

THE PATENTS ACT, 1970

SECTION 25(1)

In the matter of an application for patent No. 1602/MAS/98 filed on 17 July, 1998.

And

In the matter of a representation under section 25(1) of the Patents Act, 1970 as amended by the Patents (Amendment) Act, 2005.

And

In the matter of rule 55 of the Patents Rules, 2003 as amended by the Patents (Amendment) Rules, 2005.

M/s. Novartis AG, Switzerland

..... The Applicant

M/s. CIPLA Ltd., India

..... The Opponent

HEARING HELD ON October 14, 2005

Present :

M/s. Nalini Chidambaram,
Mr. Sanjay Kumar,
Mr. Gladis Daniel,
Ms. Nitin Sen

}

Agents for the Applicant

Dr. Gopakumar G. Nair
Mr. Ramesh Kumar

}

Agents for the Opponent

DECISION

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

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 July 5, 2005 with a request for hearing under rule 55 of the Patents Rules, 2003 as amended by Patents (Amendment) Rules, 2005.

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 August 5, 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 September 22, 2005.

Before discussing the grounds of opposition, it is pertinent to briefly mention here the background of the application. The present application claims β -crystal form of methanesulphonic 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 October 6, 1993, and its equivalent US Patent no. 5521184, etc.

Not an invention:

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 (May 5, 1996) and Blood (November 1, 1997) wherein imatinib mesylate has been disclosed. He further said that there is no ingenuity or human intervention in the preparation of the β -crystal salts. This invention claims only a new form of known substance i.e. the β -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.

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.

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 therefor.

I do not agree with the contention of the Applicant that the 1993 Patent discloses only the free base. The 1993 patent discloses methanesulphonic 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 (Gleevec[®]) as the product. All these points clearly prove that imatinib mesylate is already known from the prior art publications.

Section 3(d):

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.

Countering the arguments of the Opponent, the Applicant said that the β -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.

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'er β -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 β -crystal form of imatinib mesylate and has said that the difference in bioavailability is only 30% 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 β -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.

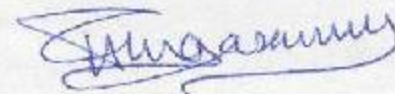
Priority:

The opponent said this application was filed in India on July 17, 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.

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.



V. RENGASAMY

Asst. Controller of Patents & Designs

Copy to: **014856**

- 1) M/s. Remfry & Sagar,
Remfry House at the Millennium Plaza,
Sector - 27, Gurgaon - 122 002
- 2) M/s. Gopakumar Nair Associates
3rd Floor, Shivmangal,
Between Gundecha & Growel,
Akurli Road, Kandivli, Mumbai - 400 101.