clinical trials conducted by the applicant which admittedly showed 30% enhancement of bio-availability over the known substance.

(iv) The Asst. Controller ought to have been aware of the fact that in the field of pharmacology, generally speaking, any substance which has a variance of 20-25% bio-availability (either more or less) is not considered bio-equivalent with the other compound under comparison and therefore, cannot be termed the 'same substance'. This is well documented and a plethora of documents are available in the public domain.

(v) Because given the uniqueness of the 'efficacy' requirement, absence of a definition of efficacy and the constituents thereof and precedents from other jurisdictions, the Asst. Controller ought to have held 30% enhancement of bio-availability as a significant improvement with regard to efficacy.

(vi) Because the Asst. Controller has not cited any legal or factual reason/justification as to why 30% enhancement of bio-availability was not a significant improvement.

(vii) Because the Asst. Controller erroneously ignored the affidavit placed on record by the Petitioner that apart from having more bio-availability, the subject compound is far more suitable for the preparation and formation of drugs usable for the treatment of BCR-abl-positive cancer and tumours such as leukaemias (especially chronic myeloid leukaemia or GIST) compared to the free base. This fact should have been taken into consideration whilst deciding on the efficacy of the subject compound.

B. Because the Asst. Controller failed to take all the material/submissions of the Petitioner into consideration and dispose of them specifically. In view of this the order is bad in law and against the principles of natural justice.

C. **Not an Invention**

(i) Because the Asst. Controller, under law, ought to have considered the subject compound, Imatinib mesylate to be novel at the date of filing of the present patent application as long as there was no specific and

enabling disclosure of the subject matter in the prior art before the filing date.

(ii) Because the extension request in the US Patent and Trade Mark Office for Patent No. 5521184 which cites "imatinib mesylate" under trade mark "Gleevec" as the commercial embodiment of the patent, correctly relates to Imatinib mesylate as the claims of the 1993 patent embrace Imatinib mesylate without an 'enabling disclosure'. The said patent term extension certificate issued by the USPTO mentions Gleevec as the "product". It is submitted that the patent term extension certificate was issued by the USPTO years after the present patent application was filed. The certificate does not disclose more than what was disclosed in the 1993 patent for imatinib free base. In fact, a specific disclosure of a drug in a patent is no pre-condition for the issuance of a patent term extension certificate by the USPTO. The Petitioner submits that referring to the certificate is inadmissible and does not contribute in clarifying the question whether the claimed subject is anticipated by prior art.

At any rate, there is no mention of the i.e. the beta crystalline form of imatinib mesylate in the extension certificate, which remains novel and inventive and has not been disclosed in any patent, document or publication.

(iii) Because the Asst. Controller erroneously came to the conclusion that the subject compound is anticipated by prior publication. In fact, the subject specification in the beginning itself cites the 1993 compound as does the granted patents for beta crystalline form of imatinib mesylate in other jurisdictions. Further, it is submitted that the 1993 patent discloses Imatinib and a list of suitable pharmaceutically acceptable salts including mesylate. There is no example disclosing the preparation of Imatinib mesylate. In fact. the 1993 patent does not mention Imatinib mesylate at all. No procedure is described how to prepare the salt, what conditions to apply and what physical properties the obtained salt might have. Therefore, the the Petitioner submits that the salt is novel over the 1993

patent. Consequently, both the 1993 patent and the patent for beta crystalline form of imatinib mesylate are subsisting on the Register in those jurisdictions without any conflict. It is submitted that the Asst. Controller ought to have appreciated the contention of the Petitioner that there is a difference between disclosure and claim scope. Without prejudice to the above, a subject matter which is merely embraced by patent claims, but which is not being specifically disclosed in the prior art can still be validly claimed in a patent as a selection patent/invention.

(iv) Because the Asst. Controller erred in ignoring the contention of the Petitioner that in absence of Respondent No. 3 producing test results to prove that they have practised any claim/example of the 1993 US Patent No. 5521184 (hereinafter referred to as 1993 Patent) to produce the subject compound, as is required by law, the challenge to the subject application by Respondent No. 3 on the grounds of inherency or inevitability loses its base.

(v) Because the Asst. Controller was erroneous in placing reliance on reports submitted by IICT and IIT and coming to the conclusion that Respondent No. 3 had satisfactorily proved that the salt is inevitably obtained in the beta-form which is the most thermodynamically stable product. It is submitted that the tests conducted by IICT and IIT cannot be relied upon for making such erroneous observation as the beta seed crystal was present in the starting material before various solvents were added to the free base suspension. If such seed crystals were present, formation of the beta crystalline form would inevitably follow. It is pertinent to point out that the tests show that the end products were achieved by practising the methods described in the subject application and not through the prior art of the 1993 patent or otherwise.

(vi) Because the Asst. Controller erred in not appreciating the fact that the "Nature Medicine" paper submitted by Respondent No.3 mentions Imatinib mesylate, but does not disclose any procedure how to prepare Imatinib mesylate. In other words, the Nature Medicine paper does not

enable the manufacture of the mesylate. Therefore, the salt is novel and not anticipated by any of the cited documents.

(vii) Because the Asst. Controller ought to have appreciated that Respondent No. 3 failed to give any explanation to the contention of the Petitioner that if the methanesolfonic acid addition salt when produced exists only 'inherently' as a beta form and is the naturally occurring, stable form, then why and how had the Respondent managed to obtain marketing approval for the alpha form from the Drug Controller General of India. The present claims are drawn to the beta crystal form of Imatinib mesylate. As already disclosed in the present specification, Imatinib mesylate exists in different forms, for instance as described in the specification, the alpha and the beta crystal form. The beta crystal form is thermodynamically more stable at room temperature. Once the beta crystal form was invented, the isolation of the less stable alpha form required working under conditions of highest purity. As soon as seeds of the more stable beta crystal form are present, the alpha form can hardly be obtained. Before the stable beta form was invented by the Petitioner in 1997, it was possible to obtain the salt in less stable ("meta-stable") forms, such as the alpha form. If suitable purity conditions are met, the alpha form can be obtained also today.

(viii) Because the Asst. Controller failed to appreciate that other crystal forms of Imatinib mesylate were described in WO2004/106326 (published 09.12.04) of Hetero Drugs Limited (so-called H1 form and amorphous hydrate). This document shows that the crystalline form of imatinib mesylate that is obtained depends on the conditions chosen for the manufacture of the salt. Obtaining the beta crystal form is by no means inevitable as concluded by the Asst. Controller. As mentioned, distinct forms of Imatinib mesylate exist including the alpha, alpha 2, beta and H1 forms. The Asst. Controller has erred in concluding that obtaining the beta crystal form is inevitable, when the patent specification itself discloses two distinct forms, the alpha and the beta form

(ix) It is submitted that it is a settled proposition of law that any information as to the alleged invention given by any prior publication must be for the purpose of practical utility, equal to that given by the subsequent patent. The latter invention must be described in the earlier publication that is held to anticipate it in order to sustain the defence of anticipation. It is not enough to prove that an apparatus described in an earlier specification could have been used to produce this or that result. It must also be shown that the specifications contain clear and unmistakable directions so to use it. It must be shown that the public have been so presented with the invention that it is out of the power of any subsequent person to claim the invention as his own.

(x) It is further submitted that in regard to sufficiency of knowledge the courts have held that the earlier publication must give the requisite knowledge clearly, and it is not enough that it merely gives the means of attaining such knowledge. It must give sufficient information to a workman skilled in the particular art or craft in order to enable him to carry out the invention. The courts have gone to the extent of observing that even where the prior document and the subsequent specification are identical or nearly identical in language, it does not necessarily follow that the Court must conclude that the first is an anticipation of the second.

D. **Obviousness**

(i) Because the Asst. Controller erroneously rejected the application of the Petitioner on the ground of obviousness. The Asst. Controller failed to take into consideration the fact that one can never predict that a specific beta crystal form exists. Specifically, there is no general teaching or suggestion in the prior art that would have allowed one to predict how to make the beta crystal form which could be achieved only by human intervention and ingenuity. As mentioned earlier, Imatinib mesylate exists in several forms including the alpha, alpha 2, beta and H1 form. No teaching or suggestion existed in any prior art document to identify and to anticipate the favorable properties or characteristics of the beta crystal

form of Imatinib mesylate prior to it being invented. Furthermore, when averring that the beta crystal form is inherently formed upon working the 1993 patent, the Asst. Controller has confused the concepts of novelty and obviousness. Inherent formation of the beta crystal form may be an argument against novelty, but not against an inventive step.

It is submitted that the 1993 patent only discloses the free base imatinib and does not disclose any salt thereof. In the subject application the Petitioner claimed a specific form of a specific salt of imatinib, imatinib mesylate, a compound which was not disclosed in the 1993 patent. It is clear from the description that there has been human intervention in the creation of the beta crystalline form of imatinib mesylate which is a novel product and not obvious to the person skilled in the art. It is submitted that the Asst. Controller ought to have appreciated the contention of the Petitioner that the 1993 free base compound does not, and cannot, exhibit polymorphism to yield the beta crystal form. Human intervention has to be present in order to produce the subject compound, imatinib mesylate, let alone the beta crystal form.

E. **Priority**

(i) Because the Asst. Controller erred in rejecting the application of the Petitioner on the ground that the subject application wrongly claims priority. It is submitted that in this case, the issue of priority cannot be taken as a ground for rejection of an application in pre grant opposition since it is not covered by Section 25(1) of the Act.

(ii) Without prejudice to the above, it is submitted that the Asst. Controller ought to have appreciated the contention of the Petitioner that priority date is a legal fiction designed to let the applicant claim a date from the basic/first filed application in a convention country so as to avoid anticipation by publication of the invention between the priority date and the filing date in India. It is submitted that in the present case the novelty of present invention remained intact since there had been no prior

publication anywhere in the world and the Swiss application was not published until 2003, i.e., until the patent was granted in that country.

F. **Other grounds**

(i) Because the Asst. Controller ought to have exercised his powers under section 77 (1) (a) of the Act for cross-examining the concerned personnel of IICT and IIT, especially when the said reports/tests were controverted by the Petitioner in cogent terms.

(ii) Because the Asst. Controller on the principle of comity failed to give due weight to the fact that in 35 countries, with strict and advanced regulatory regimes, patent has been granted for the subject compound. It is respectfully submitted that Respondent No. 3 has failed to discharge the burden to show that the 35 grants of patent were wrong.

(iii) Because the Asst. Controller erred in ignoring the contention of the Petitioner that no other manufacturer, including Respondent No. 3, could make the subject compound from the 1993 patent and the other companies had to wait for the commercial embodiment of the Petitioner's product in 2002, sold under the trade mark GLIVEC/GLEEVEC before they could launch their products in the market in 2003. In view of the above, the Asst. Controller was erroneous in rejecting subject application on the basis of anticipation and/or obviousness.

(iv). Because the amendments are contrary to the doctrine of legitimate expectation in that the product patent regime, as it now stands, is completely contrary to what had been envisaged in 1995 when filing of 'black-box' applications was commenced. It was legitimately expected that the provisions of TRIPS would be implemented in their letter and spirit and a uniform patent regime would be established in all WTO countries as was envisaged. However, there is now an uneven playing field wherein Indian applicants can file patent applications (and enforce patents) for subject matter which is now forbidden in India or is subject to conditions

outside of Article 27 of TRIPS. The Petitioner's subject application and indeed all other black box applications carry great economic worth and are vital to sustain the research and development in the industry so that innovative drugs can continue to be invented.

(v). Because the Asst. Controller failed to take all the material/submissions of the Petitioner into consideration and dispose of them specifically. In view of this the order is bad in law and against the principles of natural justice.

Under these circumstances it is prayed that this Hon'ble Court may be pleased to issue a WRIT OF CERTIORARIFIED MANDAMUS or any other writ, order or direction calling for the records pertaining to the impugned order dated January 25, 2006 passed by Respondent No. 2 in the application No. 1602/MAS/1998; and quash the same and consequently direct the Respondent No.2 to allow the Petitioner's patent application No. 1602/MAS/1998; and pass such further or other orders as this Hon'ble Court may deem fit and proper in the circumstances of the case and thus render justice.

Solemnly affirmed at Chennai
on this the 19th day of May 2006 Before me,
and signed his/her name in my
presence:

ADVOCATE:

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