

IN THE HIGH COURT AT CALCUTTA
ORIGINAL SIDE
(Intellectual Property Rights Division)

BEFORE:

The Hon'ble Justice Ravi Krishan Kapur

IPDPTA/1/2025
IA NO: GA-COM/1/2025

VIIV HEALTHCARE COMPANY AND ANR
VS
DY CONTROLLER OF PATENTS AND DESIGNS AND ORS.

For the appellant	: Ms. Archana Shankar, Advocate Ms. Mini Agarwal, Advocate
For the Controller of Patent	: Mr. Swatarup Banerjee, Advocate Ms. Mary Dutta, Advocate Mr. Sariful Haque, Advocate
For the respondents 2 to 5	: Mr. Anand Grover, Senior Advocate Ms. Jhuma Sen, Advocate Ms. Swatika Chatterjee, Advocate Mr. Mehboob Rahaman, Advocate
For the respondent no.6	: Mr. Subhatosh Majumdar, Advocate Ms. Mitul Dasgupta, Advocate Ms. Amrita Majumdar, Advocate Mr. Teesham Das, Advocate
For the respondent no.7	: Mrs. Rajeshwari, Advocate Mr. Tahir Aj, Advocate Mr. Paritosh Sinha Advocate. Mr. K.K. Pandey, Advocate Ms. Pooja Sett, Advocate Ms. Mallika Bothra, Advocate
Judgment on	: 14.05.2025

Ravi Krishan Kapur, J.:

1. This appeal has been filed under section 117A of the Indian Patents Act 1970 challenging an order dated 3 October, 2024 passed by the

respondent no.1, Deputy Controller of Patents and Designs rejecting Indian Patent Application No. 3865/ KOLNP/ 2007.

2. During the pendency of this appeal, in view of a settlement by and between the appellants and the respondent no.6, the respondent no.6 had withdrawn the pre-grant opposition filed by them. Hence, the appellant and the proceeding insofar as the respondent no.6 is concerned stood settled on the following terms and conditions:

- a) That the appellants have no objection to the making, using, offering for sale and selling of Dolutegravir only by the respondent no. 6 including its successors, assigns, affiliates, subsidiaries, distributors, agents, representatives, and any other entities under its control or acting on their behalf for the manufacture and marketing of Dolutegravir at any future point of time (no right to sub-license) claimed by Indian patent application no. 3865/KOLNP/2007 in India and the appellants would not sue the respondent no.6 for infringement should the patent be granted to appellant upon remand.
- b) That the respondent no. 6 undertakes not to make or sell Cabotegravir at any time prior to April 28, 2026.
- c) The respondent no. 6 shall withdraw and not pursue the pre-grant opposition in relation to IN 3865/KOLNP/2007 should the impugned order of the respondent no. 1 dated October 3, 2024 be set aside and application no. IN 3865 be remanded to the respondent no. 1 for fresh adjudication and that said pre-

grant opposition proceeding would not be adjudicated upon by the respondent no. 1.

- d) The respondent no. 6 shall not participate in these proceedings and shall withdraw from all further participation.
- e) The respondent no. 6 would also not institute a fresh proceeding against the grant and subsequent to grant, till the expiry of the patent.

In this background, this appeal has been contested by the respondent no.1 Controller, the respondent nos.3 and 5 and the respondent no.7.

3. Briefly, the impugned application IN 3865 relates to a “Polycyclic Carbamoylpyridone Derivative having HIV Integrase Inhibitory Activity”. In particular, the application for patent is directed to two new HIV integrase inhibitors, Dolutegravir and Cabotegravir. Claims 1 to 3 are in relation to the compound Dolutegravir and claims 4 to 6 are in relation to the compound Cabotegravir.
4. For convenience, the relevant dates summarizing the proceedings under the Act are set out below:

Sr. No.	Date	Event
1	28 th April 2006	The International (PCT) Application number PCT/U2006/116764 deriving priority from the two applications was filed
2	10 th October 2007	The National phase application under Section 7(1A) was entered in India and patent application number 3865/KOLNP/2007 was assigned to it.

Sr. No.	Date	Event
3	18 th July 2008	Indian Patent Application 3865/KOLNP/2007 was published.
4	22 nd April 2009	Appellants filed request for examination of the 3865/KOLNP/2007
5	27 th February 2012	The respondent No. 1 examined the patent 2012 application and issued the First Examination Report (FER)
6	30 th August 2012	The appellants filed response to the First Examination Report issued by the respondent No. 1 issued on 27 th February 2012.
7	16 th October 2012	The respondent No. 1 issued the subsequent examination report (SER).
8	13 th February 2013	Appellants filed response to the subsequent examination report (SER) and amended claims 1 to 9, filed with SER response
9	12 th February 2013	The respondent No. 2, Delhi Network of HIV+ People (DNP+) (Opponent-1), filed the first Pre-Grant Opposition under Section 25(1) read with Rule 55.
10	26 th June 2013	Appellants filed reply statement to the pre-grant opposition filed by Respondent No. 2, Delhi Network of HIV+ People (DNP+) along with affidavit of Dr Brian John (Affidavit-Johns-1).
11	20 th December 2015	The respondent No. 3, Bengal Network of HIV+ People (BNP+ and Mr Firoz Shah) filed the second pre-grant opposition (Opponent 2).
12	3 rd February 2016	Third pre-grant opposition was filed by the respondent No. 4, Mr. Sanjeev Sharma (Opponent-3)
13	4 th February 2016	Appellants filed the evidence of their expert, Dr. Sheo Bux Singh (Affidavit-Dr Singh-1) and hearing was scheduled for 15 th February 2016.
14	4 th February 2016	Hearing u/s 25(1) in the pre-grant opposition filed the respondent No. 2 was concluded.
15	12 th April 2016	Appellants filed reply statement to the second pre-grant opposition filed by the respondent No. 3, (BNP+ and Mr Firoz Khan, i.e, BNP+) along with affidavits of Dr Brian John (Affidavit-Dr. Johns-2) and Dr. Sheo Bux Singh (Affidavit-Dr Singh-2).
16	2 nd May 2016	The respondent No. 3 (Opponent-2) made request for Cross-

Sr. No.	Date	Event
		Examination of the Appellant's expert Dr. Brian Johns and Dr. Sheo Bux Singh.
17	22 nd July 2016	Fourth Pre-Grant Opposition under Section 25(1) was filed by Respondent No. 5, Dr. Mira Shiva (Opponent-4)
18	13 th June 2017	Appellants consented for the cross-examination of Dr Sheo Bux Singh.
19	21 st July 2017	Appellants filed reply statement against the pre-grant opposition filed by the respondent No. 4 and 5, along with affidavit of Dr. Sheo Bux Singh (Affidavit-Dr Singh-3) and (Affidavit-Dr Singh-4).
20	16 th August 2017 17 th August 2017	Hearing u/s 25(1) was concluded in the pre-grant opposition filed the Respondent No. 3, 4 and 5.
21	18 th August 2017	Cross examination of Dr. Sheo Bux Singh was concluded on 18-Aug-2017 in the pre-grant Opposition filed by Respondent No. 3.
22	31 st October 2018	The respondent No. 6, Natco Pharma Ltd., (Opponent-5) filed the fifth pre-grant opposition.
23	28 th January 2019	Appellants filed the reply statement to the pre-grant opposition filed by the respondent No. 6, along with the evidence of Dr Sheo Bux Singh and Dr Brian Johns filed in the other pre-grant opposition proceedings.
24	18 th March 2019	Hearing under 25(1) in respect of pre-grant opposition filed by the respondent No 6, Natco Pharma Ltd, was concluded.
25	30 th March 2019	The respondent No. 6, Natco Pharma Ltd., filed the writ petition W.P. 7470 (W) of 2019 before Calcutta High Court advocating the cross-examination request.
26	5 th April 2019	Hearing in the Writ Petition 7470 (W) of 2019 was concluded and order was issued.
27	14 th June 2019	The respondent No. 1 issued order on the request of cross-examination in view of the Writ Court order dated April 05, 2019
28	2 nd December 2019	Sixth pre-grant opposition was filed by the respondent No. 7 (Opponent-6, Sankalp Rehabilitation Trust)
29	22 nd May 2020	Appellants filed the reply statement to the sixth pre-grant opposition along with the affidavit of Dr Sheo Bux Singh and Dr Brian Johns.

Sr. No.	Date	Event
30	9 th September 2020	Hearing u/s 25(1) was concluded in relation to the sixth pre-grant opposition filed by the respondent No. 7 (Opponent-6, Sankalp) was concluded
31	8 th April 2024	New hearing officer, respondent No. 1, communicated the progress of the pre-grant proceeding and invited the parties to submit any new documents within 10 days' time period.
32	18 th April 2024	The respondent No. 6, NATCO Pharma Ltd., made a request for fresh hearing
33	11 th June 2024	The respondent No. 1. issued a hearing notice scheduling hearing on 1 st and 2 nd July 2024 in the six-pre grant opposition proceedings.
34	27 th June 2024	The respondent No. 6, NATCO Pharma Ltd., filed a request for adjournment and therefore to defer the hearing scheduled on July 01, 2024 until the fresh writ is decided.
35	30 th June 2024	The respondent No. 7, filed writ before High Court at Calcutta against the order of the respondent No. 1 dated June 14, 2019.
36	1 st July 2024	The respondent No. 1 concluded hearing in the first pre-grant opposition filed by the Respondent No. 2, Delhi Network of Positive People.
37	2 nd July 2024	Respondent No. 1 concluded hearing in the third pre-grant opposition filed by the respondent No. 4, Mr Sanjeev Sharma and hearing under Section 14.
38	15 th July 2024	The respondent No. 1 concluded hearing in the second pre-grant opposition filed by Respondent No. 3, 4 and 7
39	16 th July 2024	The respondent No. 1 concluded hearing in the fifth pre-grant opposition filed by the respondent No. 6, Natco Pharma Ltd.
40	3 rd October 2024	The Respondent No. 1 issued the impugned order refusing the grant of patent for the Indian Patent Application, 3865/KOLNP/2007.

5. Upon the filing of the above application, several pre-grant oppositions were filed by respondent no. 2 [Delhi Network of People Living with HIV/AIDS(DNP+)] respondent no. 3 [Bengal Network of People Living with

HIV/ AIDS (BNP+) and Mr. Firoz Khan, the respondent no. 4 [Mr Sanjeev Sharma]; the respondent no. 5 [Dr. Mira Shiva], the respondent no. 6 [Natco Pharma Ltd.] and the respondent no. 7 [Sankalp Rehabilitation Trust] between the period 2013 to 2020.

6. The hearings in the pre-grant oppositions filed by the respondent No. 2 were concluded on 4 February 2016. Further hearings to the pre-grant oppositions filed by the respondent no. 3; respondent no. 4 and respondent no. 5 were concluded on 16 and 17 August 2017 respectively. In addition, the cross-examination of the appellant's expert witness, Dr. Sheo Bux Singh stood concluded on 18th August 2017. Thereafter, hearing to the pre-grant opposition proceedings of the respondent no. 6 and the respondent no. 7 was concluded on 18th March 2019 and 9th September 2021 respectively.
7. In an earlier writ petition being WP 7404 of 2019, a Co-ordinate Bench of this Court by an order dated 13 April 2019 had directed the Controller to consider the request for cross-examination filed by the respondent no.6. Pursuant to such direction, the respondent no.1 passed an order refusing the application for cross-examination of the respondent no.6. Being aggrieved by the order dated 14 June 2019, a second writ petition was filed numbered WP 16643 of 2024 wherein, a Co-ordinate Bench had passed the following order:

“Thus, the authority is directed to consider the opposition of Natco Pharma Limited, without taking into account the six affidavits filed by the experts.

It is further directed that the opposition of Natco Pharma Limited, shall be decided on the basis of records other than those relating to the proceedings of other objectors in which the affidavits

of the experts had been either referred to or relied upon or discussed.

The writ petition is accordingly disposed of.

There shall be no order as to costs.

All parties are to act on the basis of server copy of this order.”

8. A plain reading of the above order indicates that the concession by the appellants before the Court was only limited to the opposition proceeding filed by Natco Pharma and not in relation to any other objections which were pending before the respondent Controller. It is significant to mention that despite the hearing of the above application of patent being concluded on four prior occasions by different Hearing Officers, no final order was passed. Subsequently, the matter was transferred to a new Hearing Officer who heard the matter on 1 July 2024, 2 July 2024, 15 July 2024 and 16 July 2024 respectively and passed the impugned order.
9. In passing the impugned order, the respondent no.1 has interpreted the order of the High Court dated 15 July 2024 to mean that the entire expert evidence relied on by the appellants need not be taken into consideration in deciding the above application for patent. In this context, it is important to highlight that the following expert evidence had *inter-alia* been relied on by the appellants before the Authorities.
 - a) Dr. Brian A. Johns had adduced expert evidence in the pre-grant opposition filed by the respondent no. 2, on 26th June 2013.
 - b) Dr. Sheo Bux Singh had filed evidence in the opposition filed by the respondent no. 2, on 4th February 2016.
 - c) Dr. Brian A. Johns (in the pre-grant opposition filed by the respondent no. 3) filed on 12th April 2016.

- d) Dr. Sheo Bux Singh (in the pre-grant opposition filed by the respondent no. 3) filed on 12th April 2016.
- e) Dr. Sheo Bux Singh (in the pre-grant opposition filed by the respondent no. 4) filed on 21.07.2017.
- f) Dr. Sheo Bux Singh (in the pre-grant opposition filed by the respondent no. 5) filed on 21.07.2017.

10. The impugned order has been passed on the merits of the case without taking into consideration any of the expert evidence relied on by the appellants. The interpretation given to the order dated 15 July 2024 passed by the Court is *ex facie* perverse, distorted and inherently flawed. By the impugned order, the appellants had only conceded to the objection of the respondent no.6 being disposed of without taking into account the expert evidence relied on by the appellants. There was no other concession at all which can be attributed to the appellants far less the concession that the entirety of the expert evidence on behalf of the appellant, ought not to be considered in adjudicating any of the pending objections.

11. The Act and Rules framed thereunder both contemplate expert evidence being relied on while hearing and disposal of an application for patent. This is inbuilt and is a fundamental feature in most applications for patent. In passing the impugned order and concluding that the subject application for patent is not an invention or lacked inventive steps or that there was an absence of specifications or that the specifications were not sufficiently clear the expert evidence relied on by the appellants was necessarily required to be considered regardless of the evidentiary

value. This was neither the scope nor purport of the order dated 15th July, 2024. In passing the impugned order, the Deputy Controller of Patents has misinterpreted and misconstrued the order dated 15th July, 2024 which has resulted in a complete abdication of jurisdiction. A plain reading of the order dated 15 July 2024 indicates that the concession of not relying on expert evidence was only limited to the objection of the respondent no. 6 and not to the objections of any of the other respondents.

12. It is also a matter of some regret that the subject application for patent had been pending for a considerable long period of time. It is worth recollecting that the time lines under the Act are meant to ensure that no unnecessary delays are caused during the process for grant of patent. The Patent Office is expected to pass an order within a reasonable time period and not to cause any unreasonable delay in the disposal of the application. The facts of this case demonstrate that there has been an exceptional and extraordinary delay in the disposal of the above application. Such delay is simply not justifiable and emasculates the very object of the Act. (*Procter and Gamble Co. vs. Controller of Patents and Designs 2023 SCC OnLine Del 7832, R.C. Sharma vs. Union of India 1976 (3) SCC 574 and BASF SE vs. Joint Controller of Patents and Designs & Ors. IPDPTA 5 OF 2024*).

13. For the above reasons the impugned order is unsustainable. The mis-interpretation of the order dated 15 July 2024 passed in WP 16643 of 2024 (*Natco Pharma Co. vs. Union of India & Ors.*) is *ex facie* perverse, unsustainable and vitiates the impugned order in its entirety.

14. In such circumstances, the appeal stands allowed. In view of the peculiar facts and circumstances of the case the following directions are passed:

- (i) To issue a hearing notice within two weeks from the date of this order and dispose of the subject application along with all objections(save and except NATCO) within eight weeks from the date of communication of this order.
- (ii) All the documents/publication filed by the appellants in the proceedings under Section 14 and in the pre-grant oppositions proceedings by the respondent no. 2 to respondent no. 7 are to be considered.
- (iii) NATCO (respondent no.6) shall withdraw their opposition in terms of the Settlement as enumerated in paragraph 2 above.
- (iv) The evidence of all experts to be considered in the proceedings filed by the remaining respondent no. 2 to 5 and the respondent no. 7 (save and except the respondent no.6).
- (v) In order to obviate any apprehension of predetermination, the Controller who had passed the impugned order shall not rehear the matter and the subject application along with all the objections are to be considered by any other Controller or Appropriate Hearing Officer.
- (vi) With the above directions and to the above extent, IPDPTA/1/2025 stands allowed. It is made clear that there has been no final adjudication on the merits and all questions are left open to be decided in accordance with law.

15. With the above directions and to the above extent, IPDPTA 1 of 2025 stands allowed. Accordingly, GA-COM/1/2025 stands disposed of.

(Ravi Krishan Kapur, J.)