THE PATENTS ACT, 1970
(AS AMENDED)
SECTION 15

IN THE MATTER OF APPLICATION FOR
PATENT APPLICATION NO. 991/MUMNP/2003

PFIZER PRODUCTS INC. -----------------------------   Applicant

AN USA COMPANY AT EASTERN POINT ROAD,
GROTON, CONNECTICUT 06340,
UNITED STATES OF AMERICA

Hearing held on 29th March, 2011

Present:

1. Ms. Payal Kalra                        Applicant’s Agent

DECISION

An application for a patent bearing number 991/MUMNP/2003 was filed in Patent Office, Mumbai on 27th October, 2003 entitled “CHIRAL SALT RESOLUTION” which is a national phase application of PCT application No. PCT/IB02/01905, dated 29th May, 2002. A request for examination under section 11-B was filed on dated 27th October, 2003 and was assigned a Request No. 1774/RQ/2003. As per the provision under Section 11-A of Patents Act, the said application was published on 16th May, 2007. The said case was examined under 12 and 13 of Patents Act and First Examination Report (henceforth referred to as FER) was issued on 13th March, 2008. The applicant filed reply and amended claims on 27th January, 2009 stating that
they have complied all the requirements of FER and requested grant of patent to the said application. Consequent to the submission of reply to FER, Second Examination Report (henceforth referred to as SER) was issued on 14th March, 2011 with a hearing notice to the applicant to attend hearing on dated 29th March, 2011 at 12.30 P. M. before the Controller, containing the following objections;

1. Invention claimed in the amended claims vide your letter dated 23/01/2009 are not persuasive. Claim 1 and its dependent claims 2 and 3 form one group of invention and claims (4-6) forms another group of invention because the said precursors do not share the essential structural element with the final products or the intermediates (the chemical structure of the precursors and the final products are technically not closely interrelated). So these two groups of invention can’t be accommodated in a single application.

2. It is not clear as to how these claims (7-8) and (9-12) have been made during the amended stage. Such claims are not allowable u/s 59 of Patents Act.

3. Invention claimed in any of the claims are not novel in view of the prior art documents. See the International Search Report as well as a further citation WO 0142246.

4. The applicant is advised to furnish the information relating to the objections, if any, in respect of the novelty and patentability of the invention including the claims of the application allowed of the corresponding application prosecuted before European Patent Office and USPTO within prescribed period under Rule 12(3) of Patents Rule 2003, as amended.

Hearing fixed as per the above schedule was attended by the applicant’s agent, Ms. Payal Kalra. The basic issue of the hearing were exclusively related to the objections raised vide office letter dated 14th March, 2011. During hearing, the applicant argued countering the objections already on record and was advised to file a written submission to her argument. Written submission of the argument along with amended claims was filed by the applicant on 15th April, 2011 which is as follows:

Reference is made to the official letter dated March 14, 2011 intimating that a hearing has been fixed for the subject application on March 29, 2011. In view of the objections raised by the learned Controller, the applicant presents the following reply.
Regarding paragraphs 1 and 2, it is submitted that claims have been thoroughly revised in accordance with the requirement of the learned Controller. In this respect, the objected claims have been deleted from the present application to meet the Controller's requirement.

In view of the amendments carried out in claims, reconsideration and withdrawal of said objection is respectfully requested.

Regarding paragraph 3, the applicant resists the Controller's objection and submits that the subject matter of revised claims is novel and inventive over the documents cited by the learned Controller and constitutes an invention under Section 2 (1) (j) of the Act. The applicant further submits that no such objection of novelty and inventive step was raised in the First Examination Report; accordingly, the said objection may not be raised at the stage of hearing.

Further, the applicant submits that the corresponding patent applications filed in U.S., Europe and Australia and Canada have been granted after extensive novelty and inventive step search.

In view of the above submissions and amendments carried out in claims, reconsideration and withdrawal of said objection is respectfully requested.

The Learned Controller is requested to reconsider and waive the objections in light of the revision carried out in the claims and submissions presented above and grant a patent on the application at the earliest.

Should the Controller be still of the opinion that certain clarifications/amendments are required, the applicant's attorney may be kindly intimated. In any event, the applicant humbly prays that a reasoned decision under Section 15 be rendered in the subject matter.

The amended claims filed after hearing vide the applicant’s communication dated 15th April, 2011 are as follows:

1. The compound 3-\{(3R,4R)-4-Methyl-3-[methyl-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-amino]-piperidin-1-yl\}-3-oxo-propionitrile or a pharmaceutically acceptable salt thereof.
2. A pharmaceutical composition comprising a compound, or a pharmaceutically acceptable salt thereof as claimed in claim 1 along with a pharmaceutically acceptable carrier used for (a) treating or preventing a disorder or condition selected from organ transplant rejection, xeno transplantation, lupus, multiple sclerosis, rheumatoid arthritis, psoriasis, Type I diabetes and complications from diabetes, cancer, asthma, atopic dermatitis, autoimmune thyroid disorders, ulcerative colitis, Crohn's disease, Alzheimer's disease, leukaemia and other autoimmune diseases or (b) the inhibition of protein kinases or Janus Kinase 3 (JAK3) in a mammal, including a human, wherein said composition optionally comprising one or more additional agents which modulate a mammalian immune system or anti-inflammatory agents, effective in such disorders or conditions.

After hearing the case and in view of the applicant’s written submission and the amended claims (1-2) available on record, I draw the following conclusion on the patentability issue of the instant application and infer whether a patent can be granted or refused under the provisions of the Act.

At the outset, I am not convinced with the applicant’s contention that the objections on novelty and inventive step can’t be raised at the stage of hearing since the said objections was not raised in the First Examination Report. I refer to the provision contained under Section 13(3) of Patents Act, which pronounces that, “Where a complete specification is amended under the provisions of this Act before the grant of a patent, the amended specification shall be examined and investigated in like manner as the original specification”. So, the instant amended case was examined and investigated like an original specification, and relevant fresh objections were raised that were not issued in First Examination Report.

Again, I am referring to the provision under Section 8(2) of the Act, which states that “at any time after an application for patent is filed in India and till the grant of a patent or refusal to grant of a patent made thereon, the Controller may also require the applicant to furnish details, as may be prescribed, relating to the processing of the application in a country outside India, and in that event the applicant shall furnish to the Controller information available to him within such period as may be prescribed”. One of the many spirits of such a provision is
that the applicant to make available to the Controller, the technical assessment of the disclosed and consequently claimed invention by different countries for grant of a patent. The citation (WO 01 42246) in the present case is an extract of the European Patent Office action dated 29th April, 2004, on the corresponding application filed before EPO and you have not furnished the said details which was asked to provide vide FER dated 13th March, 2008. So the cited prior art document might have been known to the applicant well on or after 29th April, 2004, which has been suppressed to furnish to the Controller which is not a good spirit. As the applicant is aware of such an event, in the later stage it can’t be denied that this event was a new objection which was not raised in FER, but only during hearing. It is to be realized that the said objection was conveyed vide office letter dated 14th March, 2011 well before the hearing date.

Now I will look into the claimed invention available on record vis-a-vis the teachings of the prior art WO 01 42246 published on 14th June, 2001, well before the priority date of the instant claim claimed in claim 1 (i.e. 06th December, 2001). The said prior art in the opening line in page 30 (claim 20) discloses a compound 3-{4-Methyl-3-[methyl-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-amino]-piperidin-1-yl}-3-oxo-propionitrile. The present application in claim 1 claims a compound 3-{(3R,4R)-4-Methyl-3-[methyl-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-amino]-piperidin-1-yl}-3-oxo-propionitrile. The compound of the prior art and the instant claim are same. I do not find any distinctive difference between these two compounds and hence conclude that invention claimed in claim 1 of the instant application is not novel and protection can’t be given to it. The applicant’s submission in this context is not appreciated. Instead of any explanation to this issue, the applicant submits that such an objection which is not raised in FER can’t be raised in hearing.

From the present amended claims it can be argued that the compound claimed in claim 1 is the enantiomeric form of compound of the Cited prior art and hence novel and Inventive. However, I refer to the provision under Section 3(d) of Patents Act, which states that:

“The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or the mere use of a known process, machine or apparatus unless such process results in a new product or employs at least one new reactant.”
**Explanation** – For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

As per the provision of the above section certainly the enantiomer of the known compound 3-{4-Methyl-3-[methyl-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-amino]-piperidin-1-yl}-3-oxo-propionitrile which the applicant claims should show an enhanced efficacy over the compound of the prior art. On the interpretation of Section 3(d) and the explanation there under by Madras High Court in the matter of Novartis AG & Anr. Vs. Union of India & Others, (2007) 4 MLJ 1153, the Court held that “Therefore it is clear from the amended section and the explanation that in the pharmacology field, if a discovery is made from a known substance, a duty is cast upon the patent applicant to show that the discovery had resulted in the enhancement of a known efficacy of that substance and in deciding whether to grant a Patent or not on such new discovery, the Explanation creates a deeming fiction that all derivatives of a known substance would be deemed to be the same substance unless it differ significantly in properties with regard to efficacy. In our opinion, the amended section and Explanation give importance to efficacy. We have already referred to the meaning of "efficacy" as given in Dorland's Medical Dictionary. Scientifically it is possible to show with certainty what are the properties of a "substance". Therefore when the Explanation to the amended section says that any derivatives must differ significantly in properties with regard to efficacy, it only means that the derivatives should contain such properties which are significantly different with regard to efficacy to the substance from which the derivative is made. Therefore in sum and substance what the amended section with the Explanation prescribes is the test to decide whether the discovery is an invention or not is that the Patent applicant should show the discovery has resulted in the enhancement of the known efficacy of that substance and if the discovery is nothing other than the derivative of a known substance, then, it must be shown that the properties in the derivatives differ significantly with regard to efficacy.”

In absence of disclosure of any test results, I do not admit that the claimed compound has enhanced efficacy over the prior art compound **WO 01 42246** and hence not patentable under Section 3(d) of Patents Act.
Again the amended claim 2 bears no technical effect over claim 1 as it relates to a pharmaceutical composition comprising the compound of claim 1 and is used for treatment of a number of diseases. As the claimed compound is not novel, and would not be patentable u/s 3(d) of Act, the claimed composition is not treated as patentable under similar lines.

Taking into consideration the disclosure made, the arguments offered during hearing, the submission made by the applicant as well as the interpretation of Madras High Court as made in the above para, I do not find that the claimed invention is patentable under the provisions of the Act.

After having considered the submissions submitted by the applicant in the hearing, the written submission and amended claims filed, in view of the above discussions and findings by me, it is hereby ordered that the invention disclosed and claimed in the instant application i.e., “CHIRAL SALT RESOLUTION” is not considered as an invention Under the provisions of the Act as discussed above and I therefore, hereby refuse this Application No. 991/MUMNP/2003 to proceed further.

Dated this 09th June, 2011.

(Dr. Amarendra Samal)  
Asst. Controller of Patents & Designs

Copy to:-

Ms. Payal Kalra  
Of Remfry & Sagar, Attorneys-at-Law  
Remfry House at the Millennium Plaza  
Sector 27, Gurgaon – 122 002  
New Delhi National Capital Region