IN THE SUPREME COURT OF INDIA

[Order XVI Rule 4(1)(a)]

CIVIL APPELLATE JURISDICTION

SPECIAL LEAVE PETITION

(Under Article 136 of the Constitution of India)

S.L.P. (CIVIL) No. .....OF 2011

POSITION OF PARTIES

	Before the IPAB	**In this Court**
BETWEEN		
M/s Cancer Patients Aid Association, India, Through its Director 5, Malhotra House, Opposite GPO, Mumbai 400 001.	Respondent No. 3	Petitioner
AND		
1. Union of India Through the Secretary Department of Industry, Ministry of Industry and Commerce, Udyog Bhavan, New Delhi.	Respondent No. 1	Proforma Respondent No. 1

2.	The Controller General General of Patents & Designs, Through the Patent Office, IPR Building, GST Road, Guindy, Chennai 600 032.	Respondent No. 2	Proforma Respondent No. 2
3.	Novarits AG Schwarzwaldalle 215, 4068 Basel and Lichstrsasse 35, 4002, Basel, Switzerland Represented by Ranjana Mehta Dutt Remfry House, Millennium Plaza, Sector 27, Gurgaon-122002 Haryana	Appellant	Contesting Respondent No. 3
4.	Natco Pharma Ltd. Through its Company Secretary & General Manager "Natco House", Road No. 2, Banjara Hills, Hyderabad 500 033.	Respondent No. 4	Proforma Respondent No. 4
5.	M/s Cipla Ltd., India, Through its Managing Director 289, Bellasis, Opposite Hotel Sahil,	Respondent No. 5	Proforma Respondent No. 5

	Mumbai Central East, Mumbai 400 008		
6.	M/s Ranbaxy Laboratories Ltd., India Through its Managing Director C/o M/s Ranbaxy Research Limited Plot No. 77B, Sector 18,Gurgaon 122 001, Haryana	Respondent No. 6	Proforma Respondent No. 6
7.	M/s Hetro Drugs Ltd., India Through its Managing Director H. No. 8-3-168/7/1, Erragada Hyderabad 500 018.	Respondent No. 7	Proforma Respondent No. 7
8.	Assistant Controller of Patents and Designs, Through the Patent Office, IPR Building, GST Road, Guindy, Chennai 600 032.	Respondent No. 8	Proforma Respondent No. 8

PETITION UNDER ARTICLE 136 OF THE CONSTITUTION OF INDIA

To,

The Hon'ble Chief Justice of India

And His Companion Judges of the

Supreme Court of India

The Special Leave Petition of the Petitioner most respectfully showeth:

1. The Petitioner above-named respectfully submits this petition seeking special leave to appeal against certain findings of the impugned order dated 26 June 2009 passed by the Hon'ble Intellectual Property Appellate Board (hereinafter referred to as the "IPAB") in TA/1-5/2007/PT/CH and Miscellaneous Petition Nos. 1–5 of 2007 in TA/1-5/2007/PT/CH and Miscellaneous Petition No. 33 of 2008 in TA/1/2007/PT/CH. Vide the impugned order, the Hon'ble IPAB erroneously held that the claims of Patent Application No. 1602/MAS/1998 (hereinafter referred to as the "subject patent application") satisfy the criteria of novelty and inventive step and that the subject patent application can rightly claim priority from Switzerland. The Respondent No. 3 herein has also filed Special Leave Petition (Civil) Nos. 20539–20549 of 2009 challenging the impugned order in which the Petitioner is Respondent No. 4. The aforementioned Special Leave Petitions have not yet been admitted. The Petitioner has objected to the maintainability of Special Leave Petition (Civil) Nos. 20539–20549 of 2009 filed against it as a challenge to the impugned order ordinarily lies to the Division Bench of the Hon'ble Madras High Court. Had the Respondent No. 3 filed a writ petition before the Hon'ble Madras High Court, the Petitioner would have been able to assail the findings in the impugned order assailed in this Special Leave Petition in its counter. In view of the fact that the Special Leave Petition is still pending before this Hon'ble Court, the Petitioner is constrained to file this Special Leave Petition before

this Hon'ble Court without prejudice to its contention that Special Leave Petition (Civil) Nos. 20539–20549 of 2009 filed by the Respondent No. 3 are not maintainable.

2. QUESTIONS OF LAW

The following questions of law arise for consideration by this Hon'ble Court:

I. Whether the notification dated 30.11.1998 notifying Switzerland as a convention country or the amendment to section 133 of the Patents Act, 2005 has a retrospective effect?

II. Whether the subject patent application could claim priority from a patent application filed in Switzerland, when Switzerland was not a convention country at the time the subject patent application was filed in India?

III. Whether the doctrine of enabling disclosure under novelty requires the prior art to disclose the exact characteristics or the exact method of preparing of the claimed compound?

IV. Whether the doctrine of inherent anticipation requires evidence that other forms of a particular molecule could not be formed?

V. Whether the standard of an uninventive man could be applied to the analysis of inventive step?

VI. Whether polymorphism of a compound ought to be disclosed in a prior art document before a claimed invention relating to polymorphic forms could be held to lack inventive step?

VII. Whether the doctrine of selection patents is applicable in India under patent law?

VIII. Whether the claims of the subject patent application could be held to be novel or possess inventive step or a valid selection patent?

IX. Whether the complete specification of the subject patent application supports an argument for selection patent?

X. Whether data provided to establish enhanced efficacy under section 3(d) of the Patents Act, 1970 need not be statistically significant?

3. DECLARATION IN TERMS OF RULE 4(2)

The Petitioner states that no other petition seeking leave to appeal has been filed by the present Petitioner against the order dated 26 June 2009 of the Respondent No. 9 herein.

4. DECLARATION IN TERMS OF RULE 6

The Annexures P-1toP-3 produced along with Special Leave Petition are true and correct copies of the pleadings/documents which formed part of the records of the case in the courts below against whose orders the leave to appeal is sought for in the petition.

5. GROUNDS

The Petitioner is filing this Special Leave Petition on the following grounds, amongst others, which are taken without prejudice to one another:

I. WRONG CLAIMING OF PRIORITY

A. The Hon'ble IPAB failed to consider and appreciate that the Respondent No. 3 wrongly claimed priority date and that the subject patent application could not be considered to be a convention country application.

(i) That, on 17 July 1998, Novartis AG filed a convention country application in India under section 135 of the Patents Act, 1970, which was allotted Application No. 1602/MAS/1998, claiming priority from a patent application filed in Switzerland on 18 July 1997. Both these patent applications related to the beta-crystalline form of imatinib mesylate.

(ii) That, at the time the subject patent application was filed in India, section 133 of the Patents Act, 1970 required the Central Government to notify, in the Official Gazette, countries which provided reciprocity as convention countries.

(iii) That, as on 17 July 1998, Switzerland had not been recognised as a convention country as recognised by India.

(iv) That Switzerland was notified as a convention country in India only in November 1998, well after the subject patent application was filed in India.

(v) That the said notification does not have retrospective effect.

(vi) That the amendment to section 133 of the Patents Act, 1970 in 2005 does not apply retrospectively.

(vii) That it is an established position of law that amendments to a law cannot have retrospective effect unless they have been specifically made to apply retrospectively. This is amplified by section 6 of the General Clauses Act, 1897.

(viii) That, therefore, the present application cannot claim priority from Switzerland.

B. The Hon'ble IPAB erred, inter alia, in holding that the subject patent application rightly claimed priority and in:

(i) Observing that convention priority date ought not to be decided according to the old and unamended law, but on the basis of the amended section 133 of the Patents Act, 1970.

(ii) Holding that the Respondent No. 3 was fully justified and entitled to get the convention priority date of 18 July 1997 under the amended section 133 of the Patents Act, 1970.

(iii) Holding that that the provisions of section 6 of the General Clauses Act, 1897 did not apply to the present as the original Act, i.e. Patents Act, 1970, had not been repealed.

(iv) Reversing the Respondent No. 8's finding on the issue of priority.

II. LACK OF NOVELTY

A. The Hon'ble IPAB failed to consider and appreciate that the claims of the subject patent application do not satisfy the test of novelty.

(i) That the Respondent No. 8 held that US 55211184 (1993) (hereinafter referred to as "the Zimmerman patent (1993)") disclosed imatinib mesylate, and that the salt could be obtained in a customary manner.

(ii) That the Zimmerman patent (1993) claimed the imatinib free base and all pharmaceutically acceptable salts thereof. It specifically disclosed the methane sulphonate acid addition salt of imatinib (hereinafter referred to as "imatinib mesylate") and stated that they could be prepared in accordance with processes known per se.

(iii) That the claims of the alleged invention was explicitly disclosed in at least four other documents published between 1996 and 1997, i.e. Buchdunger, et al in "Inhibition of the Abl-Protein-Tyrosine Kinase in Vitro and in Vivo by a 2-Phenylaminopyrimidine derivative", Cancer Research 56, 1 January 1996, 100–104; C. Gambacorti-Passerini, et al, "Inhibition of the ABL Kinase Activity Blocks the Proliferation of BCR/ABL+ Leukemic Cells and Induces Apoptosis", Blood Cells, Molecules and Diseases (1997) 23 (19) Oct 15: 380–394; Deninger, et al, "The Tyrosine Kinase Inhibitor CGP57148B Selectively

Inhibits the Growth of BCR-ABL-Positive Cells", Blood, vol 90, no. 9, 1 November 1997, 3691–3698; and Carroll, et al, "CGP 57148, a Tyrosine Kinase Inhibitor, inhibits the growth of cells expressing BCR-ABL, TEL-ABL, and TEL-PGDFR Fusion Proteins", Blood, vol 90, no. 12, 15 December 1997, 4947–4952.

(iv) That it is an established position of law that a disclosure is enabling if it is sufficient in itself to enable the ordinary skilled man, armed with common general knowledge of the art, to perform the subject matter of the invention by using ordinary methods of trial and error, which involve no inventive step.

(v) That, given the disclosure of the imatinib free base in the Zimmermann patent (1993) along with the specific identification of methanesulfonic acid as a candidate to form a pharmaceutically acceptable salt and other relevant prior art cited by the Petitioner, the Zimmerman patent (1993) provides ample information for one skilled in the art to produce imatinib mesylate.

(vi) That, under the doctrine of inherent anticipation, where there are multiple polymorphs of a given compound, and the method described in the first patent for a specific form inevitably and inherently results in the production of even trace amounts of the later polymorphic form, the later polymorph is deemed to be inherently anticipated

(vii) That the studies conducted by the Indian Institute of Technology (IIT), Delhi, and Indian Institute of Chemical Technology (IICT), Hyderabad, submitted by the Respondent No. 4 and which are part of the common record, show that using a variety of methods, the beta-crystalline form of imtainib mesylate was invariably produced.

(viii) That the Respondent No. 8 had sufficient evidence before it to conclude that at least in certain conditions, the beta-crystalline form of imatinib mesylate was inherently formed from practicing conventional methods of producing the mesylate salt.

(ix) That there was no need to show that the beta-crystalline form of imatinib mesylate was always produced, or that the alpha-form or other forms of imatinib mesylate could not be formed; as long as the beta-crystalline of imatinib mesylate was formed inherently from practicing the imatinib mesylate salt.

(x) That there were sufficient grounds to establish inherent anticipation.

(xi) That, on the presentation of scientific evidence to show inherency, the burden shifted to the patent applicant, i.e. the Respondent No. 3 in this case, to disprove the inherency.

(xii) That the Respondent No. 3 had not disproved the inherent anticipation of the beta-crystalline form of imtainib mesylate.

(xiii) That the disclosures in the Zimmerman patent (1993) and other articles referred to above, individually, constituted an enabling disclosure of the beta-crystalline form of imatinib mesylate.

(xiv) That, in light of the above, the claims of the subject patent application did not satisfy the test of novelty.

B. The Hon'ble IPAB erred, inter alia, in holding that the claims of the subject patent application are novel and in:

(i) Observing that the Zimmerman patent (1993) had not given any working example as to how a salt of imatinib could made including of imatinib mesylate in as much as the Zimmerman patent (1993) specifically disclosed "imatinib mesylate" and stated that it could be prepared in accordance with processes known per se, and a complete specific disclosure of the method of preparation of imatinib mesylate is not required.

(ii) Holding that the disclosure given in the Zimmermann patent (1993) could at best lead to the preparation of imatinib mesylate as the exact preparation of any salt had not been disclosed therein.

(iii) Observing that no concrete method had been disclosed in the prior art to prepare even imatinib mesylate.

(iv) Observing that none of the documents cited by Respondent No. 4, either individually or collectively, disclosed or gave any idea of any specific crystalline form of imatinib mesylate as a substance, leave apart

the beta crystalline form, any pharmaceutically composition containing the same or any process for making the said beta form, particularly after holding that CGP57148B disclosed in the prior art documents was the code name for the beta-crystalline form of imatinib mesylate.

(v) Observing that it would be an inventive effort to find out the exact process conditions to get a particular form, including that of the beta-crystalline form of imatinib mesylate.

(vi) Conflating the analysis of novelty and inventive step.

(vii) Observing that it could not be said with certainty that one would reach directly to beta-crystalline form of imatinib mesylate by a generally conventionally know prior art procedure.

(viii) Holding that there had been no prior exact conditions known in the art which could lead a skilled person in the art to prepare inevitably the beta-crystalline form of imtatinib mesylate.

(ix) Holding that no uninventive man could find out the conditions to reach the beta-crystalline form of imatinib mesylate before the priority date of the subject application.

(x) Holding that the IICT and IIT experiments did not conclusively prove that imatinib mesylate existed only in the beta-crystalline form.

(xi) Holding that IICT and IIT experiments getting only beta-crystalline form of imatinib mesylate did not prove that any process for converting imatinib to imatinib mesylate or practising conventional methods would inevitably lead to the beta-crystalline form of imatinib mesylate.

(xii) Holding that the IICT and IIT experiments did not prove without any doubt that practising conventional methods led to preparing imatinib mesylate only in the beta-crystalline form.

(xiii) Observing that a person skilled in the art could not predict the polymorphism or prepare the subject compound from the available disclosure therein, when the evidence on record clearly showed otherwise.

(xiv) Not applying the doctrine of inherent anticipation and holding that the Zimmermann patent (1993) or the information of imatinib mesylate as CGP57148B did not give any indication of polymorphism or any crystalline form, either individually or together, after holding that CGP57148B disclosed in the prior art documents was the code name for the beta-crystalline form of imatinib mesylate.

(xv) Holding that inherent anticipation fails when there are possibilities of formation of multiple forms and applying the same to the case at hand.

(xvi) Holding that when there is an existence of multiple polymorphic forms of imatinib mesylate, the question

of the burden of disproving the inherency by the Respondent No. 3-patent applicant did nor arise.

(xvii) Holding that the decision of the House of Lords in Synthon BV v. Smithkline Beecham plc (2005) IKHL 58 had no application to the case before it.

(xviii) Holding that, by using general knowledge in the art and by ordinary methods of trial and error, which involved no inventive step, no one could reach to the beta-crystalline form of imatinib mesylate before the priority date of the impugned application.

(xix) Holding that the beta-crystalline form of imatinib mesylate was not known or anticipated before the priority date of the impugned application, particularly after holding that CGP57148B disclosed in the prior art documents is the code name for the beta-crystalline form of imatinib mesylate.

(xx) Reversing the order of Respondent No. 8 on the ground of anticipation, particularly after holding that CGP57148B disclosed in the prior art documents was the code name for the beta-crystalline form of imatinib mesylate.

III. LACK OF INVENTIVE STEP

A. The Hon'ble IPAB failed to consider and appreciate that the claims of the subject patent application do not satisfy the requirement of inventive step.

(i) That, assuming without admitting that the prior art disclosures did not fully disclose the compound claimed in the subject patent application, the claims of the subject patent application do not meet the inventive step requirement laid down under the Patents Act, 1970.

(ii) That under section 2(1)(ja) of the Act, "inventive step" is defined as "a feature of an invention that involves technical advance as compared to the existing knowledge…and that makes the invention not obvious to a person skilled in the art" (emphasis supplied).

(iii) That a patent applicant would thus need to show that the claimed invention involves a technical advance as compared to the existing knowledge and that it is not obvious to a person skilled in the art.

(iv) That the extent of research or human intervention is not the criteria for determining whether or not a particular invention claimed is obvious to a person skilled in the art.

(v) That the Respondent No. 8 had held that it is obvious to obtain imatinib mesylate and the beta-crystalline form of imatinib mesylate is inherent and that there was nothing erroneous in this finding of the Respondent No. 8.

(vi) That, as of 1998, it was well known in the pharmaceutical field that the conversion of a lead

molecule into a pharmaceutically acceptable salt can result in numerous advantages, including improved dissolution rate and bioavailability. That several documents described the benefits of converting a base into a pharmaceutically acceptable salt [Gould, et al, Salt selection for basic drugs" International Journal of Pharmacuetics 33 (1986) 201-217] and described a procedure for discovering the ideal salt candidate [Morris, et al, "An integrated approach to the selection of optimal salt form for a new drug candidate," International Journal of Pharmacuetics 105 (1994) 209-217]. Thus, one ordinarily skilled in the art would have been well aware of the potential benefits of converting the free base imatinib into a pharmaceutically acceptable salt. Further, the use of methanesulfonic acid to obtain a pharmaceutically acceptable salt from a free base was known in the industry.

(vii) That it is obvious for a person skilled in the art to evaluate the crystal structure and changes in crystal structure and look for different forms with differing physical properties.

(viii) That it is expected that different polymorphic forms will have different physical properties, such as flow properties, hygroscopicity, etc.

(ix) That the beta-crystalline form of imatinib mesylate was obvious to a person skilled in the art and the

alleged discovery thereof constituted merely identifying the properties of imatinib mesylate in a given set of circumstances.

(x) That the beta-crystalline form of imatinib mesylate does not represent a technical advance.

(xi) That, therefore, the claims of the alleged invention lacked inventive step.

B. The Hon'ble IPAB erred, inter alia, in holding that the claims of the subject patent application possess inventive step and in:

(i) Applying the standard of an uninventive man to determine the criteria of inventive step.

(ii) Holding that an uninventive man had no magic formula to choose mesylate from the big list of salts given in the Zimmermann patent (1993), especially when it held that imatinib mesylate was a known substance as on the priority date.

(iii) Holding that polymorphism was not a general phenomenon of a salt.

(iv) Holding that no polymorphism could be predicted from imatinib mesylate from any prior art document.

(v) Holding that the phenomenon of polymorphism was not universal.

(vi) Holding that the existence of polymorphism has to be discovered by finding out its different forms by way

of research and human intervention and that this was done in the case before it.

(vii) Holding that no one could predict the possibility of existence of polymorphism in imatinib mesylate before the subject patent application.

(viii) Holding that there was no motivation by an uninventive man to try for finding out different polymorphic forms and their relative properties suitable for solid dosage formulation for cancer drug.

(ix) Holding that it was not possible for an uninventive man to discover and reach the beta-crystalline form of imatinib mesylate, or find its advantageous properties or to find a suitable process for its preparation or make a solid composition containing the said crystal form.

(x) Holding that there was at least one inventive step leading to the alleged discovery of beta-crytalline form of imatinib mesylate.

(xi) Holding that, without a thorough research, the discovery of the beta-crystalline form of imatinib mesylate could not have been possible.

(xii) Holding that the Appellant had made a technical advance as compared to the existing knowledge by way of demonstration of polymorphism, isolation, characterization of beta (and alpha) crystal forms of imatinib mesylate, identifying suitable properties in

the beta-crystalline form usable in the making of oral solid drug formulation for curing cancer.

(xiii) Disagreeing with the Respondent No. 4's contention that imatinib mesylate always existed in the crystal form named as the beta-crystalline form of imatinib mesylate.

(xiv) Applying the test of novelty to the analysis of inventive step and subsequently holding that the Respondent No. 4 had not submitted any evidence that prior to the subject patent application, any person other than the Respondent No. 3 had prepared imatinib mesylate and found it to be present only in the beta-crystalline form.

(xv) Holding that the reference to Pfizer v. Apotex Inc., 480 F. 3d 1348 (Fed. Cir. 2007) had no application to the case at hand.

(xvi) Holding that the Respondent No. 3 discovered a new form of imatinib within imatinib mesylate for which there as no prior hint or motivation for trial to a person skilled in the art.

(xvii) Holding that there was no evidence or document on record which gave any hint of possibility of polymorphism in imatinib mesylate, as this is not relevant to an analysis of inventive step.

(xviii) Observing that the Petitioner and other Respondents in the appeal before it presumed polymorphism in

imatinib mesylate and advanced their arguments accordingly.

(xix) Holding that it could not agree that the Respondent No. 3's alleged invention lacked inventive step.

(xx) Reversing the Respondent No. 8's decision on inventive step.

IV. NON-APPLICABILITY OF DOCTRINE OF SELECTION PATENTS

A. The Hon'ble IPAB failed to consider and appreciate that the common law doctrine of selection patents is not applicable in India.

(i) That the doctrine of selection patents is a common law doctrine.

(ii) That this doctrine is no longer applicable in India on account of the present statutory law.

(iii) That the Indian Patents and Designs Act, 1911 incorporated the definition of invention from the Patents and Designs Act, 1907 (United Kingdom). Section 93 of the Patents and Designs Act, 1907 (United Kingdom) defined an invention as meaning "any manner of new manufacture, the subject of letters patent and grant of privilege …, and includes an alleged invention". Section 2(8) of the Indian Patents and Designs Act, 1911 defined an invention as meaning "any manner of new manufacture and includes and improvement and an alleged invention".

It did not define novelty, inventive step or industrial application.

(iv) That the English courts, in 1930, then developed the doctrine of selection patents against this definition of an "invention".

(v) That, given the identical provisions of patent law, the Bombay High Court, in deciding F.H. & B. Corp. v. Unichem Laboratories, AIR 1969 Bom 255, applied the English common law doctrine of selection patents to the case at hand.

(vi) That, in 1970, Parliament enacted the Patents Act, 1970. The term "invention" was defined by section 2(1)(j) as meaning "any new and useful—(i) art, process, method or manner of manufacture; (ii) machine, apparatus or other article; (iii) substance produced by manufacture".

(vii) That, Section 3 of the Patents Act, 1970 sets out what are not inventions and in sub-section (d) excludes "the mere discovery of any new property or new use for a known substance …".

(viii) That, in 2002, the definition of invention in section 2(1)(j) of the Patents Act was amended to read as "invention means a new product or process involving an inventive step and capable of industrial application".

(ix) That, in 2005, the definition of inventive step was added by section 2(1) (ja) of the Patents Act, which

reads as "'inventive step' means a feature of an invention that involves a technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art".

(x) That amended section 2(1)(ja) and section 3(d) of the Patents Act, 1970, in fact, exclude and overrule the common law doctrine of selection patents.

(xi) That the mere showing of an added advantage or avoidance of a disadvantage is not sufficient to meet the requirement of inventive step in India. Assuming without admitting that such advantage or avoidance of disadvantage constitutes technical advance, a patent applicant would have to satisfy the Patent Controller that the alleged invention is not obvious to a person skilled in the art.

(xii) That section 3(d) of the Patents Act, 1970 explicitly excludes the patenting of discovery of a new property or a new use of a known substance. This clearly statutorily excludes the concept of selection patents.

(xiii) That, without prejudice to the above submission that the doctrine of selection patents is not applicable in India, in the present case, the Respondent No. 3's argument of a two-step improvement, i.e. from the free base to the mesylate and from the mesylate to the beta-crystal form, was fatal to the argument of selection patents.

(xiv) That, without prejudice to the Petitioner's contentions in respect of novelty and inventive step, if the Respondent No. 3's argument of a two-step invention were to be accepted, the Zimmerman patent (1993) disclosed only imatinib free base and suggested various possible salt candidates. Applying the doctrine of selection patents to this argument, only imatinib mesylate would be arrived from the various possible salt candidates. On the other hand, if the Zimmerman patent (1993) is held to disclose imatinib mesylate, then as per the Respondent No. 3's argument, it did not specifically disclose the possibility of existence of imatinib mesylate in various polymorphic forms, from which the selection of the beta-crystalline form could be made.

(xv) That, without prejudice to the above, if the doctrine of selection patents is applicable in India and is applicable to the case at hand, then it must be admitted that the polymorphic forms of imatinib mesylate are disclosed in the prior art documents.

(xvi) That the alleged invention could not succeed as a selection patent in India.

B. The Hon'ble IPAB erred, inter alia, in holding that selection patent is applicable in India and that the claims of the subject patent application constitute a valid selection and in:

(i) Holding that the establishment of inventive selection as a case of selection patent is equivalent to establishment of an inventive step including novelty.

(ii) Holding that it could not deny that there could not be any possibility under the Indian law, where the requirements of selection patents could not be fulfilled, for the grant of a patent in India where the inventive step could be demonstrated by way of an inventive selection.

(iii) Holding the complete specification contained a statement providing a primary ground for selection.

(iv) Holding that a valid selection of imatinib mesylate had been made from a big number of salts of imatinib from the Zimmermann patent (1993), when it simultaneously held that, as of the priority date, imatinib mesylate had already been disclosed and prepared and was in existence.

(v) Agreeing with the Respondent No. 3's argument that, after a painstaking research, it had identified imatinib mesylate and, within it, it had surprisingly found a crystalline form named as the beta-form which was also surprisingly discovered to possess very advantageous properties as disclosed in the specification.

(vi) Observing that the beta-crystalline form of imatinib mesylate was not known or disclosed or published anywhere,

(vii) Holding that the isolation of the beta-crystalline form, its characterisation by physico-chemical methods and particular utility as a cancer curing solid dosage formulation with good storage capacities and advatangeous properties were surprising, unexpected or unpredictable and could not be termed as mere verification.

(viii) Holding that the Respondent No. 3's subject patent application satisfied all the minimum requirements or conditions for determining a case of selection patent.

(ix) Holding that the Respondent No. 3 demonstrated inventive step not only by the classical way but also by way of selection.

V. REQUIREMENT OF STATISTICAL SIGNIFICANCE OF DATA PROVIDED

A. The Hon'ble IPAB failed to consider and appreciate that data submitted to prove efficacy should be statistically significant.

(i) That, without prejudice to the contention that bioavailability is not the same as efficacy and that efficacy is independent of bioavailability, the data on increased bioavailability submitted by the Respondent No. 3 could not have been relied upon as it was not statistically significant.

(ii) That the Respondent No. 8, in its counter affidavit filed before the Hon'ble Madras High Court in Writ

Petition No. 24754 of 2006, had stated that the increased bioavailability "may or may not be statistically significant".

(iii) That, for any data to be considered relevant, the data must be statistically significant ($p<0.05$). This is different from significance in efficacy. A difference in efficacy between two forms may be small, and thus not significant in terms of enhancing efficacy, but may, with a large enough sample size, be considered statistically significant. Likewise, a seemingly large difference in efficacy may prove not to be statistically significant because the sample size was too small, or the variance in the population too large.

(iv) That, in order to show significant enhancement of efficacy, the Respondent No. 3 had to show both significant enhancement and also that the difference is statistically significant.

(v) That the Respondent No. 3 had not provided raw data of the subject rats. Therefore, it was not possible to accurately calculate the statistical significance of the data.

(vi) That the data provided by the Respondent No. 3 in the "Study conducted in rats concerning the relative bioavailability of the free base and imatinib mesylate in the beta crystalline form after oral administration" was not statistically significant with respect to Cmax

(p = 0.3851). It was only the data pertaining to AUC (0-48) that was statistically significant (p = 0.0415).

(vii) That, for the purposes of bioavailability, both the AUC and Cmax parameters are relevant and ought to be statistically significant.

B. The Hon'ble IPAB erred, inter alia, in holding that data to meet the requirements of section 3(d) need not be statistically significant and in:

(i) Holding that it could not reject the data derived from the rat study submitted by the Petitioner on the doubt that the test data was not statistically significant.

(ii) Holding that patentability did not depend on whether the test data on the rat study was statistically significant.

6. GROUNDS FOR INTERIM RELIEF

No interim relief is prayed for.

7. MAIN PRAYERS

It is, therefore, most humbly prayed that this Hon'ble Court may be pleased to:

(i) Grant special leave to appeal against the order passed by the Intellectual Property Appellate Board dated 26 June 2009 in TA/1-5/2007/PT/CH and Miscellaneous Petition Nos. 1–5 of 2007 in TA/1-5/2007/PT/CH and Miscellaneous Petition No. 33

of 2008 in TA/1/2007/PT/CH in respect of its findings on novelty, inventive step and claiming of priority; and

(ii) Call for the records relating to TA/1-5/2007/PT/CH and Miscellaneous Petition Nos. 1–5 of 2007 in TA/1-5/2007/PT/CH and Miscellaneous Petition No. 33 of 2008 in TA/1/2007/PT/CH ;

(iii) Pass such other and further orders as this Hon'ble Court may deem fit in the facts and circumstances of the case.

8. INTERIM RELIEF

No interim relief is prayed for.

AND FOR THIS ACT OF KINDNESS, THE PETITIONER SHALL EVER PRAY

Drawn on: 16.03.2011 FILED BY:

Filed on: 19th March 2011

New Delhi (Chanchal Kr. Ganguli)

ADVOCATE FOR THE PETITIONER