



## Delhi Registry –Cum-Bench

G-62 to 67 & 196 to 204, August KrantiBhawan, Bhikaji Cama Place,  
New Delhi – 110 066

Tele No: 011-26180613/14

Website: <http://www.ipab.gov.in>

MP.NO.8/2019  
OA/20/2019/PT/DEL

MONDAY, THIS THE 20<sup>th</sup> DAY OF JULY, 2020

HON'BLE SHRI JUSTICE MANMOHAN SINGH  
HON'BLE DR. ONKAR NATH SINGH

CHAIRMAN  
TECHNICAL MEMBER (PVPAT)

**1. NOVERTIS AG**

LICHTSTRASSE 35, 4056, BASEL, SWITZERLAND

...APPLICANT/APELLANT

(Represented by: Mr. Hemant Singh & Ms. Mamta Jha)

Versus

**1. THE CONTROLLER GENERAL OF PATENTS,  
DESIGNS AND TRADE MARKS**

BOUDHIK SAMPADA BHAWAN, S.M. ROAD,  
NEAR ANTOP HILL POST OFFICE, ANTOP HILL,  
MUMBAI - 400 037

**2. DEPUTY CONTROLLER OF PATENTS &  
DESIGNS**

PATENT OFFICE, BOUDHIK SAMPADA  
BHAWAN, PLOT NO. 32, SECTOR 14, DWARKA,  
NEW DELHI - 110 075

**3. NATCO PHARMA LIMITED**

NATCO HOUSE, ROAD NO. 2, BANJARA HILLS,  
HYDERABAD - 500 034

...RESPONDENT

(Represented by – Mr. Tahir A.J.)

### **ORDER**

#### **HON'BLE SHRI JUSTICE MANMOHAN SINGH, CHAIRMAN**

1. By this order, we propose to decide the pending application of stay of impugned order dated 16.08.2019.
2. The appellant/Patentee has filed the present appeal seeking setting aside and quashing of the impugned order dated 16.08.2019 passed by the Respondent Nos. 1 & 2 in the post grant opposition proceeding under Section 25(2) filed by the Respondent No.3 vide which the Appellant's patent 276026 has been

revoked. The Appellant along with appeal had also filed the stay application seeking stay of the impugned order dated 16.08.2019 passed by Respondent No. 2.

3. It is stated by the Appellant in the interim application that the impugned order suffers from grave error of law and fact. The following are reasons given in the application, as under:-

- (i) *Though the pleadings and the evidence in accordance with the provisions of Section 25(2) of The Patents Act, 1970 read with Rule 58 and 59 of the Patents Rules applicable to the post grant opposition were completed by both the parties on 22<sup>nd</sup> February, 2018, the Ld. Controller/ Respondent Nos. 1 & 2 have taken on records additional evidence filed by the Opponent on 4<sup>th</sup> April, 2019 along with petition under Rule 138 of Patent Rules in breach of the provisions of the Act;*
- (ii) *No copy of the additional evidence filed on 4<sup>th</sup> April, 2019 was served on the Patentee by the Opponent. The same was noticed by the Patentee's attorney from the website of Indian Patent Office on 5<sup>th</sup> April, 2019. A letter was submitted objecting to taking on record such additional evidence by such Patentee's attorney on 8<sup>th</sup> April, 2019.*
- (iii) *The opposition proceedings were taken up for hearing on 9<sup>th</sup> and 10<sup>th</sup> April, 2019. No notice was issued by the Controller on Rule 138 application with additional evidence filed by the Opponent. No orders were passed either accepting or rejecting the said evidence. No orders were passed either granting opportunity to the Patentee to file any rebuttal evidence;*
- (iv) *The Ld. Single Judge of Hon'ble Delhi High Court in CS (Comm)229/2019 passed an order observed as under:-*

*“The Controller General was expected to follow strict timelines once judgment was reserved. Neither party ought to have been permitted to file anything further. However, the same has been breached as the Controller did not give any clarity as to whether affidavit dated 30<sup>th</sup> April, 2019 was taken on record or not and whether any submissions were to be filed by the parties after the hearing was concluded.*

*The Court further observed that in future, the Patent Office shall ensure that when the hearing is concluded, it is clarified whether any timeline is being given for filing written submission or not.*

*The Court further observed that Controller General shall now go ahead and proceed to pass order within one month from today. No further filing shall be done by either party.*

*Evidentially, the Hon'ble Court clearly observed that orders shall be passed on all the documents placed on record as on 11/07/2019 and no further documents shall be filed by the*

*parties. However, despite the Ld. Controller having been made aware of the said order dated 11/07/2019 disregarded the evidence filed by the Appellant in an arbitrary manner while passing the impugned order.*

*(v) A judgment has been delivered on 16<sup>th</sup> August, 2019 revoking the patent wherein the Controller has relied upon the additional evidence filed by the Opponent on 4<sup>th</sup> April, 2019 while disregarding the rebuttal evidence filed by the Patentee including expert's affidavit on 9<sup>th</sup> July, 2019.*

*(vi) Even on the merit, the Ld. Controller has gone completely wrong in arriving at a finding that the impugned patent lacks novelty. The Ld. Controller has further completely disregarded the recommendation and the findings of the Opposition Board constituted under Section 25(2) of the Act which had recommended vide order dated 18<sup>th</sup> May, 2018 that the patent is novel, normal and inventive and upheld its validity. The said recommendation of the Opposition Board has been disregarded by the Ld. Controller without assigning any reasons whatsoever.*

*(vii) Further, the Ld. Controller has completely disregarded that the inventive step which has been claimed by the Patentee in the impugned patent IN026 is novel pyrimidine compounds having two phenyl rings attached to the pyrimidine ring at its 2<sup>nd</sup> and 4<sup>th</sup> position via amine groups wherein the phenyl group attached to pyrimidine ring at the 2-position is tri-substituted (i.e. R6, R8 and R9 may not be hydrogen atom) and on the R8 and R9 is a heterocyclic ring of pyrrolidinyl, piperidinyl or azetidiny, each of which is attached to the phenyl ring via a carbon atom. This combination of the tri-substituted phenyl ring and the heterocyclic group of either R8 or R9 attached to that phenyl ring via a carbon atom renders the compound of Formula 2 as per claim 1 novel and inventive.*

4. In the appeal, the respondent no.3/Natco has filed the counter-affidavit of Madineedi Adinarayan, where the case of the appellant was denied. In nutshell, on merit, the case of Natco is that from the documents on record, the Controller has correctly arrived at the conclusion that Ceritinib is disclosed by prior art, especially IN'653 which was published as WO'980. The appellant had alleged that the novelty or inventive step lies in pyrimidine compounds having two phenyl rings attached to 2<sup>nd</sup> and 4<sup>th</sup> position to the pyrimidine ring via amine groups wherein the phenyl group attached to pyrimidine ring at the second position is tri-substituted (ie. R6, R8 and R9 may not be hydrogen atom). It was also claimed that the combination of trisubstituted phenyl ring and heterocyclic group attached to phenyl ring via carbon atom is one of the novel features of the claimed compounds. However, this feature is already found in IN'653 as well as IN'650. The Controller correctly appreciated the fact that these features are found in the prior art and revoked the patent. The Controller correctly appreciated the facts on record and concluded that the claims especially the

compounds of IN'026 are found in IN'560 and as such, the claims of IN'026 lack novelty and inventive step. The Controller while disagreeing with the conclusions of the Opposition Board gave elaborate reasons for the same, which is reflected in the order dated 16.08.2019. It is submitted that the order though precise, deals with all the technical issues and as such, cannot be faulted.

5. It is submitted on behalf of respondent no. 3 that the Controller has given her own views regarding the novelty and inventive step of the compound Ceritinib and found that the product lacks novelty. By doing so, the Controller has rejected the recommendations of the Opposition Board. The Controller has rejected the evidence filed by the respondent but only considered documents found to be relevant. The Patents Act and the rules framed thereunder do not bar the Controller from considering any document which is relevant for purposes of determining the novelty and inventive step of the compounds claimed. The Controller could not have considered the evidence of the appellant at any rate since it was filed belatedly and after the judgement was reserved. As regards, novelty and inventive step, the Controller considered the arguments of the appellant as well as this respondent; however, the Controller was not persuaded by the arguments of the appellant and found that Ceritinib is disclosed by prior art.
6. The respondent no 3 filed the written submissions in the stay application and counter statement.
7. On 16.9.2019, counsel for the appellant argued the appeal for some time. On that date, it was stated by him orally that in case, we are not able to decide the appeal we may decide the stay application before 21/09/2019 when the Chairman retires.
8. On 21.9.2019, the Chairman had retired and thereafter in view of order passed by the Hon'ble Supreme Court on 18.12.2019 the term for the Chairman of IPAB was extended for one year w.e.f. 21.9.2019. It appears that since no order was passed, the appellant filed the writ-petition before Delhi Hon'ble Court in the meanwhile.
9. The appeal was taken up for hearing on 20.1.2020 when counsel for the appellant agreed to move application before Hon'ble High Court to withdraw the writ petition filed in the absence of hearing of its appeal because Chairman was not available as well as in view of order passed by the Supreme Court. The appeal was listed for hearing on 19.2.2020. Both counsels were agreeable to argue the matter without any delay as counsel for the appellant orally pressed for interim order if the respondent no. 3 intends to delay the hearing of appeal.
10. On 29.1.2020 the Hon'ble High Court of Delhi dispose of the writ petition bearing number WP(C) 11346/2020. It was observed in the order that the matter be decided expeditiously in the presence of both parties. The following order was passed:-

**IN THE HIGH COURT OF DELHI AT NEW DELHI**  
**W.P.(C) 11346/2019 & CM APPL. 46769/2019, 2833/2020**

NOVARTIS AG

... Petitioner

Through: Ms. Mamta Jha & Mr. Ankit  
Arvind,

Advocates (M-9873603089)

Versus

UNION OF INDIA & ORS.

...

Respondents

Through: Mr. Kirtiman Singh, CGSC  
with Mr.

Noor,

Rohan Anand, Mr. Waize All

Advocates for UOI.

Rahman

Mr. Rajeshwari & Mr. Saif

7409531351)

Ansari, Advocate (M-

**CORAM;**

**JUSTICE PRATHIBA M. SINGH**

**ORDER**

**29.01.2020**

*Ld. Counsel for the Petitioner seeks to withdraw the present petition as it is submitted that the IPAB is currently functioning and the hearing has in this matter has been fixed for 19<sup>th</sup> February, 2020. Accordingly, the petition is dismissed as withdrawn.*

*It is submitted by ld. counsel for the Respondents that the Technical Member who is currently functioning in the IPAB is looking after the Protection of Plant Varieties and Farmers' Rights Act, 2001 and therefore, considering the order in **Mylan Laboratories Limited v Union of India WP (C)5571/2019(Decided on 8<sup>th</sup> July, 2019)**, the Board can seek assistance of any other expert in the field of pharmaceuticals. Let a request to this effect be made to the Chairman, IPAB, who shall consider the same.*

*Considering the delay which has already occurred in this matter due to the non-functioning of the IPAB, it is requested that the matter be decided expeditiously.*

*If the IPAB is non-functional for any reason, then the parties are permitted to avail of their legal remedies.*

*The next date of hearing is cancelled.*

**PRATHIBA M.SINGH, J.**

*January, 20, 2020.*

11. The appeal was adjourned to 13.3.2020 and was taken up on 16.3.2020. Counsel for the appellant argued at great length. The appeal was adjourned to 14.4.2020. Due to lockdown because of COVID-19, the hearing could not be taken place. It was taken in the month of June, 2020 and was listed for hearing on 9.7.2020 for final arguments. In the meanwhile as requested two weeks time was granted to the parties to file written-submissions in the main appeal.
12. It appears that respondent no 3 on 29.6.2020 filed the writ petition before the High Court inter-alia seeking certain reliefs including that the application for appointment of scientific expert is not decided before hearing of appeal. Copy of petition was received by the IPAB through Government counsel who addressed the communication to Ministry also. The said petition was disposed of on 1.7.2020 with certain directions, including to decide the pending application as for appointment of scientific expert filed by the respondent no. 3.
13. When the matter was taken up on 09.07.2020 after disposing of writ petition filed by the respondent no. 3, who sought an adjournment for two weeks, the following order was passed:

**ORDER SHEET**

**09/07/2020**

*Counsel for the  
Applicant/Appellant*

*Mr. Hemant Singh*

*:*

*Counsel for the  
Respondent*

*Mr. Tahir A.J. for  
respondent No.3*

*The above appeal is listed today for remaining  
argument.*

*2. While disposing of the writ petition filed by  
respondent No.3 herein, the Hon'ble High Court of Delhi on  
01.07.2020 has passed certain directions, which are  
reproduced here:*

" 12. In these facts and circumstances, in my opinion, it would be appropriate for the petitioner to reiterate the submissions made herein before the IPAB including the request to IPAB to deal with its application dated 17.02.2020 expeditiously. In case, such a request is made before the IPAB, the IPAB is requested to deal with the request/application expeditiously as per law keeping in view the judgment of this court in '**Mylan Laboratories Ltd. v. Union of India**' and also the order of this court dated 29.01.2020 in W.P.(C) No.11346/2019.

13. At this stage, learned counsel for respondent No.3 submits that these requests of the petitioner may needlessly delay the disposal of the appeal on technical grounds which are being raised by the petitioner. These aspects would surely be dealt with by the IPAB while dealing with the requests of the petitioner.

14. It is needless to add that this court has not made any observations on the merits of the contentions raised by the learned senior counsel for the petitioner and the learned counsel for respondent No.3."

3. On behalf of respondent no. 3 the application for adjournment of two weeks was filed yesterday on the grounds that one of the counsels is met with an accident who suffered many bruises.

4. Mr Hemant Singh advocate appearing on behalf of appellate has strongly opposed the adjournment. He states that because of impugned order passed by the respondent no. 2 the interim orders passed by the Hon'ble High Court of Delhi in a suit for infringement filed by the appellate against the respondent no .3 has been vacated on the ground of non existent of Patent in dispute. It is also submitted by him that despite of orders passed by the High Court to hear the appeal expeditiously, the respondent no 3 is delaying the hearing of appeal. It is submitted by him that other counsels appearing should argue the matter. More than 8 months have been passed after starting of hearing in the appeal. Even the respondent No.3 has not filed the written arguments despite of last order and it shows that the delay in arguing the matter is deliberate.

The other submission is that his client stay application was kept pending as counsel appearing on behalf of respondent no 3 assured IPAB to argue the main appeal itself.

He says that in case the matter is being adjourned, at least the orders be passed in his clients stay application which is

*already heard and on the basis of pleading, written submissions and arguments already the pending application be decided.*

5. *When such situation is explained to the counsel appearing on behalf of respondent no 3 who is agreeable that let the appeal and application for appointment of scientific expert be adjourned and order be passed in the pending stay application.*

6. *In view of above, let the appeal and application filed by the respondent no 3 is adjourned to 23.7.2020. The order in stay application is reserved. The written arguments are already placed on record by both parties.*

***Technical Member (PVPAT)***

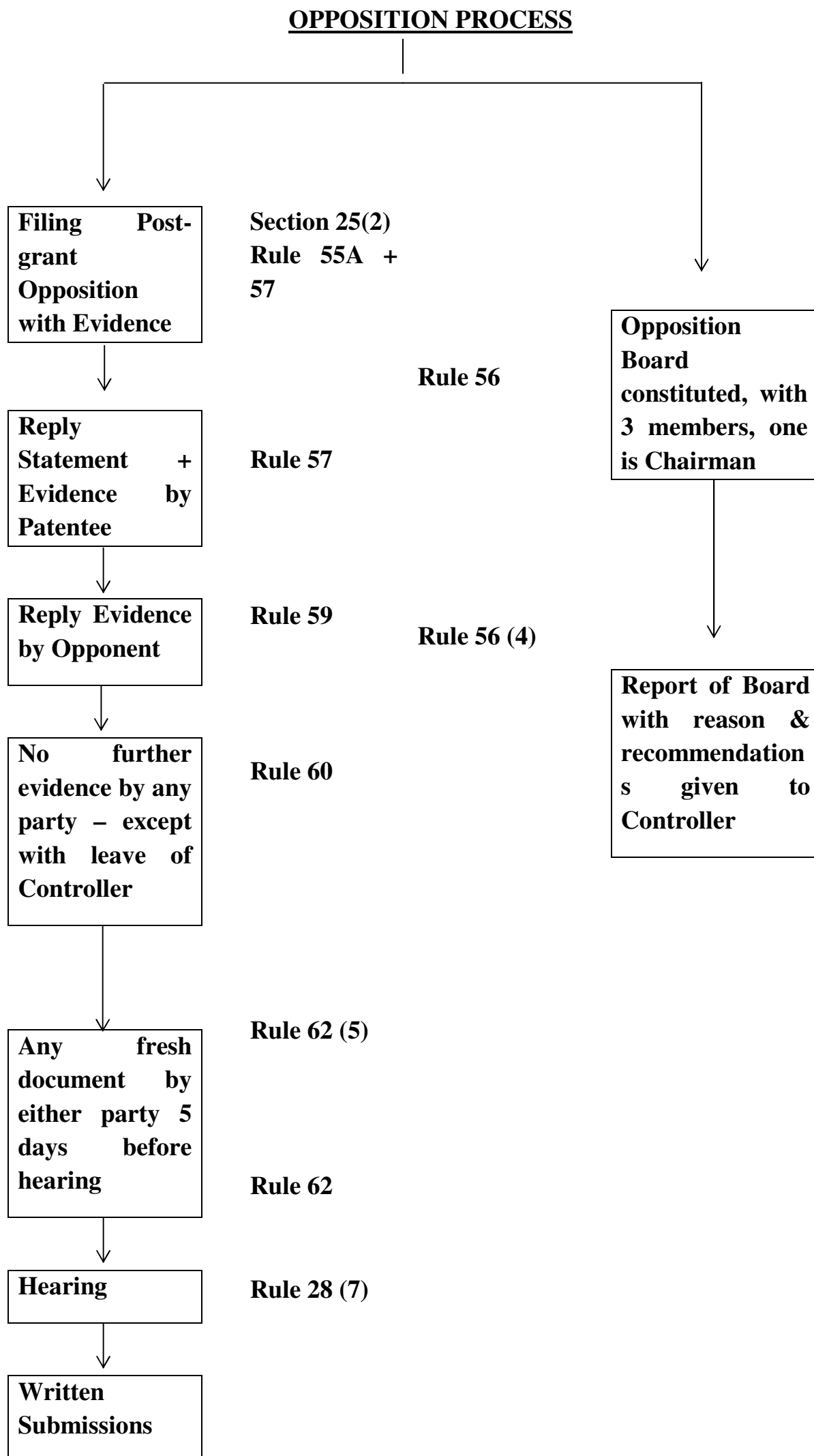
***Chairman***

14. The Respondent no 3 had already filed the written submissions in the stay application. Copies of written submissions filed before respondent no. 2 / Controller of Patent are already placed on record. The appellant has also filed the trial court record covering more than 3500 pages before hearing of appeal.
15. In view of last order, we have no option to decide the stay application as counsel for the appellant is pressing for hearing and because of delay occurred in the matter. The counsel for appellant says that in the absence of stay and in view of impugned order, the interim order passed by the High Court has been vacated in a suit filed against the respondent no.3 because of non existence of Patent, in question. Since such situation suits the respondent no. 3, now the appellant is pressing for disposal of stay application because of delay of hearing of appeal.
16. The present order is being passed in continuation with orders dated 21.08.2020, 09.07.2020 and on the basis of pleadings of the parties, written submissions and the arguments addressed in the stay application and in the main appeal which is now adjourned to 23.07.2020 when the application for appointment of expert shall also be considered before further hearing of the appeal. Parties have raised various issues in appeal, we are only concerned with the stay application at present . It is to be examined as to whether the operation of impugned order is to be stayed or not. In deciding the present application, we intent to only deal with the two issues between the parties.
17. The question before us as to whether the appellant is entitled for any relief in view of admitted facts between the parties by disposing of stay application.
18. Issue No.1  
Whether the impugned order passed by respondent no 2 was contrary to the order/direction passed by the Hon'ble Delhi High Court.

The facts are given as under:-



i) Let us first give the details of Opposition Process :-



- ii) In the present case, parties admittedly completed their respective evidence under rules 57 to 61 of the Act after the completion of pleading. There is no provision or rule to produce new evidence once the hearing to be conducted by the parties under Rule 62. There is a window of sub rule 4 of Rule 62 where either party is allowed to rely on any publication at the hearing by giving notice to the other party and to controller not less than five days notice of his intention with details of such publication.
- iii) It is not denied that the respondent has also produced the documents other than publication who has also filed detailed affidavit. It is the case of appellant that no copy was served nor the documents and when it came to the notice, the prayer was opposed by filing of reply on 8.4.2019.

#### The appellant response

After hearing, the order was reserved. The appellant for the safety side had rebutted the additional evidence on merit on filing of affidavit on 9.7.2019. However when the impugned order was passed in August 2019 after issuing the directions by the Hon'ble High Court who was dealing with the suit for infringement of Patents on 11.7.2019.

It is evident that in the impugned order, neither reply filed by the appellant was discussed, nor the rebuttal affidavits dated 9.7.2019 which dealt with additional evidence, were filed by the respondent.

It is not denied by the respondent that no notice was issued to the appellant in the application filed by the respondent for additional evidence nor time was granted to file reply by passing the orders on file. It is also admitted by the counsel for the respondent that rebuttal evidence has not been dealt with except stating that the rebuttal affidavit was filed after the order was reserved.

19. No doubt that Code of Civil Procedure 1908 is not applicable however its principles are applicable as under Section 77 of the Act the Controller has power of a Civil Court and he has to exercise the discretion by following the natural justice and not by his/her whimsical way. The Patent Act is a Special Act. Parties are having valuable rights. The Controller has to exercise its discretion as per settled law. There is no Section or Rule to suggest to produce additional evidence. Sub Rule 4 of Rule 62 only allows either party to rely on publication. In the present case, the additional evidence is not merely publication but also additional affidavit and evidence/ documents. Copy was not supplied. No notice was issued as per record nor time for reply was given. The rebuttal affidavits filed on behalf of appellant have not been dealt with. Even nothing is on record to show that assuming the evidence is likely to be taken on record, no order of rebuttal evidence was passed. Simply the final order was passed without any discussion of the objections of the appellant and the issues dealt in the rebuttal affidavits. It is settled law that when additional evidence is sought to be admitted, the opposite party should be given an opportunity to contest the admissibility of the evidence and without allowing opportunity to the other side to rebuttal, such order is erroneous and findings are liable to be

reversed. Even if additional evidence is produced in pending appeals, the appellant court has a power to remand the matters for trial de novo.

20. It is the case of the appellant that the evidence filed by the appellant could not have been taken on record even otherwise, since evidence as such is only supportive of facts and is not the fact by itself. It is submitted that on record, there are sufficient facts to establish that the compound Ceritinib is disclosed by and covered by the prior art. The appellant has been unable to repel this contention. It is also submitted that the Opposition Board was constituted on or about 18.05.2018 and the said Opposition Board only considered the opposition as filed by this Respondent, the Reply Statement filed by the appellant and the rejoinder of the respondent. However, the Opposition Board appears to have considered only the appellant's version and has failed to appreciate that the invention of the compound Ceritinib is obvious and in fact, the compound Ceritinib lacks novelty in view of the prior art. The Opposition Board also did not have the benefit of going through the patent term extension document. It was alleged that the said petition under Rule 137 filed by the opponent prayed that the affidavits of Dr. Durga Prasad and documents dated April 5, 2019 should be forwarded to the Opposition Board. In this regard, the learned Controller during the hearing on 9<sup>th</sup> April, 2019 noted that Opposition Board has considered the affidavit of Dr. Durga Prasad in its recommendations. As regards the documents filed on April 5, 2019, the same cannot be considered as it constitutes further evidence under Rule 60. Additionally, Rule 62 clearly provides that if any party desires to rely upon any publication at the hearing not already mentioned in the notice, statement or evidence, such party shall give to the other party and to the Controller not less than five days' notice of his intention, together with details of such publication. Admittedly, Rule 62(4) has not been invoked, at all, by the Opponent. In any case, there was no service of any publication upon the Patentee as mandated under Rule 62(4). Rule 60 is specific provision/rule relating to file further evidence as against Rule 62 which is applicable in respect of publications(s) as aforesaid in general. Provision of Rule 60 override the provisions of Rule 62 in relation to file further evidence. Accordingly, the provisions of the Rule 62 or 62(4) are not applicable in the present case. Furthermore, the new/additional documents relied upon by the Opponent during hearing is not a publication but an affidavit by an expert and its annexures which are essentially in nature of further evidence, which are totally impermissible under Rule 60 of the Patents Act.
- 20.1. In the meanwhile, on 04.04.2019, i.e. five days before the scheduled final hearing before the Controller, Natco filed additional evidence by way of affidavit dated 03.04.2019 of Dr. Ramesh Dandala along with documents which were primarily related to patent term extension filed by the Appellant before United States Patent & Trademark Office in respect of Ceritinib. It is alleged by the appellant that the documents were beyond pleadings but they were also not permissible under Rule 60 of The Patent Rules 2003 which prohibit filing of any additional evidence after the hearing has been fixed by the Controller under Rule 62 which had been fixed on 09.08.2018.

- 20.2. It is stated that Appellant learnt about such additional evidence only through perusal of the case file on the website of IP office on 08.04.2019. The Appellant submitted strong opposition to such filing while reserving the right to file rebuttal evidence.
- 20.3. It is alleged on behalf of appellant that the same were filed without serving copy thereof to the Appellant along with an application under Rule 138 of The Patents Rules. These documents and evidence could have been filed earlier but were deliberately chosen not to be filed within prescribed time frame, denying and defying opportunity to the Appellant to file its response before the scheduled hearing. The Appellant filed its reply objection to the petition under Rule 138 of the Opponent stating that the additional documents and evidence should not be taken on record particularly in the facts of the case wherein (i) the copy of the petition and evidence was not served upon the patentee (ii) the patentee only noticed 138 applications and the voluminous affidavit and documents on the website on its own (iii) the conduct of the Opponent seeking several adjournments for the hearing (iv) the pleading and evidence in the opposition was concluded in February, 2018 (v) the filing of large number of documents/record of publically available documents along with evidence after expiry of more than a year without serving copy upon the patentee is *malafide* and evidence ought to be rejected.
- 20.4. The respondent no. 2 heard final arguments without issuing any notice on Rule 138 application of Natco or without giving any opportunity to Appellant to file any rebuttal evidence to Natco's evidence dated 05.04.2019. The respondent no. 2 also did not pass any order accepting or rejecting Rule 138 application of respondent no.3/Natco.
- 20.5. It is stated on behalf of appellant that the appellant came to know from the IP office website on 02.05.2019 that Natco has uploaded written note of submissions dated 25.04.2019 with no advance copy served on the Appellant. Accordingly, the Appellant also submitted its written note of submission dated 24.05.2019.
- 20.6. As no orders were received from the Controller either accepting or rejecting Rule 138 application of Natco, by way of abundant caution, and to avoid any prejudice, the Appellant submitted rebuttal evidence dated 09.07.2019. The rebuttal was required since Dr. Dandala, made gross misrepresentation and testified falsely by way of his affidavit dated 02.04.2019 that Ceritinib is disclosed in US 7964592. Dr. Dandala further raised fresh pleas of invalidity based on obviousness and new documents including article entitled "Inhibition of the NPM-ALK Fusion Tyrosine Kinase in Hematopoietic Neoplasia by the Small Molecule Tyrosine Kinase Antagonist TAE684" (Blood); US Patent No. 7,964,592; FDA submission – Orange Book; Patent Term Extension – US Patent No. 7,964, 592; Complaint for Patent infringement – Rigel Pharmaceuticals, Inc. vs. Novartis Pharmaceuticals Corp; Indian Patent No. 239514; U.S. Patent No. 8,188,276 which required rebuttal and explanation.
- 20.7. The Appellant submitted affidavits of Dr. Altenbach dated 02.07.2019 rebutting the plea of obviousness and Mr. Irving Fishman dated 08.07.2019 explaining the laws pertaining to patent linkage, orange book and the provisions

for patent term extension under the US patent laws and the reliance of Dr. Dandala on patent linkage envisaged under the US laws are wholly irrelevant and have no application to the issue of patentability under the Indian Patents Act.

21. In the meanwhile, the Appellant on 02.05.2019 filed a suit for patent infringement before the Hon'ble Delhi High Court against the Respondent No. 3/Natco as the Respondent No. 3 without awaiting the final order to be passed by the Respondent No. 2 in pending opposition, had gone ahead and launched Ceritinib capsules, the patented drug, in the market on 29th March, 2019. The Hon'ble Court on being *prima facie* satisfied with the case, granted an order of injunction against the respondent no.3. However, the said interim order was vacated on 20.08.2019 once the impugned order was passed on 16.08.2019.
- 22.. In order to understand the said issue, para 6 of the impugned order where the question of additional evidence is dealt with, is reproduced.

*“6. During Hearing the Opponent 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 IN232653 (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 extention was filed, but Patentee failed to give any reasonable and convincing argument.”*

23. It is to be examined as to whether the hearing officer has followed the principles of natural justice.

24 Reply by the respondent No.3

The reply of the learned counsel for the respondent is that since the final order has been passed, the hearing officer must have gone through the entire records and it is irrelevant if it is not dealt with comprehensively. Counsel for the respondent No.3 however admitted before use that rebuttal evidence produced by the appellant on 09.07.2019 has not been considered by respondent No.2.

25. The hearing officer who is respondent no 2 herself appeared on 21.8.2019 and on enquiry, she admitted that no notice to the application was issued to the counsel for the appellant in the application for filing the additional evidence on behalf of respondent no 3. It was informed that there is no practice and procedure and record is silent in this regard as nothing was noted. It was stated by her that orally it was informed to the counsel for appellate to file reply.

26. The explanation given by respondent no 2 is not acceptable as in another appeal no 46/2020 being heard by IPAB where the impugned order was passed by another officer, we have noticed that under similar circumstances, while dealing the application of filing the additional evidence, proper notice was issued, time for reply was given and the hearing was conducted before final hearing in the application for filing the additional evidence by the respondent. Admittedly, in the present case, the hearing officer heard the final hearing. The additional evidence was dealt with and filed by the respondent no. 3, but neither reply to application of additional evidence was considered nor rebuttal evidence filed by two affidavits to additional evidence was considered. The respondent no 3 has argued that the same were not filed in time and it was filed after the reserve of orders. The said arguments of the respondent no. 3 have no force as the same are contrary to the order of the Hon'ble High Court dated 11.07.2019.
27. On the petition filed by the appellant before the Hon'ble Court, the Hon'ble High Court by its Order dated 11.07.2019 directed the Controller to pass an order on the post-grant opposition and not permit any of the parties to file any further documents. The Hon'ble High Court observed that no order was passed by the Controller accepting or rejecting the evidence of Respondent No.3/Natco and rebuttal evidence has been filed by the Appellant on 09.07.2019. The relevant extract from the order dated 11.07.2019 are as under:

*“1.....Controller General did not give any clarity as to whether affidavit dated 30.04.2019 was taken on record or not and whether any submissions were to be filed by the parties after the hearing was concluded.”*

*“3..... The Controller General shall now go ahead and proceed to pass orders in the post-grant opposition within a period of one month from today. No further filing shall be done by either party.”*

28. The Ld. Single Judge of Hon'ble Delhi High Court in CS(Comm) 229/2019 passed an order observed that -

*“ The Controller General was expected to follow strict timelines once judgment was reserved. Neither party ought to have been permitted to file anything further. However, the same has been breached as the Controller did not give any clarity as to whether affidavit dated 30<sup>th</sup> April, 2019 was taken on record or not and whether any submissions were to be filed by the parties after the hearing was concluded”.*

The Court further observed that in future, the Patent Office shall ensure that when the hearing is concluded, it is clarified whether any timeline is being given for filing written submission or not. The Court further observed that Controller General shall now go ahead and proceed to pass order within one month from today. No further filing shall be done by either party.

Evidently, the Hon'ble Court clearly observed that order shall be passed on all the documents placed on record as on 11/07/2019 and no further documents shall be filed by the parties. The reply to additional evidence was already filed on 9.7.2019. No further documents were filed by the appellant

after the said order. Even if the respondent no. 3 had any objection about filing of reply to the additional evidence prior to the said date, it could have been pointed out to the court. Actually, it was accepted by the parties that before the said order dated 11.07.2019, the respondent no. 2 shall pass the final order whatsoever is available on record.

- 29.. The respondent no. 2 having been made aware of the said order dated 11/07/2019 disregarded the evidence filed by the while passing the impugned order.
30. It is admitted by the counsel appearing on behalf of respondent no 3 that rebuttal evidence filed by the appellant by way of two affidavits have not been considered
31. In view of above, prime facie, it is clear to us that such important issue raised in the appeal requires consideration as to whether the respondent no. 2 has complied the order passed by the Hon'ble High Court strictly and if not what are the consequences. The same has been argued in appeal and we have to give our findings in this regard.
32. Whether the respondent no. 2 was misled by respondent no. 3 in its pleadings.
  - a) Admittedly, in the rejoinder filed by respondent no. 3 in opposition proceedings, in order to meet the plea raised by the Appellant, it was pleaded that representative examples from the prior art documents demonstrate combination of present invention i.e. substituted phenyl ring and the heterocyclic ring attached to that ring via a carbon atom as given in the table contained in the rejoinder. The respondent no. 3 reproduced example 28, 66, 67, 74 and 131 which are examples cited in IN'026 and cited them in table-2 as examples of WO'980 (IN'653).

The relevant part of para-4 A of rejoinder is reproduced hereunder:

*“All contents of para A are denied. It is reiterated that the prior art is replete with examples demonstrating the combination of the present invention i.e. tri-substituted phenyl ring and the heterocyclic group attached to that phenyl ring via a carbon atom. All averments made in the opposition with respect to with the basic structure of the compounds of the impugned patent are reiterated herein.*

*Some representative examples from prior art documents demonstrating combination of present invention i.e. substituted phenyl ring and the heterocyclic group attached to that phenyl ring via a carbon atom are given below in Table 2-6.*

*Table 2: Compounds of WO'980”*

- b) It is stated on behalf of appellant that the said act of fraud is committed by Respondent No.3 in the present proceedings which itself was sufficient for rejection of the post-grant opposition and an appropriate for initiation of prosecution proceedings against Directors of Respondent

No.3 for perjury be passed. We have noticed that in the impugned order, nothing has been discussed. It was simply ignored.

c) The submission of the appellant is that the plea of anticipation is liable to be rejected as there is no pleading in the notice of opposition that the inventive step of IN'026 is disclosed in any of the cited prior arts as there is also no example disclosed, described or individualized in any of the prior art which is the same as compound of IN'026.

33. When it was pointed to counsel for the respondent no 3, no satisfactory reply was given. It was submitted by the counsel that the impugned order was passed on the basis of other materials also. It is not explained how the example 28, 66, 67, 74, and 131 reproduced in the pleadings which are the example taken from impugned Patent 276026 and cited in table 2 as example of WO "980 ( IN 653). As far as pleading of misleading facts by any party, no doubt, it is a serious matter. IPAB has also compared the pleadings in this regard,. The statement made by Mr. Hemant Singh appears to be correct.

34. We do not propose to make any comment at present. We do not wish to decide these two issues finally as these are required to be decided in appeal, but we are of the opinion that the appellant has made a strong case of stay of the operation of impugned order dated 16.8.2019.

35. Thus, we direct that, till the appeal is finally decided, the operation of impugned order dated 16.8.2019 shall remain stayed.

36. We may clarify that the findings are tentative and shall have no bearing when the appeal will be decided on merit on all issues without the influence of this order. We have only decided two issues which are of civil nature.

37. The application/representation made after reserving the orders on stay application are not maintainable and the same are rejected.

38. No costs.

**-Sd/-**

**(Dr. Onkar Nath Singh)  
Technical Member (PVPAT)**

**-Sd/-**

**(Justice Manmohan Singh)  
Chairman**

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