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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 2009
With prayer for interim relief

POSITION OF PARTIES

	BEFORE THE IPAB	IN THIS COURT

BETWEEN

NOVARTIS AG
LICHSTRASSE 35,
4002, BASEL, SWITZERLAND,

REPRESENTED BY
RANJNA MEHTA DUTT
POWER OF ATTORNEY HOLDER

	Appellant	Petitioner
	in TA/001-005/2007/PT/CH	

AND

1)	UNION OF INDIA THROUGH THE SECRETARY, DEPARTMENT OF INDUSTRY, MINISTRY OF INDUSTRY AND COMMERCE, UDYOG BHAVAN, NEW DELHI	Respondent-1 in TA/001-005/2007/PT/CH	Respondent-1
2)	THE CONTROLLER GENERAL OF PATENTS & DESIGNS THROUGH THE PATENT OFFICE 'IPR BUILDING', G.S.T. ROAD, GUINDY, CHENNAI –600032	Respondent-2 in TA/001-005/2007/PT/CH	Respondent-2
3)	ASSISTANT CONTROLLER OF PATENTS & DESIGNS, PATENT OFFICE 'IPR BUILDING', G.S.T. ROAD, GUINDY, CHENNAI –600032	Respondent-4 in TA/001-005/2007/PT/CH	Respondent-3
4)	M/S CANCER PATIENT AID ASSOCIATION THROUGH ITS MNANGING DIRECTOR 5, MALHOTRA HOUSE, OPP: G.P.O., MUMBAI -400 001	Respondent-3 in TA/001/2007/PT/CH	Respondent-4
5)	NATCO PHARMA LTD.		

THROUGH ITS MNANGING DIRECTOR
'NATCO HOUSE'
ROAD NO: 2 BANJARA HILLS,
HYDERABAD-500 033. Respondent-3 Respondent-5
in TA/002/2007/PT/CH

6) CIPLA LTD
THROUGH ITS MNANGING DIRECTOR
289, BELLASIS,
OPP: HOTEL SAHIL, MUMBAI CENTRAL (E),
MUMBAI - 400 008 Respondent-3 Respondent-6
in TA/003/2007/PT/CH

7) RANBAXY LABORATORIES LTD.,
THROUTH ITS MNANGING DIRECTOR
C/O RANBAXY RESEARCH LIMITED
PLOT NO. 77 B, SECTOR-18,
GURGAON 122 001
HARYANA Respondent-3 Respondent-7
in TA/004/2007/PT/CH

8) HETERO DRUGS LTD.,
THROUGH ITS MNANGING DIRECTOR
H.NO. 8-3-168/7/1, ERRAGADA,
HYDERABAD-500 018. Respondent-3 Respondent-8
in TA/005/2007/PT/CH

ALL THE RESPONDENTS ARE CONTESTING RESPONDENTS

A 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 sheweth:-

MOST RESPECTFULLY SHOWETH:

1. The Petitioner above-named respectfully submits this petition seeking special leave to appeal against the impugned order dated June 26, 2009 passed by the Intellectual Property Appellate Board (IPAB) in respect of Misc. Petition nos. 1-5 of 2007 in TA/1-5/2007/PT/CH & Misc. Petition No.33 of 2008 in

TA/1/2007/PT/CH & TA/1-5/2007/PT/CH disposing of the appeals preferred by the Petitioner.

2. QUESTIONS OF LAW:

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

A. Whether the IPAB was right in rejecting the subject application of the Petitioner by applying the tenets of Section 3(d) of the Act?

B. Whether the IPAB was right in not appreciating the true import of Section 3(d) of the Act?

C. Whether the IPAB was right in defining the term "efficacy" appearing in Section 3(d) of the Act by limiting it to mean "therapeutic efficacy" in case of an invention relating to a pharmaceutical drug?

D. Whether the IPAB was right in giving a restrictive meaning to the term "efficacy" by relying upon the judgment by Madras High Court in case of *Novartis AG v Union of India* (2004) MLJ 1153 wherein the main issue before the Court was constitutional validity of Section 3(d) of the Act and the observation in relation to the term "efficacy" being "therapeutic efficacy" was a mere o*biter dicta*?

E. Whether, in absence of any guidelines as to what constitutes "enhanced efficacy" of a known substance, the IPAB was right in observing that enhanced bio-availability of the drug could not be a criteria to determine the "therapeutic efficacy" of a drug especially when the Petitioner has placed reliance on certain scientific literature establishing otherwise and which the IPAB chose to ignore?

F. Whether the IPAB was right in applying the provisions of 3(b) of the Act which by no stretch of imagination were applicable to the present case?

G. Whether the IPAB was right in rejecting the subject application under Section 3(b) of the Act considering that none of the Respondents has raised this as a ground of opposition either before the Patent Office or before the IPAB?

H. Whether the IPAB was right in observing that the Petitioner was under an obligation to mention relevant closest prior art in the patent specification, considering no such duty was cast upon it under Section 10(4) of the Act at the time of filing the application or otherwise?

I. Whether the IPAB was right in observing that for pharmaceutical products Section 3(d) mandates higher standard of inventive step inasmuch as once the IPAB had upheld the novelty, inventive step and industrial applicability of the Petitioner's drug, it qualified as an invention within the meaning of section 2(1)(j) of the Act and the Act did not prescribe a higher standard of inventive step for pharmaceutical products?

J. Whether the IPAB was right in rejecting the subject application on the ground of higher pricing of the drug in question by erroneously applying provisions of Section 3(b) of the Act which has no relation whatsoever thereto?

K. Whether the IPAB was right in observing that efficacy data ought to have been part of the patent specification which was impossible inasmuch as Section 3(d) of the Act as it stands today in the statute book was not existent at the time of filing the subject application?

L. Whether the IPAB was right in holding that 30% more bioavailability demonstrated by the Petitioner's drug was of no consequence in deciding the patentability of the invention under section 3(d) and consequently, denying product patent to the Petitioner?

M. Whether the IPAB was right in not appreciating the tests /clinical trials conducted by the Petitioner which admittedly showed 30% enhancement of bio-availability of the Petitioner's drug over the "known substance"?

N. Whether, given the uniqueness of the 'efficacy' requirement for the grant of a patent in India, absence of a definition of "efficacy" in the Act and precedents from other jurisdictions, the IPAB was right in not holding that 30% enhancement of bio-availability was significant in properties with regard to efficacy?

O. Whether, given the uniqueness of the 'efficacy' requirement for the grant of a patent in India, absence of a definition of "efficacy" in the Act and precedents from other jurisdictions, the IPAB was right in not appreciating the affidavits deposed by technical experts?

P. Whether the IPAB has rightly not appreciated the fact that in absence of any guidelines as to what would constitute "efficacy", significant or otherwise, Section 3(d), will give unbridled power to Respondent No. 3 to decide on the patentability of a product?

As stated above, it may be emphasized here that the present case is a glaring example of the IPAB and Respondent No. 3 of rejecting arbitrarily the subject application in respect of the product.

3. DECLARATION IN TERMS OF RULE 4(21)

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The Petitioner states that no other petition seeking leave to appeal has been filed by it against the impugned order dated June 26, 2009 passed by the Intellectual Property Appellate Board (IPAB) in respect of Misc. Petition nos. 1-5 of 2007 in TA/1-5/2007/PT/CH & Misc. Petition No.33 of 2008 in TA/1/2007/PT/CH & TA/1-5/2007/PT/CH

4. DECLARATION IN TERMS OF RULE 6

The annexure P1 produced alongwith the special leave petition are true copies of the pleadings/documents which formed part of the records of the case in the Court/Tribunal against whose order the leave to appeal is sought by this petition.

5. GROUNDS

Leave to appeal is sought for on the following grounds:

Being aggrieved by the impugned order passed by the IPAB, the Petitioner hereby applies for Special Leave to Appeal on the following, amongst other, grounds which are taken without prejudice to each other:

A) Because the IPAB while rightly reversing the decision of Respondent No. 3 with respect to novelty, inventive step, priority date and refusal of Petitioner's subject application under section 3(d) in regard to process claims, erroneously upheld the said decision on refusal under section 3(d) with respect to its product claims, inasmuch as the subject application of the Petitioner does not fall within the prohibition contemplated by Section 3(d) of the Act.

B) Because the IPAB failed to appreciate the true import and connotations of section3(d) which is reproduced below:

Section 3 What are not inventions.- The following are not inventions within the meaning of this Act,-"

Clause (d):

"the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process result in a new product or employs at least one new reactant.

Explanation: For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivative of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

C) Because the IPAB failed to appreciate that reference to the term "efficacy" is made twice in Section 3(d) of the Act. On one hand, a known substance shall have a "known efficacy" and on the other, the new form of the "known substance" shall be considered to be the same substance unless it differs "significantly in properties with regard to efficacy". It was concluded by the IPAB that Imatinib as well as Imatinib Mesylate had been disclosed in the US Patent Number 5521184 (hereinafter referred to as "the 1993 patent") but failed to appreciate

that the 1993 patent merely disclosed data obtained in cells and rodents and observed that the enhanced efficacy had to be demonstrated in clinical studies.

D) Because the IPAB has not appreciated that "efficacy" needs to have the same meaning when applying 3(d) for the known substance and its new form. It either means preclinical or clinical efficacy or both. It was wrongly alluded by the IPAB that the Petitioner had to conduct clinical studies to provide the data demonstrating the "enhanced efficacy". If the efficacy of the known substance has to have a "known efficacy", it has to be derivable from, and quoted by the Examiners in documents available in the prior art at the date of patent filing. Asking the Petitioner to generate data to demonstrate efficacy of a known substance, which efficacy is claimed to be known, documents a misconception in the application of Section 3(d).

E) Because the IPAB has not appreciated that clinical efficacy is not an intrinsic property of a substance, known or not. Clinical efficacy is shown only in a specific clinical setting. In other words, it is shown in studies for a defined human patient population (defined, e.g., by age, gender, disease status or earlier treatment), using a specific form of a drug substance (e.g., a specific salt or crystal form), in a specified dosage (e.g., 400 mg twice daily), a mode of administration (infusion, tablet, drink solution, drug eluting stent, etc.), and some times being applied in conjunction with co-medication or under other specified circumstances (pre-surgery, before bone marrow transplant, etc.). Finally, the clinical studies finally allow conclusion about the efficacy of a given drug product in a defined setting. No conclusion can be drawn about efficacy in general. If a drug product is applied in wrong dosage or to the wrong

patients, no clinical efficacy can be established. This highlights the misconception of Section 3(d) as such. It further highlights that, if 3(d) may be applied at all, it can be applied only to new forms of an approved drug product. For an approved drug efficacy is demonstrated, not in general, but at least in a given clinical setting that serves as a basis for approval. Comparative studies can be done with the new form in order to gather Section 3(d) data. Apparently, such a scenario does not apply to the Petitioner's drug- Glivec, which, as explained, earlier is without precedent. In other words, no other form of Imatinib Mesylate had shown efficacy in Chronic Myeloid Leukemia (CML) before Glivec employing the β crystal form of Imatinib Mesylate was tested and approved.

F) Because the IPAB failed to appreciate that asking a patent applicant to conduct clinical studies comparing a new form of a known substance with a known substance that was merely a research compound in a clinical setting that allows observing a difference in efficacy is highly unethical. That would imply that a research compound is tested in human patients for the first time for the sole purpose of gaining patent protection in India. The aim of the study would be to demonstrate inferior efficacy of the research compound tested in real patients. If the new form of the known substance would be a drug for the treatment of a life-threatening disorder, a difference in efficacy would imply to put the life of patients at risk for the sake of gaining an Indian patent. This is clearly not the intention of the Indian Legislature when Section 3(d) was enacted.

G) Because the IPAB erred in not appreciating crucial aspects of the Petitioner's subject application for the drug- the β crystal of Imatinib

Mesylate; which renders the provision of section 3(d) inapplicable. The crucial aspects are as listed below:

(i) The Petitioner's drug- Glivec is a breakthrough cancer medicine for the treatment of CML and GIST. Genuine Glivec was originally launched as the β crystal form of Imatinib Mesylate. There was no other form of Imatinib available before the development and launch of Glivec, neither the alpha form of Imatinib Mesylate, nor any other salt of Imatinib.

(ii) Section 3(d) was introduced by the Indian Legislature as a means to prevent "evergreening". It should only be applicable, when a known drug product is replaced by a new version of the same product. This is not the case for Glivec.

(iii) When Imatinib free base was first invented in 1993 and described in a patent application, the subject application could not be made in India as the Indian law did not provide for product patents before 1995/2005. In 1998 the instant application claiming the β crystal form of Imatinib Mesylate was filed as a Black Box application, being the first subject application ever filed in India relating to Glivec. It is to be appreciated here that no exclusivity could be 'evergreened' in India by the Petitioner's subject application, as the Petitioner's subject application is the first subject application for Glivec in India.

(iv) Section 3(d) refers to the known efficacy of a known substance. This puts the burden on the Patent Examiner to quote prior art disclosing such known efficacy. During the prosecution of the subject application before Respondent No.3, the Petitioner was asked to produce comparative data in order to demonstrate enhanced efficacy. Clinical efficacy was shown by Novartis for the β crystal form of Imatinib Mesylate. It was not shown for any other form of Imatinib before.

(v) There is no known clinical efficacy for any form of Imatinib other than the β crystal form since it is the only form that has been studied extensively in patients. In a true evergreening situation, there should be an existing product which has been studied in clinical trials and a newer follow-on product which would presumably have its own efficacy data. At least in this scenario, the efficacy of the two compounds may be compared. The most obvious consequence is that Section 3(d) simply does not apply to Glivec since the known compound did not have a known efficacy. The other consequence is that if section 3(d) is to be applied in view of the 'Explanation' clause, flexibility to use a surrogate for efficacy - in this case the bioavailability of the drug should be considered.

H) Because the IPAB failed to appreciate the submission of the Petitioner that bioavailability is a critical element of clinical "efficacy" and is one element amongst many others which can be shown by the Petitioner to establish a significant difference "in properties with regard to efficacy." [Explanation to section 3(d)]. It may be mentioned that in fact the Respondent Nos 5, 6 and 7, who are in the present proceedings objecting to bioavailability as an element of establishing "efficacy" are getting their manufacturing and marketing approval for their own products under the Drugs and Cosmetics Act, 1940 on the basis of bio-availability/bio-equivalence. There are several possible elements constituting the compendious term 'efficacy' as is also established by the fact that the legislature has used the plural form 'properties' as opposed to the singular form 'property'. Therefore, the scope of the term 'efficacy' is required to be broader and need not be narrowed down to only mean clinical efficacy. Hence, enhanced efficacy can be demonstrated by any technical feature of a new form such as bioavailability, solubility,

stability, hygroscopicity or storability, all attributes which are possessed by the Petitioner's drug.

I) Because the IPAB failed to appreciate that in order to apply the provision of Section 3(d) of the Act to a pharmaceutical product it has to be in relation to an "approved drug" by the regulatory authority as a known substance in the case of a drug can only mean "approved drug". It is further submitted that "Glivec" was originally launched as β Crystal form of Imatinib Mesylate and there was no other form of Imatinib available as a drug before the development and launch of Glivec, neither the Alpha form nor any other salt of Imatinib. In view of the above, there was, so to say, no "known substance" with which the comparison could have been drawn by the Petitioner to establish enhanced efficacy. In other words, the provisions of Section 3(d) are inapplicable to the present case.

J) Because the IPAB erroneously proceeded to observe that the patentability does not depend on whether the test data on the rat study is statistically significant. Assuming, without admitting, that Section 3(d) is applicable to the present case, in order to overcome the impediment of Section 3(d) of the Act, the Petitioner rightly established the rat study data as statistically significant.

K) Because the IPAB erred in observing that bio-availability and efficacy are not one and the same inasmuch as it is never been the case of the Petitioner that bio-availability and efficacy are the same. It is the case of the Petitioner that in order to establish enhanced efficacy of the product, enhanced bio-availability can be one of the criteria.

L) Because the IPAB while rightly concluding that Imatinib and its Mesylate salt in crystal form have a difference of 30% bio-availability erroneously

proceeded to observe that they are the same substances with respect to therapeutic efficacy. It is submitted 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, cannot, therefore, be termed the 'same substance'.

M) Because the IPAB gave an unduly restrictive meaning to the term "efficacy" thereby limiting it to "enhanced efficacy" by erroneously relying upon Madras High Court judgment in case of *Novartis AG v. Union of India* (2009) MLJ 1153 even though the main issue before the Court there was the constitutional validity of Section 3(d) of the Act and an observation by the Court on the term "efficacy" was a mere *obiter dicta.*

N) Because the restrictive interpretation of the term 'efficacy' in respect of inventions falling under drugs/pharmaceuticals/pharmacology has done injustice to the Petitioner inasmuch as crucial and advantageous properties of a drug like improved stability, less hygroscopicity and improved flow properties are pertinent in determining the efficacy of a drug were ignored.

O) Because the IPAB erred in rejecting Petitioner's arguments and corresponding conclusive experimental data/supporting literature on the relationship between bioavailability and efficacy to demonstrate enhanced efficacy of Petitioner's drug, by wrongly observing that 'bioavailability is not the same as therapeutic efficacy' and rejecting the contention of the Petitioner that bioavailability is one of the parameters by which efficacy of a drug may be judged/established and that enhanced bioavailability leads to enhanced efficacy.

P) Because the IPAB completely ignored to take into consideration the references that were made by the Petitioner to various text books/journals which unequivocally showed that by increasing bioavailability of a drug, enhanced efficacy of the drug was obtained. The extracts from these articles are reproduced below:

(ix) Methods in Molecular Biology 437 - Drug Delivery System, edited by Kewal K. Jain, page 186:

The drug toxicity to healthy tissues and the cell resistance to treatments described earlier pose a twofold challenge for drug delivery technology – to improve the delivery selectivity and to overcome the cell resistance – to simultaneously maximize the therapeutic efficacy and minimize the side effects.

Therefore, by increasing bioavailability of drugs at sites of action, drugs in these carriers have shown enhanced efficacy against resistant tumors and fewer side effects.

(x) Drug Delivery and Targeting For Pharmacists and Pharmaceuticals Scientists, page 03:

In terms of drug efficacy, the bioavailability of a drug is almost as important as the potency of the active agent itself.

(xi) Martin's Physical Pharmacy and Pharmaceuticals Sciences, Fifth Edition, page 357:

Thus, bioavailability is concerned with how quickly and how much of a drug appears in the blood after a specific dose is administered. The bioavailability of a drug product often determines the therapeutic efficacy of that product because it affects the onset, intensity, and duration of therapeutic response of the drug.

(xii) Article on "Dermal Absorption: Increased Bioavailability can result in increased efficacy" in American Association of Pharmaceutical Scientists Journal. 1999/1338

Conclusion: *Enhancement of the dermal bioavailability of glucocorticoids such as BMV, which normally permeate the skin poorly, can result in significant improvement in therapeutic effectiveness.*

(xiii) Extract from Am J Top Med Hyg October 2008 issue; 79(4):620-3: Pharmacokinetics of the anti malarial drug piperaquine in healthy Vietnamese subjects:

Piperaquine AUC was proportional to the two doses tested and a moderate-fat meal enhanced the biovailability of piperaquine by 41%, which should improve the therapeutic efficacy of this drug.

(xiv) Extract from Elsevier periodicals Semin Oncol 2007; 34-1-5:

Emerging evidence suggests that the use of EDTs may promote a more favorable and predictable pharmacokinetic profile with increased bioavailability of taxanes at the tumor site, limiting their exposure to normal tissues and improving the therapeutic benefits associated with taxane treatment.

(xv) Extract from Elsevier periodicals Int J Dermatol 1999; 38-628-32:

Conclusion: A novel foam formulation with enhanced BMV bioavailability has been shown to be of increased efficacy in the treatment of scalp psoriasis without an associated increase in toxicity.

(xvi) Handbook of property estimation methods for chemicals environmental and health sciences By Robert S.Boethling and Donald Mackay at page 262:

Bioavailability is clearly an important factor that can affect the therapeutic efficacy of toxicity of chemical substances. A candidate drug substance that contains structural features necessary for a specific pharmacologic property will have limited, if any, therapeutic value if it has low bioavailability.

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Q) Because the IPAB erred in observing that the Petitioner is not entitled to make out a case for patent in its favour by importing new matter in the specification discovered/established later and consequently holding that patentability which includes determining whether the invention falls under Section 3(d) or not will have to be established on the basis of the original disclosure in the specification. The IPAB failed to appreciate the following key aspects which cannot be harmonized with its observation:

(i) The Petitioner's subject application was filed in India in 1998, seven years before Section 3(d) as it presently stands, was even conceived. It follows without argument that the new standards of 3(d) cannot be applied on the present application without affording the applicant a chance to meet these new criteria. It has to be appreciated that at least for applications filed before April 4, 2005, when the new law entered into force, transitional rules have to be applied allowing the applicant either to put such data validly on file with the Patent Office or to amend the specification by inclusion of the required data.

(ii) Conducting clinical studies cannot be a pre-requisite for grant of a patent. Clinical studies comparing a new form of a known substance with a known substance can take several years until conclusive results are finally obtained. Giving a new product to patients in Phase II or Phase III studies would destroy the novelty of such product and render it unpatentable in almost all jurisdictions worldwide. Originator companies developing new Pharma products need a solid basis allowing them to make the huge investment required for the clinical development of new products. Accordingly, it undeniably follows that patent filings claiming the active ingredient of the new product as well as all other potentially

inventive aspects of the drug product (formulation, salt or crystal form, mode of administration, etc) have to be made before clinical studies are started and, hence, cannot include the final results of such comparative studies.

R) Because the IPAB erred in observing that the Imatinib Mesylate was a known substance before the priority date of the Petitioner's application for patent and consequently holding that the bioavailability studies submitted by the Petitioner to demonstrate the enhanced efficacy of its product-β crystal form of Imatinib Mesylate, is not complete without corresponding comparison with Imatinib Mesylate salt. The IPAB did not appreciate the following crucial points in arriving at this erroneous finding:

(i) Imatinib free base is the right standard for comparative data under Section 3(d) of the Act. Imatinib, but not Imatinib Mesylate is specifically disclosed in Petitioner's 1993 patent.

(ii) Whereas the 1993 patent enables a skilled person to prepare Mesylate salts of Imatinib, there is no specific example provided in the 1993 patent for the manufacture of any Imatinib Mesylate.

(iii) The prior art further comprises a publication in a scientific journal (Cancer Research, January 01, 1996) that mentions Imatinib Mesylate. In a foot note in the publication, it is mentioned that the preparation of the Mesylate salt will be described at a later point in time.

(iv) The Petitioner's subject application for the first time describes the preparation of Imatinib Mesylate

(v) Whenever Imatinib Mesylate is actually prepared, it will be obtained in a defined form. Depending on the conditions applied, it will

be obtained as monoMesylate or diMesylate. Furthermore, the monoMesylate will be obtained in alpha crystal, alpha2 crystal, β crystal, H1 crystal, amorphous form, other crystal forms or mixtures thereof.

(vi) A comparison with Imatinib Mesylate is simply untenable and impossible, as the expression "Imatinib Mesylate" does not identify a real substance. In order to identify a real substance, further information needs to be added in order to specify what form of Imatinib Mesylate is addressed. Information suitable to that end would be the name (alpha crystal, alpha2 crystal, β crystal, H1 crystal, amorphous form), physical data (a melting point, X-ray data, solid state NMR) or the conditions applied to prepare Imatinib Mesylate as these conditions will determine the crystal form obtained.

(vii) The IPAB concluded that Imatinib Mesylate is a known substance for the purpose of determining novelty. At the same time IPAB concluded that the β crystal form of Imatinib Mesylate, claimed in the Petitioner's subject application, is novel. According to Section 3(d), a new form of a known substance shall be considered to be the same substance if no significant enhancement of efficacy is observed. There can be no doubt that a known substance and a new form thereof in reality are not the same. 3(d) generates a legal fiction. The critical data to be evaluated is comparative data about the efficacy of the known substance and the new form of the known substance.

S) Because the IPAB ought to have appreciated the tests /clinical trials conducted by the Petitioner which admittedly showed 30% enhancement of bio-availability over the "known substance".

T) Because, given the uniqueness of the 'efficacy' requirement for the grant of a patent in India, absence of a definition of "efficacy" and precedents

from other jurisdictions, the IPAB ought to have held 30% enhancement of bio-availability was significant in properties with regard to efficacy.

U) Because the IPAB, given the uniqueness of the 'efficacy' requirement for the grant of a patent in India, absence of a definition of "efficacy" in the Act and precedents from other jurisdictions, erred in not appreciating the affidavits deposed by technical experts.

V) Because the IPAB has failed to appreciate that in absence of any guidelines as to what would constitute "efficacy", significant or otherwise, Section 3(d) will give unbridled power to Respondent No. 3 to decide the patentability of a product. As stated above, it may be emphasized here that the present case is a glaring example of the IPAB and Respondent No. 3 of rejecting arbitrarily the subject application in respect of a product.

W) Because the IPAB wrongly observed that Imatinib free base cannot be the right standard to be used under Section 3(d) for comparison with Imatinib Mesylate in the β crystal form. Under Section 3(d) of the Act, enhanced efficacy needs to be demonstrated and a comparison of the claimed new form of a known substance with the known substance itself has to be accomplished. Hence, the "known substance" needs to be a substance, which is factually available, i.e., which is exemplified in the prior art in a manner that it can be obtained by a person skilled in the art. Whereas Imatinib free base is exemplified in the 1993 patent and hence, constitutes a known substance, this cannot be said for any form of Imatinib Mesylate. The concept of novelty can work with fiction, which is not the case for Section 3(d). Efficacy data as required by Section 3(d) of the Act from preclinical or clinical studies cannot be generated with a fictitious substance. Scientists and physicians can only test existing

substances not substance which are deemed to lack novelty and thus are "known" for the purpose of novelty determination.

Consequently, it infallibly follows that Imatinib free base is the right standard for comparison with β crystal form of Imatinib Mesylate and, in any event, the 30% increased bioavailability of the β form of Imatinib Mesylate over the free base renders the invention patentable under Section 3(d).

X) Because the IPAB failed to appreciate that development of a drug and patent filing timelines are incongruous and accordingly, ought not have called for efficacy data to be present in the specification as filed.

Y) Because the IPAB erred in relying on an additional ground under section 3(b) of the Act in refusing the Petitioner's subject application which was not the case of either of the Respondents either before Respondent No. 3 or before the IPAB.

Z) Because the IPAB failed to appreciate the true import of section 3(b) of the Act, which under any conceivable circumstance does not empower Respondent No. 3 or the IPAB to use the issue of pricing of a drug to evaluate the patentability of an invention.

Section 3(b) is as reproduced below:

"Section 3. What are not inventions. - The following are not inventions within the meaning of this Act,-

(b) an invention, the primary or intended use or commercial exploitation of which would be contrary to public order or morality or which causes

serious prejudice to human, animal or plant life or health or to the environment;"

The language of Section 3(b) or similar language is included in the patent law in about every country of the world. It is widely accepted that patent protection is only excluded if the invention cannot be used other than in a way which is contrary to public order or morality. The decisive matter is the purpose of the invention. Typical examples of subject-matter which should be excluded from patentability are inventions likely to induce riots or public disorder such as letter-bombs. Unethical inventions would normally be grouped under this item. Nobody would argue that the Petitioner's β crystal form is unethical – when it is quite the opposite, it saves lives. Therefore, one cannot envisage a situation where the exploitation of the Petitioner's invention would be contrary to public order or morality let alone being prejudicial to animal, human or plant life or to the environment.

AA) Because the IPAB erred in observing that a high price for a cancer drug could lead to public disorder. There is no basis in the law that supports pricing of a drug as a reason for patent refusal. It is well established that the grant or refusal of a patent is dictated by strict "patentability" criteria to be found in the Patent law in different jurisdictions. Patentability is invariably assessed independently of external factors such as pricing or market access. The issue of pricing of a drug has no relation whatsoever with the patentability of invention. Such a criterion cannot be used to deny the grant of a patent. Once the patent has been granted, the use or abuse of a patent can be regulated by other relevant provisions such as compulsory licensing.