

THE PATENTS ACT, 1970
(AMENDED BY THE PATENTS ACT 2005)
AND
THE PATENTS RULES, 2003
(AMENDED BY THE PATENTS RULES 2006)

In the matter of Patent
No. **276026** (Application
No. **3951/DELNP/2009**)

AND

In the matter of a notice of opposition
under Section 25(2) of the Patents Act
1970 as amended by the Patents
(Amendment) Act 2005

NOVARTIS AG PATENTEE

VS.

Natco Pharma Ltd. OPPONENT

Hearing held on 9TH April 2019

Present:

Applicant

- 1) Mr. Sanjeev Kumar Tiwari
- 2) Mr. Amrish Tiwari
- 3) Dr. Jyoti C. Ramani
- 4) Mr. Peter Rode
- 5) Mr. Atul Bede

Opponent

- 1) Ms Rajeshwari H
- 2) Ms Sweety Sharma
- 3) Deepika Dhar
- 4) Shyam Gupta

Examiners

- 1) Ms Vishakha Gupta
- 2) Mr Kartikey Yadav
- 3) Mr Manoj Kumar

ORDER

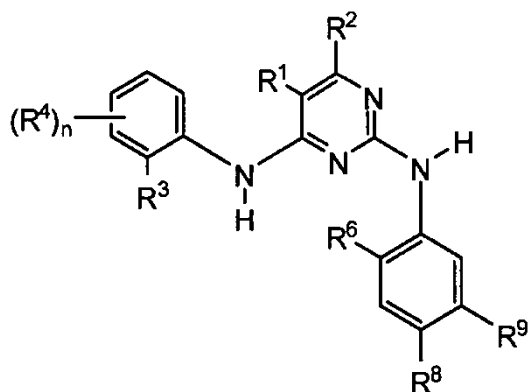
- 1) A Patent numbered **276026** was granted to Novartis AG on their Application No. **3951/DELNP/2009**. **Natco Pharma Limited filed notice of opposition on Form-7 to oppose the said patent on September 26, 2017** along with written statement and evidences under Rule 57 of the Patents Rules 2003. Thereafter, the copy of notice of opposition along with statement and evidences was sent to the Patentee by the Opponent under Rule 57. The Patentee filed reply statement and evidence under Rule 58(1).
- 2) On completion of the presentation of evidence and on receiving the recommendation of the opposition board under Section 25(4) of the Act, a **hearing under Rule 62(1) was fixed on April 9, 2019**. Opponent's agent has submitted written submissions pursuant to hearing on April 25, 2019. Applicant's agent also submitted written arguments on May 24, 2019.
- 3) The Agent for the Opponent submitted additional submissions on 7th May 2019. Thereafter, **Patentee filed a document on 9th July 2019**. The Patentee and the Opponent are regularly filing further evidences after the completion of hearing and written submissions. Since Opponent and Patentee were instructed not to file further evidences after filing written submissions, therefore, **further evidences submitted by Opponent and Patentee are not taken into record**.
- 4) In Notice of opposition filed via Form 7 u/s 25(2) of the Patents Act, 1970 and u/r 55A and 57 of the Patents Rules, 2003 (as amended in 2016) on 26/09/2017, following grounds of opposition were raised:
 - i. Section 25(2)(b)/(c): **Lack of novelty and prior claiming;**
 - ii. Section 25(2)(e): **Lack of inventive step;**
 - iii. Section 25(2)(f): Subject of claims 1 to 7 are not an invention within the meaning of this Act or is not patentable under this Act;
 - iv. Section 25(2)g: The complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed;
 - v. Section 25(2)h:
 - vi. The Applicant has failed to disclose to the Controller the information required under Section 8

5) In the following paragraphs, I wish to analyze the relevant grounds which the Opponent has raised:

i) Lack Of Novelty

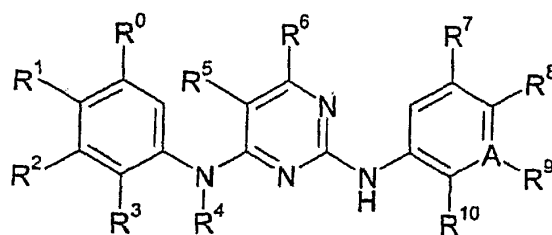
IN 232653 (2241/CHENP/2005)

If the compounds claimed in IN276026 (3951/DELNP/2009) and IN 232653 (2241/CHENP/2005) are compared then both Patents disclose substituted pyrimidine compounds.



IN276026 (3951/DELNP/2009)

I



IN 232653(2241/CHENP/2005)

II

The structure I is a structure claimed in claim-1 of impugned Patent IN276026 (3951/DELNP/2009). This structure I is the representative of the compounds claimed in IN276026 (3951/DELNP/2009). The structure II is the representative of the compounds claimed in IN232653 (2241/CHENP/2005). **The structure I and II are structurally same only the presentation on paper is different. The** tri substituted phenyl moiety attached to -NH is horizontally placed in structure II whereas it is vertically placed in structure I.

In Structure I R^4 is Hydrogen and n is 0 or 1 which means R^4 is hydrogen when $n=0$ While in structure II R^0 R^1 and R^2 are also hydrogen.

In Structure I R^3 is $(CR_2)_{0-2}SO_2R^{12}$ means it includes only $SO_2 R^{12}$ when (CR_2) is 0 while R^{12} is C1-C6 alkyl. Whereas in structure II R^3 also discloses C1-C8 alkyl (includes C1-C6 alkyl), sulphonyl which is equivalent to $SO_2 R^{12}$

In Structure I linking nitrogen (N) between the rings is attached with hydrogen (H) while in Structure II nitrogen is attached to R^4 wherein R^4 is disclosed as hydrogen.

In Structure I R^1 & R^2 is equivalent to R^5 and R^6 of structure II.

In Structure I R^1 is halo or C_{1-6} alkyl; R^2 is H; in Structure II each of R^5 and R^6 is independently hydrogen, C_1-C_8 alkyl (which includes C_1-C_6 alkyl) or halogen.

In Structure I, tri substituted phenyl moiety is substituted by R^6 , R^9 and R^8 which is equivalent to R^{10} , R^7 and R^8 respectively of structure II.

In Structure I R^6 is isopropoxy or methoxy; in Structure II R^{10} is C_1-C_8 alkoxy (which includes isopropoxy or methoxy)

In Structure I R^9 is C_{1-6} alkyl, cyano, $CONR(R^{12})$; R^{12} is H or C_{1-6} alkyl. In Structure II R^7 is C_1-C_8 alkyl or cyano. For e.g. R^9 in Structure I and R^7 in Structure II are methyl group.

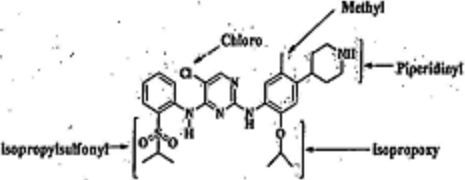
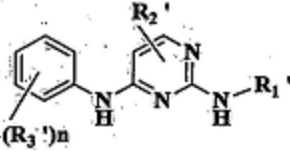
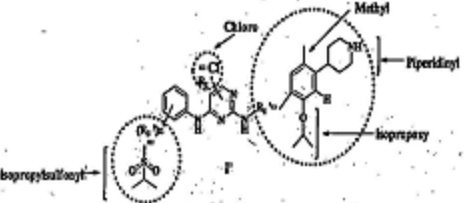
In Structure I R^8 is $(CR_2)_qY$ wherein $q=0$ which means R^8 is Y and is directly attached to C atom of the ring; Y is pyrrolidinyl, piperidinyl or azetidiny, each of which is attached to the phenyl ring via a carbon atom.

In Structure II R^8 is unsubstituted or substituted 5 or 6 membered heterocyclyl comprising 1,2, or 3 hetero atoms selected from N, O and S (which includes pyrrolidinyl, piperidinyl or azetidiny). Thus, these hetrocycles are also attached to ring through C atom.

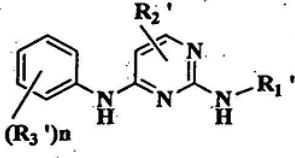
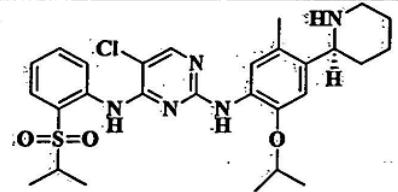
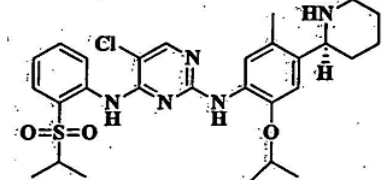
In Structure II if R^9 is hydrogen and A is equal to carbon then Structure II is equivalent to structure I with respect to the position 3 in phenyl ring (in between R^6 and R^8 of structure I).

Therefore, Structure I is narrower Markush structure of Structure II

IN240560 (553/CHENP/2006)

IN 276026	IN240560 (Prior art)
<p data-bbox="236 1368 456 1395">Claim 4 of US'026</p>  <p data-bbox="236 1641 694 1760">5-chloro-N2-(2-isopropoxy-5-methyl-4-(piperidin-4-yl)phenyl)-N4-[2-(propane-2-sulfonyl)-phenyl]-pyrimidine-2,4-diamine</p> <p data-bbox="411 1890 520 1917">Ceritinib</p>	<p data-bbox="721 1368 1139 1424">Claim 1 markush structure discloses ceritinib.</p>  <p data-bbox="986 1637 1011 1664">I'</p> <p data-bbox="721 1697 1208 1823">R1' = phenyl substituted by 3 radicals; Methyl, isopropoxy, and piperidinyl R2' = halo R3' = $-S(O)_{0-2}R'6$, and R'6 is selected C_{1-6}alkyl</p> <p data-bbox="721 1854 823 1881">Ceritinib</p> 

The substituents R1' R2' R3' R'6 as defined in IN240560 when substituted in Markush structure given in claim 1 of IN240560 results in the structure given in claim 4 of IN276026 (impugned Patent) as shown below:-

IN 276026	IN240560
<p align="center">Claim 4 of IN 27026</p>	 <p align="center">I'</p>
 <p>(S)-5-chloro-N2-(2-isopropoxy-5-methyl-4-(piperidin-2-yl)phenyl)-N4-(2-(isopropylsulfonyl)phenyl)pyrimidine-2,4-diamine</p>	<p>R1' = phenyl substituted by 3 radicals; Methyl, isopropoxy, and piperidinyl R2' = halo R3' = -S(O)₀₋₂R'6, and R'6 is selected C₁₋₆alkyl</p> 

Therefore, conclusively it can be said that impugned Patent IN276026 (3951/DELNP/2009) lacks novelty with respect to IN232653 (2241/CHENP/2005) and IN240560 (553/CHENP/2006).

Since IN232653 (2241/CHENP/2005) and IN240560 (553/CHENP/2006) was published by WIPO on 23/09/2004 and 24/02/2005 respectively. The priority date of the impugned Patent IN276026 (3951/DELNP/2009) was 08/12/2006; therefore, it lacked novelty on the date of filing of first convention application filed in USA i.e. **08 Dec 2006**.

ii) Lack of Inventive Step

The novelty aspect of the impugned Patent IN276026 (3951/DELNP/2009) with respect to IN232653(2241/CHENP/2005) and IN240560 (553/CHENP/2006) has been discussed in detail earlier, therefore, for the sake of brevity I am of the opinion that the impugned Patent IN276026 lacks inventive step also. Similarly impugned Patent IN276026 (3951/DELNP/2009) lacks inventive step with respect to WO2001/64654 also.

Considering above reasons subject matter of granted claims does not constitute an invention under section 2(1) (j) of the Patents Act 1970, therefore, I allow ground raised by the opponent under Section 25(2)(b) of the Patents Act 1970.

iii) Section 25(2)(f): Subject of claims are not an invention within the meaning of this Act or is not patentable under this Act

Section 3(d) in The Patents Act, 1970 states that

(d) 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 of the mere use of a known process, machine or apparatus unless such known 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 substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;

Since the compounds lack novelty and inventiveness, therefore, the subject matter of claims is not patentable under Section 3(d) of The Patent Act, 1970. The Patentee has not provided any *in vivo* efficacy data in comparison to compounds disclosed in IN232653 (2241/CHENP/2005) and IN240560 (553/CHENP/2006). Interestingly, it has been noted that the applicant of the impugned Patent and both the prior art documents is same i.e. Novartis AG.

Considering above reasons, I allow ground under Section 25(2)(f) of the Patents Act 1970 raised by the opponent.

6. During Hearing the Opponent has submitted an important document (seeking extension of Patent term in USA by Patentee) which has brought into light the relationship of the impugned Patent 276026 (corresponding US patent no. 8377921) with cited documents IN 232653 (corresponding US patent no. 7964592); IN240560 (corresponding US patent no. 7893074) and WO2001/64654 (corresponding US patent no. 7153964). Since, this document was very important and relevant in deciding the case before me, therefore, document was taken into record and a copy was given to Patentee to rebut the objection raised by opposition. The Patentee was given additional time (written submission filed on 24.05.2019) to file the rebuttal regarding this disclosure of Orange Book where the details of extension was filed, but Patentee failed to give any reasonable and convincing argument.

7. As decided in the preceding grounds of opposition, granted claims are already in public domain before priority date of the granted claims. Therefore these claims are not new and have no inventive step.

Considering above reasons subject matter of granted claims does not constitute an invention under section 2(1) (j) of the Patents Act 1970.

The Opponent has succeeded in the grounds under sections 25(2) (b), 25(2) (e) and 25(2) (f) of the Patents Act, 1970. I do not agree with the recommendations of the opposition Board. Having considered all the relevant documents and pleadings of both

the parties, and in view of my findings above, as per Section 25(4) of the Patents Act 1970. I hereby revoke the Patent numbered 276026 granted on the Patent Application No. 3951/DELNP/2009. There is no order as to the costs.

Dated: 16.08.2019

Dr. Kavita Taunk

(Deputy Controller of Patents and Designs)

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