

THE PATENTS ACT, 1970

SECTION - 25(1)

In the matter of an application for patent
No. 1602/MAS/98 filed on July 17, 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. Hetero Drugs Limited, India The Opponent

HEARING HELD ON December 15, 2005

Present:

Mr. Sanjay Kumar,
Mr. Habubullah Badsha,
Ms. Nishu Sen
Mr. Saibal Mukherjee

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Agents for the Applicant

Mr. Anil Misra

}

Agent 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. Hetero Drugs Ltd., India, on August 22, 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. Romfy & Sagar, New Delhi filed reply statement along with evidence by way of affidavit affirmed by Dr. Paul William Manloy of Switzerland November 14, 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 Maximini of Switzerland.

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-ylpyrimidin-2-ylamino)phenyl]-benzamide commercially called as Inatinib 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 Inatinib had already been disclosed in the European Patent publication no.EP-A-056409, published on October 6, 1993, and its equivalent US Patent no.5521084, etc.

Priority:

The Opponent argued that the application claims convention priority from an earlier Swiss application. Switzerland was not a convention country on the date of the filing of the application. Despite full knowledge of the above fact, the Applicant has chosen not to amend the application to represent the correct position. No patent can be granted on the basis of false and misleading submissions. The application should therefore 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.

Anticipation:

The Opponent said that imatinib mesylate is known from the US Patent no: 5521184, hereinafter called the 1993 Patent. The Opponent cited other prior publications, viz., *Nature Medicine*(May5,1996), *Cancer Research* (Vol. 56, Issue 1, 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. Imatinib mesylate can exist only in a single form namely the β -crystalline form. It therefore follows that the subject matter of the application is anticipated by the 1993 Patent namely the US Patent No.5521184 and its equivalent patents.

The Applicant replied 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 addition 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 this invention is anticipated by prior publications.

Section 3(d):

The Opponent said that he is reiterating the submissions made under the ground of anticipation and further said that the application claims only a polymorphic form of imatinib mesylate. As per section 3(d) of the Patents Act, any salt, polymorph or derivative of known substance is not patentable unless such salt, polymorph or other substance shows enhanced efficacy of the substance. As regards efficacy, the specification itself states that wherever 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.

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 wherever β -crystals are used the imatinib free base or other salts can be used. 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.

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/NAAS/1998.

Dated this the 23rd day of January, 2006.



V. RENGASAMY

Asst. Controller of Patents & Designs

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