
(2006) 10 IPAB CK 0001

In the Intellectual Property Appellate Board

Novartis Ag.

APPELLANT

Vs

Cipla Ltd.

RESPONDENT

Date of Decision : 14-10-2006

Acts Referred:

Patents Act, 1970 — Section 2(1)(j), 3(d), 25(1)
Patents Rules, 2003 — Rule 55

Citation : (2007) 1 MIPR 296

Hon'ble Judges : V. Rengasamy, J

Bench : Single Bench

Advocate : Nalini Chidambaram, Sanjay Kumar, Gladis Daniel, Nitin Sen,
Gopalkumar G. Nair, Ramesh Kumar

Judgement

V. Rengasamy, J.

1. An application for patent claiming Switzerland priority date of 18th July, 1997 was filed by M/s. Novartis AG on 17th July, 1998, for an invention

titled ""Crystal Modification of A.N.-Phenyl-2-Pyrimidineamine derivative, processes for its manufacture and its use"" and the same was allotted the application No. 1602/MAS/1998.

2. A representation by way of opposition under Section 25(1) of the Patents Act, 1970 as amended by the Patents (Amendment) Act, 2005, was filed

by M/s. Gopakumar Nair Associates, Mumbai on behalf of M/s. CIPLA Ltd., Mumbai on 5th July, 2005, with a request for hearing under Rule 55 of

the Patents Rules, 2003 as amended by Patents (Amendment) Rules, 2005.

3. The Applicant through their agents M/s. Remfry & Sagar, New Delhi, filed reply statement along with evidence by way of affidavit affirmed by Dr.

Paul William Manley of Switzerland on 5th August, 2005. In their reply statement, the Applicant had requested for a hearing under Rule 55 of the

Patents Rules, 2003. They filed another affidavit affirmed by Giorgio Pietro Massimini of Switzerland on 22nd September, 2005.

4. Before discussing the grounds of opposition, it is pertinent to briefly mention here the background of the application. The present application claims

the α -crystal form of methanesulfonic acid salt of 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[4-pyridin-3-yl] pyrimidin-2-ylamino) phenyl]-

benzamide commercially called as imatinib mesylate. Invention of the base compound, 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-[4-pyridin-3-yl]

pyrimidin-2-ylamino) phenyl]-benzamide called as imatinib had already been disclosed in the European Patent publication No. EP-A-056409, published

on 6th October, 1993, and its equivalent US Patent No. 5521184, etc.

Not an invention:

5. Initiating the arguments, Dr. Gopakumar G. Nair, Agent for the Opponent, said imatinib mesylate is known from the US Patent No: 5521184,

hereinafter, called the 1993 Patent. The Opponent cited two other prior publications, viz., Nature Medicine (5th May, 1996) and Blood (1st November,

1997) wherein imatinib mesylate has been disclosed. He further said that there is no ingenuity or human intervention in the preparation of the α -

crystal salts. This invention claims only a new form of known substance, i.e., the α -crystal salts which are inherently disclosed in the 1993 Patent.

Hence, the alleged invention is not an invention under Section 2(1)(j) of the Patents Act as the alleged product and the process are not novel and

devoid of any inventive step.

6. Agent for the Applicant argued that compared to the disclosure made in the 1993, patent, the present invention involves two fold improvement over

the prior art - (i) the imatinib free base has been chemically changed into a salt form (ii) a particular crystal form of the salt has been made through

human intervention.

7. Further the Applicant said that, the 1993, Patent does not disclose imatinib mesylate but merely the corresponding free base and it may be correct to

say that the claims of the 1993, patent embrace imatinib mesylate. There is neither an example for the preparation of imatinib mesylate in the 1993

Patent nor any claim therefore.

8. I do not agree with the contention of the Applicant that the 1993 Patent discloses only the free base. The 1993 patent discloses methanesulfonic

acid as one of the salt forming groups and also the 1993, patent specification states that the required acid additions salts are obtained in a customary manner. Further, claims 6 to 23 of the 1993, patent claim a pharmaceutically acceptable salt of the base compound. The patent term extension certificate for the 1993 patent issued by the US Patent Office specifically mentions imatinib mesylate (GleevecR) as the product. All these points clearly prove that imatinib mesylate is already known from the prior art publications.

Section 3(d):

9. The Opponent said that the application claims only a polymorphic form of the known substance, imatinib mesylate. There is no enhancement of known efficacy as required under Section 3(d) of the Patents Act. Moreover the present specification states that all the inhibitory and pharmacological effects are also found with the free base, or other salts thereof.

10. Countering the arguments of the Opponent, the Applicant said that the crystal form of imatinib mesylate is an invention and not a mere discovery.

They further said that, a discovery graduating into a patentable invention solely on the basis of efficiency defies logic and, therefore, Section 3(d) may be unable to stand legal scrutiny. The Applicant submitted that this aspect of Section 3(d) is against the tenets of our patents act and well established principles of jurisprudence and therefore, the said Section cannot be used against the subject application.

11. I do not agree with the contention of the Applicant that this application claims a new substance. It is only a new form of a known substance. As

regards efficacy, the specification itself states that where α -crystals are used the imatinib free base or other salts can be used. Even the affidavit

submitted by the Applicant states that "the proviso to the Section 3(d) is unique to India and there is no analogous provision in the law of any other

country of the world". As per the affidavit the technical expert has conducted studies to compare the relative bioavailability of the free base with that

of α -crystal form of imatinib mesylate and has said that the difference in bioavailability is only 30 per cent and also the difference in bioavailability

may be due to the difference in their solubility in water. The present patent specification does not bring out any improvement in the efficacy of the

α -crystal form over the known substances rather it states the base can be used

equally in the treatment of diseases or in the preparation of pharmacological agents wherever the β -crystal is used. Even the affidavit submitted on behalf of the Applicant does not prove any significant enhancement of known efficacy. It is found that this patent application claims only a new form of a known substance without having any significant improvement in efficacy. Hence, I conclude that the subject matter of this application is not patentable under Section 3(d) of the Patents Act, 1970 as amended by the Patents (Amendment) Act, 2005.

Priority:

12. The opponent said this application was filed in India on 17th July, 1998 as a convention application claiming Swiss priority whereas Switzerland was not a convention country on that date. Hence, this application is legally and technically disqualified and deserves to be rejected.

13. The Applicant said that, priority date is only a facility provided to the Applicant to avoid anticipation by publication of the invention between priority date and the filing date in India. It is the discretion of the Applicant to claim priority. I agree with the contention of the Opponent that this application wrongly claims priority.

In view of the above findings and all the circumstances of the case, I hereby refuse to proceed with the application for Patent No. 1602/MAS/1998.

Dated this the 25th day of January, 2006.