

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

POSITION OF PARTIES
BEFORE THE IPAB IN THIS COURT

BETWEEN

NATCO PHARMA LTD.
 REPRESENTED BY ITS COMPANY SECRETARY &
 GENERAL MANAGER (CORPORATE AFFAIRS)
 'NATCO HOUSE'
 ROAD NO: 2, BANJARA HILLS
 HYDERABAD -500 033 Respondent No.4 Petitioner

And

- 1) UNION OF INDIA
 REPRESENTED BY SECRETARY
 DEPARTMENT OF INDUSTRY
 MINISTRY OF INDUSTRY AND COMMERCE
 UDYOG BHAVAN
 NEW DELHI
 Respondent No.1 Contesting Respondent No.1
- 2) ASSISTANT CONTROLLER OF
 PATENTS & DESIGNS
 PATENT OFFICE
 'IPR BUILDING', G.S.T. ROAD,
 GUINDY, CHENNAI-600032
 Respondent No.8 Contesting Respondent No.2
- 3) NOVARTIS AG
 LICHSTRASSE 35,
 4002, BASEL, SWITZERLAND
 REPRESENTED BY RANJNA MEHTA DUTT
 POWER OF ATTORNEY HOLDER
 REMFRY HOUSE, MILLENNIUM PLAZA
 SECTOR 27, GURGAON-122002,
 HARYANA
 Appellant Contesting Respondent No.3

- 4) THE CONTROLLER GENERAL OF PATENTS & DESIGNS THROUGH THE PATENT OFFICE 'IPR BUILDING', G.S.T. ROAD, GUINDY, CHENNAI-600032
Respondent No. 2 Contesting Respondent No. 4
- 5) M/s. Cancer Patients Aid - Association, India
Represented by Managing Director S, Malhotra House, Opp. G.P.O. Mumbai - 400 001
Respondent No. 3 Proforma Respondent No. 5
- 6) M/s. Cipla Ltd, India,
Represented by Managing Director 289, Bellasis Road Opp. Hotel Sahil, Mumbai Central (E) Mumbai - 400 008
Respondent No. 5 Proforma Respondent No. 6
- 7) M/s. Ranbaxy Laboratories Ltd, India
Represented by Managing Director C/o Ranbaxy Research Limited Plot No. 77B, Sector-18 Gurgaon 122 001 Haryana
Respondent No. 5 Proforma Respondent No. 7
- 8) M/s. Hetro Drugs Ltd, India
Represented by Managing Director H. No. 8-3-168/7/1, Erragada Hyderabad - 500 018
Respondent No. 7 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 sheweth:

MOST RESPECTFULLY SHOWETH:

1. That the Petitioner above named is respectfully filing the present Petition seeking special leave against the final order dated 26.06.2009 passed by the Hon'ble IPAB, Chennai in Misc. Petition No.1-5 of 2007 in TA/2/2007/PT/CH. By the impugned order the Hon'ble IPAB, Chennai erroneously held that the beta crystal of imatinib mesylate (GLIVEC) is novel and inventive. Further, the IPAB, Chennai in the impugned order also held that the said beta crystalline form of imatinib mesylate is not patentable under Section 3(d) of the Patents Act, 1970. The findings of the Hon'ble IPAB, Chennai in the impugned order insofar as issues of novelty and inventive step are concerned are challenged by virtue of the present Petition.

It is submitted that Respondent No.3 herein has also filed a Special Leave Petitions being SLPs (Civil) No.20539-20549 of 2009 challenging the impugned order dated 26.06.2009. The humble Petitioner bonafidely believes that challenge to the said impugned order and judgement, at the first instance, lies before the Hon'ble High Court of Madras at Chennai. The Petitioner objected to

the maintainability of the SLPs (Civil) No.20539-20549 of 2009 on this count.

It is hereby clarified that this Petitioner is constrained to file this Special Leave Petition before this Hon'ble Court without seeking recourse to the Hon'ble High Court of Madras at Chennai. This is for the reason that in respect of the same impugned order the Respondent No.3 preferred Special Leave Petition 20539-20549 of 2009 to this Hon'ble Court by-passing the Hon'ble High Court of Madras at Chennai.

Therefore, there is no order passed by the Hon'ble High Court of Madras at Chennai.

That the Petitioner has not obtained all documentation pertaining to this Special Leave Petition. In view of the same, the Petitioner reserves his right to file additional documentation on obtaining the same to clarify his stand in the matter.

2. QUESTIONS OF LAW:

The following questions of law arise for the consideration of this Hon'ble Court.

- A) Whether or not Beta crystal of imatinib mesylate could be held to be novel and inventive keeping in view the following :
- a pre-1997 disclosure of the aforesaid salt in US patent no. 5,521,184 published in 1993
 - categorical admissions made by Respondent No. 3 while filing patent term extension certificate in respect of US patent 5,521,184
 - application to the USFDA by Respondent no. 3; and
 - the fact that beta crystal is a spontaneous crystal.
- B) Whether or not subsequent christening of a product such as imatinib mesylate could confer novelty and inventive step to that product, thereby enabling the grant of patent.
- C) Whether or not, the Hon'ble Intellectual Property Appellate Board (IPAB), Chennai was justified in brushing aside the reports/evidences of the Indian Institute of Technology, Delhi and the Indian Institute Chemical Technology, Hyderabad showing that the beta crystal form of imatinib

mesylate as claimed in claim 1 of the subject invention is inherently formed when the said US Patent no.5521184 is practiced, more so in view of the findings of the Appellate Board that the Respondent No.3 has failed to disprove the said reports/evidences.

- D) Whether or not selection patent is permissible under the Indian Patent laws.
- E) Keeping in view a categorical finding by the Hon'ble IPAB, Chennai that Indian Patents Act does not provide for selection patents, whether or not beta crystal of imatinib mesylate could be held to be novel and inventive as a selection patent by the IPAB, Chennai.
- F) Whether or not, the plea of selection patent raised by Respondent No. 3 automatically leads to the logical conclusion that beta crystal of imatinib mesylate was covered by the originating US patent of 1993 granted to Respondent No. 3 and inventive step if any lies only in discovery of the advantageous properties of beta crystal; meaning thereby

that beta crystal as such lacks novelty and inventive step.

G) Whether or not vital categorical shift in stand by the Respondent No.3/applicant from their primary plea of two fold inventive steps in arriving at beta crystalline form of imatinib mesylate (as espoused before the Learned Controller) to a case of selection patent (without any basis in the complete specification No.1602/MAS/98), was destructive to the case of Respondent No.3.

H) Whether or not the complete specification and the claims of the subject application No. 1602/MAS/98 of Respondent no.3 makes out a case of selection patent.

I) Whether or not the Respondent No.3 ought to have preferred a Writ Petition before the Hon'ble High Court of Madras against the impugned order dated 26.06.2009.

3. **DECLARATION IN TERMS OF RULE 4(2)**

The Petitioner states that no other Petition seeking leave to appeal has been filed by it against order dated 26.06.2009 passed by the Intellectual Property Appellate Board in respect

of Misc. Petition No.1-5 of 2007 in
TA/2/2007/PT/CH.

4. **DECLARATION IN TERMS OF RULE 6**

The Annexure P-1 to P-10 produced along with Special leave Petition are true copies of the pleadings/documents which form part of the records of the case in the Tribunal/Court against whose order the leave to appeal is sought by this Petitioner.

5. **GROUND**

The leave to appeal is sought for the following amongst other grounds:

A. The Hon'ble IPAB, Chennai erred in passing the impugned order by ignoring the following facts:

a) that the product (anti-cancer drug GLIVEC) claimed in the Indian Patent Application No.1602/MAS/1998 is the same substance as claimed in the Respondent No.3's own patent granted in 1993 (US 5,521,184).

b) that the product (anti-cancer drug GLIVEC) is the same as proven by the IIT (Indian Institute of Technology, Delhi) and IICT (Indian Institute of Chemical Technology) reports;

c) that Respondent No. 3 has admitted in their USFDA application and patent term extension certificate that the anti-cancer drug GLIVEC (claimed in Indian Patent Application No.1602/MAS/1998) is the same substance as claimed in the Respondent No.3's own patent granted in 1993 (US 5,521,184):

It is submitted that the learned Assistant Controller had based his findings considering all the documents on record as well as independent test reports of Indian Institute of Technology, Delhi and Indian Institute of Chemical Technology, Hyderabad, which were ignored by the Hon'ble IPAB, Chennai.

- B. The Hon'ble Intellectual Property Appellate Board (IPAB), Chennai erred in passing the impugned order brushing aside the reports/evidences of Indian Institute of Technology, Delhi and Indian Institute Chemical Technology, Hyderabad which show that the beta crystal form of imatinib mesylate as claimed in claim 1 of the subject invention is inherently formed when the said US Patent no.5521184 is practiced, more so in view of the findings of the Appellate Board that the

Respondent No.3 has failed to disprove the said reports/evidences.

- C. The Hon'ble Intellectual Property Appellate Board (IPAB), Chennai erred in passing the impugned order by upholding the plea of selection patent raised by Respondent No. 3.
- D. The Hon'ble IPAB, Chennai erred in passing the impugned order by failing to note that fact that plea of selection patent as raised by the Respondent No.3 presupposes and implies that beta crystal of imatinib mesylate was covered by the originating US patent of 1993 (granted to Respondent No. 3) and inventive step if any lies only in discovery of the advantageous properties of beta crystal; which are not patentable. In other words, by virtue of this plea of Respondent no. 3 the logical conclusion is that the beta crystal as such lacks novelty and inventive step.
- E. The Hon'ble Intellectual Property Appellate Board (IPAB), Chennai erred in passing the impugned order even in view of its own finding that Indian Patents Act does not provide for selection patents, and later, erroneously upholding novelty and inventive step of the beta crystal on the same very ground of 'selection patent'.

- F. The Hon'ble Intellectual Property Appellate Board (IPAB), Chennai erred in passing the impugned order by ignoring the fact that the Respondent no. 3 had shifted from its original plea (before the Asst Controller) of two fold inventive steps in arriving at beta crystalline form of imatinib mesylate (as espoused before the Learned Controller) to a case of selection patent (without any basis in the complete specification No.1602/mas/98).
- G. The Hon'ble Intellectual Property Appellate Board (IPAB), Chennai erred by passing the impugned order by failing to recognize that the complete specification and the claims of Respondent's application No. 1602/mas/98 do not make out a case of selection patent.
- H. The Hon'ble IPAB, Chennai erred in passing the impugned order and not appreciating that US Patent No. 5,521,184 anticipates the claimed invention of Respondent No.3. It is submitted that lines 60 to 67 of column 3 of complete specification of the said patent reads as under:
- "Owing to the close relationship between the novel compounds in free form and in the form of their salts, including those salts that can be used

as intermediates, for example, in the purification of the novel compounds or for the identification thereof, hereinbefore and hereinafter any reference to the free compounds should be understood as including the corresponding salts, wherever, appropriate and expedient."

Lines 53 to 55 of column 19 of the said US patent states as under:

"Acid addition salts of compound of formula 1 are obtained in customary manner, for example by treatment with an acid or a suitable anion exchange reagent."

Claim 23 of the said US patent reads as under:

"23. The compound according to claim 1 of the formula 1, said compound being N-(5-[4-(4-Methyl-piperazino-methyl)-benzoylamido]-2-methyl-phenyl)-2-pyridimine-amine or a pharmaceutically acceptable salt thereof."

Thus, it is quite clear that US patent no. 5,521,184 includes "methane sulfonic acid addition salt of imatinib", which manifests itself in crystalline form i.e. as beta crystal. It is submitted that the reports of the Indian Institute of Chemical Technology, Hyderabad and Indian Institute of Technology, Delhi categorically establish that the beta crystal form of the

methanesulfonic acid addition salt of imatinib as claimed in claim 1 of the patent Application of Respondent no. 3 is inherently formed when the US patent 5,521,184 is practiced. The Hon'ble IPAB, Chennai arrived at a conclusive finding that imatinib mesylate salt is disclosed by the said US patent. Having so found, the Hon'ble IPAB, Chennai erred in holding that the said US patent 5,521,184 does not anticipate the claimed invention.

- I. The Hon'ble Intellectual Property Appellate Board (IPAB), Chennai erred in passing the impugned order by ignoring its own finding recorded at second para of internal page 174 of the impugned judgement in the following words:

"Though no working example for preparing a salt has been given in the said 1993 Patent, we are of the opinion it is not impossible for a person skilled in the art to prepare imatinib mesylate from imatinib by a conventional process as suggested in the said 1993 patent."

Having so found, the Hon'ble IPAB, Chennai could not have found that the claimed beta crystal is novel and inventive. In fact, as submitted above, lines 53 to 55 of column 19 of the said US patent state that the salt can be

prepared by customary method. Hence the sole reasoning on which the Hon'ble IPAB, Chennai upset the findings of the learned Assistant Controller on the ground of anticipation is erroneous and liable to be set aside.

2. The Hon'ble Intellectual Property Appellate Board erred in passing the impugned order by ignoring its own following categorical findings:

- a) that CGP57148B is the beta form of imatinib mesylate, the active ingredient of "GLEEVEC";
- b) that US patent 5,521,184 does disclose a variety of salts including imatinib mesylate;
- c) that application filed with the US Federal Drug Authority (USFDA) clearly states that GLEEVEC is covered by the 1993 US patent - US patent 5,521,184;
- d) that the patent term extension certificate clearly mentions that GLEEVEC is covered by the 1993 US Patent no. 5,521,184;

The above documents ought to have been considered as clear proof that beta crystal form of imatinib mesylate was covered by and thus anticipated by US patent 5,521,184. The

Hon'ble IPAB, Chennai erred in upholding novelty in respect of beta crystal of imatinib mesylate.

- K. The Hon'ble Intellectual Property Appellate Board erred in passing the impugned order by ignoring the application of Respondent No. 3 to the US Drug Authority and US Term Extension Certificate. The Hon'ble IPAB, Chennai erroneously concluded that these documents were not known before the priority date and cannot be considered for the purposes of anticipation. It is submitted that these documents ought to have been construed as evidences of a fact that occurred prior to 1997, i.e. the fact that imatinib mesylate in beta form existed prior to 1997. Accordingly, by so misconstruing the documents, the Hon'ble IPAB, Chennai erred in holding that US patent 5,521,184 did not anticipate and destroy the novelty of beta crystal of imatinib mesylate.
- L. The Hon'ble Intellectual Property Appellate Board erred in passing the impugned order by ignoring the categorical admission of Respondent No.3 that beta crystal form of the imatinib mesylate continues to be covered by 1993 US patent no. 5,521,184. It is respectfully submitted that once

7
this admission was made by the Respondent No.3, nothing remained to be proved and the claim to beta crystal was liable to be held as anticipated by the said 1993 patent.

- H. The Hon'ble Intellectual Property Appellate Board erred in passing the impugned order by ignoring the fact that vide letter dated 13.02.2004, the UK Attorneys of Respondent No.3 had alleged that the Petitioner's anti cancer drug "VEENAT" has infringed their European Patent No. 564409 (which corresponds to said US patent no. 5,521,184 published in 1993). The said letter alleges that Petitioner's drug VEENAT contains active ingredient beta crystal of Imatinib Mesylate which is disclosed in said European Patent No. 564409 granted to Respondent No.3 1993. Such allegation was based on certain scientific analysis relied upon by the said Attorneys of the Respondent No.3. Respondent No.3 filed Civil Suit No. 261/2004 against the Petitioner at the Hon'ble High Court of Mumbai, alleging infringement of Exclusive Marketing Rights (EMR) granted to Respondent No. 3 in respect of GLEEVEC / beta crystal based on their 1997 Indian patent application. Clearly, the same product VEENAT cannot be held to infringe

two patents on the same ground. It is submitted that these two contradictory stands of the Respondent No.3 itself demonstrates that the beta crystal of imatinib mesylate is part and parcel of the European patent no. 564409 (which is an equivalent of US 5,521,184). These facts which had found favour with the Ld. Asst. Controller were erroneously disregarded by the Hon'ble IPAB, Chennai who concluded that beta crystal is novel and inventive.

- N. The Hon'ble Intellectual Property Appellate Board erred in passing the impugned order by ignoring the fact that once a case of selection patent is urged, it carries the presumption that the product selected has been disclosed and forms integral part of the originating patent/prior art. Respondent No.3 advanced the argument of two-fold inventive steps before the learned Assistant Controller, i.e. (a) changing the imatinib free base into a salt form (the methanesulfonic acid addition salt) and (b) beta crystal form of the said salt. The Hon'ble IPAB, Chennai having recorded a finding that imatinib mesylate salt already existed in the public domain prior to 1997; and that CGP571488 is the code for beta crystal form of imatinib mesylate salt, had

erroneously found that the claimed beta crystal is inventive.

- O. The Hon'ble Intellectual Property Appellate Board erred in passing the impugned order by failing to note that Respondent No.3 has made no technical advance as compared to the existing knowledge and all documents for demonstration of polymorphism, isolation, characterization of beta crystal form of the imatinib mesylate relate to imatinib mesylate only.
- P. The Hon'ble Intellectual Property Appellate Board erred in passing the impugned order by ignoring the reports of Institute of Technology, Delhi and Indian Institute of Chemical Technology, Hyderabad who by performing experiments have categorically established that a person skilled in art would invariably arrive at beta crystalline form of the imatinib mesylate if he practices the said 1993 US Patent. Thus, the finding of the Hon'ble IPAB, Chennai on the issue of obviousness is totally vitiated.
- Q. The Hon'ble Intellectual Property Appellate Board erred in passing the impugned order by ignoring having found that the concept of selection patent is not provided for under the Patents Act, 1970,

erred in holding thereafter that beta crystal form of imatinib mesylate is novel and inventive under the same selection patent doctrine.

- R. The Hon'ble Intellectual Property Appellate Board erred in passing the impugned order by ignoring beta crystal of imatinib mesylate qualifies as a selection patent, no inventive steps except by way of selection with advantageous properties could be attributed to the said invention. However, the Hon'ble IPAB, Chennai has also found that Respondent No. 3 has failed to establish that specific advantageous properties disclosed of the beta crystal are disclosed by the patent application of Respondent No. 3. Thus, in view of such finding, the Hon'ble erred in finding that the beta crystal of imatinib mesylate is novel and inventive.
- S. The Hon'ble Intellectual Property Appellate Board erred in passing the impugned order by ignoring the fact that Respondent No.3 had not demonstrated inventive step at all. Without prejudice, it is submitted that in case of given invention, inventive step can be demonstrated either by way of selection or by the classical way as in the case of general utility patent. Said two

sets of inventive steps is not possible in a singular invention.

- T. The Hon'ble Intellectual Property Appellate Board erred in passing the impugned order by erroneous approach while adjudicating upon the issue of obviousness. It is submitted that the Hon'ble IPAB, Chennai observed that the Petitioner herein has not submitted any evidence showing that prior to the impugned application for patent, no person other than Respondent No.3 had prepared the beta crystalline form of the imatinib mesylate. It is submitted that there is no requirement of patent law to demonstrate that the product should be prepared for proving obviousness; it is sufficient if a person skilled in art having regard to the state of art would have arrived at the subject invention. In the present case, the Petitioner proved on record that the person skilled in art can easily arrive at the beta crystalline form of imatinib mesylate if he follows the recipe/method provided in the said 1993 US patent.
- U. The Hon'ble Intellectual Property Appellate Board, Chennai erred in passing the impugned order as the Hon'ble IPAB, Chennai placed undue

207

reliance on the International Preliminary Examination Report issued by the European Patent Office, while upholding novelty and inventive step in respect of beta crystal of imatinib mesylate, completely ignoring the following facts:

- that case of selection patent was not pleaded before the European Patent Office;
- that no opposition was filed and none of the grounds urged by the Petitioner were urged before the European Patent Office;
- that none of the pre-1997 published documents were available for scrutiny by the European Patent Office and their conclusion was based solely on the averments by Respondent No. 3 and its interpretation of US patent 5,521,184;
- that the IIT and IICT reports that demonstrate that practice of US patent 5,521,184 automatically leads to formation of beta crystal form of imatinib mesylate was not before the European Patent Office;
- that considerations of Section 3(d) and other restrictions imposed by the Indian Patents Act

were not at issue before the European Patent Office;

- that new use of a known substance is patentable subject matter in Europe;

The aforesaid facts (though urged), if considered could not have lead the Hon'ble IPAB, Chennai to uphold novelty and inventive step in respect of beta crystal of imatinib mesylate.

- V. The Hon'ble Intellectual Property Appellate Board erred in passing the impugned order by misconstruing the reports of the IIT and IICT and holding that they do not prove that imatinib mesylate exists in beta crystal form. The Hon'ble IPAB, Chennai erroneously confused itself with other existing forms of imatinib mesylate, completely ignoring the fact that beta crystal is the spontaneous crystal form of imatinib mesylate and other forms have been developed through human intervention.

6. GROUND'S FOR INTERIM RELIEF:

No Interim relief is prayed for.

7. MAIN PRAYER

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

(i) grant Special Leave to appeal against the Order dated 26.06.2009 passed by the Intellectual Property Appellate Board, Chennai in respect of Misc. Petition No.1-5 of 2007 in TA/2/2007/PT/CH in respect of the finding/ adjudication on the issues of anticipation, inventive step/obviousness and selection patent.

(ii) To pass such other order and further orders as this Hon'ble Court may deem fit and proper in the interest of justice.

7. INTERIM RELIEF

No interim relief is prayed for.

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

Filed by

[S. HARIHARAN]

Advocate for the Petitioner

Drawn on:

Filed on: