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 I, 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 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 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 efficay of the 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 subtances 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 more 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 Appicant 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 wih the contention of the Appicant 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. The present patent specification does not bring out any improvement in the efficacy of the β-crystal form over the known subtances 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/MAS/1998.

Dated this the 25th day of January, 2006.

V. RENGASAMY
Asst. Controller of Patents & Designs

o/c

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2) Mr. Lakshmi Kumaran & Sridharan
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New Delhi – 110 029 014860

25/1/06

III/5

Original-II

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. Nitin Sen
Mr. Saibal Mukherjee } 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.

IV/1

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. Remfry & Sagar, New Delhi filed reply statement along with evidence by way of affidavit affirmed by Dr. Paul William Manley 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 Massimini 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-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.

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 I, 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 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 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 efficay of the 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 subtances 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 more 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 Appicant 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 wih the contention of the Appicant 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. The present patent specification does not bring out any

improvement in the efficacy of the β-crystal form over the known subtances 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/MAS/1998.

Dated this the 25th day of January, 2006.

V. RENGASAMY
Asst. Controller of Patents & Designs

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IV/5

Original - 5

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. Cancer Patients Aid Association, India ..... The Opponent

HEARING HELD ON December 15, 2005

Present :

Mr. Sanjay Kumar,
Mr. Habibullah Badsha,
Ms. Nitin Sen
Mr. Saibal Mukherjee } Agents for the Applicant

Mr. Anand Grover } 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. Cancer Patients Aid Association., India, on September 26, 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 October 31,2005. 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.

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.

Prior publication:

The Opponent argued that imatinib mesylate is known from the US Patent no: 5521184, hereinafter called the 1993 Patent. The patent term extension certificate granted by US Patent Office for the 1993 Patent explicitly mentions imatinib mesylate (Glveevec^{R})as the product. The Opponent further argued that imatinib mesylate salt inherently existed in the β-crystelline form which is the most stable form of the salt and further said that even the affidavit submited by the Applicant states that the β–form is thermodynamically more stable. Hence the claims of the present application stand anticipated by prior publication.

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 and the Opponent has satisfactorily proved that the salt normally exists in the β-form which is the most thermodynamically stable product. Hence I conclude that the Opponent has succeeded in proving that this invention is anticipated by prior publication.

Obviousness :

The Opponent submitted that all the arguments made in the above ground are reiterated. The Opponent further said that once the free base is disclosed by the 1993 Patent, it is obvious for a person skilled in the art to prepare corresponding pharmaceutically acceptable salts in view of the disclosure provided in the 1993 Patent specification. The β-form being the most thermodynamically stable form, imatinib mesylate inherently existed in that form. Hence the product claims are obvious.

The Appicant replied that the β-crystals are not inherently formed when the 1993 Patent is practised. Moreover, the 1993 Patent discloses only the free base, not any salt of imatinib and hence not obvious to a person skilled in the art.

I do not agree with the contentions of the Applicant that the 1993 Patent discloses only the free base for the reasons stated in the grounds of previous publication and I conclude that the Opponent has reasonably succeeded in establishing this ground of opposition too.

Section 3(d):

The Opponent 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 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 subtances 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 case does not come under the exclusion provided under section 3(d). It is denied that it is a mere discovery of a new form of a known substance. The β-crystalline form of imatinib mesylate is a new product because the crystal form is not an inherent property of imatinib acid addition salt exhibiting polymorphism and human intervention was

necessary in order to produce the subject compound. As regards efficacy, the Applicant relied on the affidafit by Mr. Massimini submitted on September 22, 2005, wherein he has conducted a study on the relative bioavailability of the free base and and imatinib mesylate in the β-crystalline form.

I do not agree wih the contention of the Appicant that this application claims a new substance. It is only a new form of a known substance. It is found that this patent application claims only a new form of a known substance without having any significant improvement in efficacy. Even the affidavit submitted on behalf of the Applicant fails to prove enhanced efficacy of the β-isomer over the known substance. 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 appication was filed in India on July 17, 1998 as a convention application claiming Swiss priority date of July 18, 1997 whereas Switzerland was not a convention country on that date. In the present case, Switzerland became convention country only in September, 1998. Hence no priority may be claimed from Swiss application.

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

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