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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**
Date of Decision: 25th March, 2022

+ **CS (COMM) 156/2021 & I.A. 6539/2021**

NOVARTIS AG & ANR. Plaintiffs

Through: Mr. Hemant Singh, Ms. Mamta Jha
 and Mr. Siddhant Sharma, Advocates.
 (M:9557629905)

versus

WINDLAS BIOTECH PVT LTD & ANR. Defendants

Through: Ms. Rajeshwari H., Mr. Vikramjeet
 and Ms. Deepanshu Nagar,
 Advocates. (M:9717996516)

10 WITH

+ **CS(COMM) 68/2022 & I.A. 1516/2022**

NOVARTIS AG & ANR. Plaintiffs

Through: Mr. Hemant Singh, Ms. Mamta Jha
 and Mr. Siddhant Sharma, Advocates.

versus

CHHABRA HEALTHCARE SOLUTIONS PRIVATE
 LIMITED

..... Defendant

Through: Ms. Archana Sahadeva and Ms.
 Pragati Agarwal, Advs.
 (M:9818758576)

20 AND

+ **CS(COMM) 557/2020 & I.As. 5231/2021, 3014/2022**

NOVARTIS AG & ANR. Plaintiffs

Through: Mr. Hemant Singh, Ms. Mamta Jha
 and Mr. Siddhant Sharma, Advocates.

versus

ERIS LIFESCIENCES LIMITED Defendant

Through: Ms. Rajeshwari H., Mr. Vikramjeet
 and Ms. Deepanshu Nagar, Advs.

CORAM:

JUSTICE PRATHIBA M. SINGH

Prathiba M. Singh, J. (Oral)

1. This hearing has been done through hybrid mode.



2. Submissions have been heard in respect of the applications filed on behalf of the Plaintiffs.
3. The present three suits have been filed seeking permanent injunction restraining the infringement of Indian Patent No.IN229051 (*hereinafter*, “*suit patent*”), damages, rendition of accounts, delivery up, etc. As per the Plaintiffs, the suit patent relates to a pharmaceutical composition consisting of Valsartan or a pharmaceutically acceptable salt thereof, and Sacubitril or a pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable carrier. The said pharmaceutical preparation is used in the treatment of cardiovascular disease.
4. The Defendants in each these suits are arrayed as under:

CS (COMM) 557/2020 'ERIS suit'	ERIS LIFESCIENCES LIMITED	Defendant
CS (COMM) 156/2021 'Windlas suit'	WINDLAS BIOTECH PVT. LTD.	Defendant No.1
	ERIS LIFESCIENCES LIMITED	Defendant No.2
CS (COMM) 68/2022 'Chhabra suit'	CHHABRA HEALTHCARE SOLUTIONS PVT. LTD.	Defendant

5. The history of the litigation goes back to a suit, being **TR COS No.1/2020**, which was filed by the Plaintiffs, against one MSN Laboratories Pvt. Ltd. (*hereinafter*, “*MSN Laboratories*” and “*MSN suit*”) before the Telangana High Court, seeking permanent injunction restraining the infringement of the suit patent, damages, rendition of accounts, delivery up, etc. In the said suit, the following order was passed on 11th December, 2020, by the Telangana High Court:



“ORDERS:

“These matters are moved as Lunch Motions.

With consent of both counsel, matters stand posted to 17.12.2020 at 2.30 pm.

Both parties are directed to maintain status-quo obtaining as on today in all respects operative for a period of one week.

Post on 17.12.2020 at 2.30 pm.”

6. The above *status quo* order was, thereafter, made absolute on 26th February, 2021. The said order was challenged before the Id. Division Bench of the Telangana High Court, wherein the appeal and cross-appeal were dismissed. The operative portion of the order dated 26th February, 2021 reads as under:

“3. Just to clarify, I may note that the High Court for the State of Telangana had on 26.02.2021 passed the following order:-

“37. For all the aforesaid reasons, there shall be interim injunction restraining the defendant/respondent, by itself or through its directors, group company, associates, divisions, assigns in business, licensees, franchisees, agents, distributors and dealers from using, manufacturing, importing, selling, offering for sale, exporting, directly or indirectly dealing in pharmaceutical composition comprising combination of valsartan or a pharmaceutically acceptable salt thereof and sacubitril or a pharmaceutically acceptable salt, and a pharmaceutically acceptable carrier or more specifically a pharmaceutical composition comprising combination of sacubitril + valsartan as sodium salt complex/compound or any other form as may amount to infringement of Indian Patent No.229051 of the plaintiff No.1.

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39. At this stage, it is represented by Sri Ashok Ram Kumar that before the status quo order was granted and after the transfer of the suit to this Court, the defendant has manufactured certain quantity of subject drug and they have expiry date and unless said stock is disposed of, grave prejudice will be caused to the defendant. He therefore submits that defendant may be permitted to sell the said quantity of drug. Having regard to this submission, defendant is permitted to sell the quantity of drugs already manufactured before the status quo order was granted by this Court on 11.12.2020. However, the defendant shall maintain account of the details of quantity of drugs already manufactured, sold in pursuant to this order and the sale proceeds. He shall furnish the details to the plaintiff No.1 and shall also file an affidavit to that effect in the suit. The permission to sell the drugs already manufactured is without prejudice to the claims of the plaintiffs and defendants in the suit.

7. Parallely, the ERIS suit was filed before this Court against ERIS Lifesciences Limited (hereinafter, “ERIS”), wherein vide order dated 21st December, 2020 passed by a Id. Single Judge of this Court, ERIS was directed to file an affidavit detailing the stock of the impugned product available with it. The said direction reads as under:

“9. Insofar as I.A.No.12285/2020 is concerned, the same is disposed of with a direction that the defendant i.e. **Eris will file an affidavit detailing out the stock available with it qua the impugned product. In this behalf, the affidavit will set forth the source from which the stock was received, the quantity of the stock received, and the sales made by the defendant after the receipt of the stock. Both, the quantity and the value of the sales**



made, will be disclosed in the affidavit.

9.1 The affidavit will be filed within 10 days from today. A copy of the affidavit will be furnished to Ms. Mamta Rani Jha i.e. the counsel-on-record for the plaintiffs.

9.2 The defendant will file a written statement and reply to the interlocutory application i.e. I.A. No. 12284/2020 within three weeks from today. Replication and rejoinder thereto, if any, will be filed before the next date of hearing.

9.3 **The parties will be governed by the order dated 11.12.2020 passed by the Telangana High Court.**

Thus, in the MSN Suit and the ERIS Suit, *status quo* orders were passed both by the Telangana High Court and this Court.

8. In terms of the direction given above, an affidavit was filed on 4th January, 2021 by one Mr. Milind Talegaonkar as an authorized signatory on behalf of ERIS. The said affidavit disclosed the quantum of purchase made from MSN Laboratories, as under:

“2. I state that the Defendant Company purchases the product ZAYO from MSN Laboratories Private Limited. I state that the Zayo product is a Crystalline Form S [Valsartan and Sacubitril].

3. *I state that the Defendant Company received certain batches of the product containing crystalline Form S [compound of Valsartan and Sacubitril] from MSN Laboratories Private Limited on 10.12.2020. The batch numbers and quantity of the product, Zayo, received from MSN Laboratories are herein below:*



Sl. No.	Product Description	Pack Style	Batch No.	Qty (Bottles)	Invoice Date from MSN Laboratories Pvt. Ltd.
1.	Zayo 50	Bottle of 30's TAB	DRA 12083B	6000	Dec 10, 2020
2.	Zayo 50	Bottle of 30's TAB	DRA 12084A	12000	Dec 10, 2020
3.	Zayo 50	Bottle of 30's TAB	DRA 12085A	12000	Dec 10, 2020
4.	Zayo 50	Bottle of 30's TAB	DRA 12095A	3000	Dec 10, 2020
5.	Zayo 50	Bottle of 30's TAB	DRA 12096A	12000	Dec 10, 2020
6.	Zayo 50	Bottle of 30's TAB	DRA 12097A	12000	Dec 10, 2020
7.	Zayo 50	Bottle of 30's TAB	DRA 12098A	12000	Dec 10, 2020
8.	Zayo 50	Bottle of 30's TAB	DRA 12099A	12000	Dec 10, 2020
9.	Zayo 50	Bottle of 30's TAB	DRA 12100A	12000	Dec 10, 2020
10.	Zayo 100	Bottle of 30's TAB	DRA 12086B	3000	Dec 10, 2020
11.	Zayo 100	Bottle of 30's TAB	DRA 12087A	6000	Dec 10, 2020
12.	Zayo 100	Bottle of 30's TAB	DRA 12088A	6000	Dec 10, 2020
13.	Zayo 100	Bottle of 30's TAB	DRA 12101B	3000	Dec 10, 2020



14.	Zayo 100	Bottle of 30's TAB	DRA 12102A	6000	Dec 10, 2020
15.	Zayo 100	Bottle of 30's TAB	DRA 12103A	6000	Dec 10, 2020
16.	Zayo 100	Bottle of 30's TAB	DRA 12104A	6000	Dec 10, 2020
17.	Zayo 100	Bottle of 30's TAB	DRA 12105A	6000	Dec 10, 2020
18.	Zayo 100	Bottle of 30's TAB	DRA 12106A	6000	Dec 10, 2020

4. I state that Eris Lifesciences has sold all the products mentioned at para 4 to the distributors/stockists on a principal to principal basis. I submit that the stockists/distributors in turn have sold the same to various hospitals and pharmacies across the country. The product is now available with the pharmacies and chemists and the stock is now no longer with the company Eris.”

9. Pursuant to the said quantum being disclosed, further orders were passed on 19th March, 2021 and 26th March, 2021. Vide order dated 19th March, 2021 in the ERIS suit, the affidavit filed by ERIS was taken on record, and it was directed that the Defendant-ERIS would abide by the statement made in the affidavit that the entire stock of the impugned products has already been sold to the distributors on a principal to principal basis. The said direction reads as under:

“4. As per the affidavit filed by the defendant dated 04.01.2021, the defendant has sold all the products mentioned in para 4 of the affidavit to the distributors/ stockist on a principal to principal



basis.

5. Defendant will abide by the above order/statement made in the affidavit. The application stands disposed of.”

10. Another suit being **CS (COMM) 156/2021** was also filed by the Plaintiffs against M/s. Windlas Biotech Ltd. (hereinafter, “Windlas”) wherein Local Commissioners were appointed for making inventories.

11. On the same date, vide order dated 26th March, 2021 in the ERIS suit, the interim order which was passed in **CS (COMM) 62/2019** titled **Novartis AG & Ors. v. Natco Pharma Limited**, in relation to the same very suit patent, was directed to operate till the further orders of the Court. Further, a direction was issued to the Defendant-ERIS to disclose the stocks received from Windlas. The said order reads as under:

“IA No.4712/2021

Issue notice.

Learned counsel for the defendant accepts notice.

This court on 27.03.2019 in CS(COMM) No.62/2019 relating to the same Patent No.229051, as is in question in this matter, had passed an interim order restraining the defendants from using the product /pharmaceutical composition or any other drug which has pharmaceutical composition comprising combination of Sacubitril + Valsartan as Sodium Salt Complex or in any other form as may amount to infringement of Indian Patent No.229051 of the plaintiffs.

Learned senior counsel for the defendant states that in view of the aforesaid orders passed by this court, the defendants shall abide by the said orders till further orders of this court.



The defendant will file an affidavit giving details of the stocks sold from Windlas Biotech Pvt. Ltd to the distributors/stockists with the names of the distributors/stockists. The names of the distributors / stockists may be filed in a sealed cover.

List on 09.04.2021.”

12. Pursuant to the directions given on 26th March, 2021, a further affidavit dated 8th April, 2021 was filed by Mr. Milind Talegaonkar disclosing the large quantum of stocks received from Windlas. The said affidavit reads as under:

“3. I state that the Defendant Company received certain batches of the product containing Crystalline Form of Supramolecular Complex [Valsartan and Sacubitril] from Windlas Biotech Private Limited in and around the month of February, March, 2021. The batch numbers and quantity of the product, Zayo, received from Windlas Biotech Pvt. Ltd. are herein below:

Sl. No.	Product Description	Pack Style (10 tablets) per strip	Batch No.	Qty (Stripes)	Inward Date
1.	ZAYO 100	STRIP	EZAY1001	47,000	04-02-21
2.	ZAYO 100	STRIP	EZAY1001	940	16-02-21
3.	ZAYO 100	STRIP	EZAY1002	49,210	16-02-21
4.	ZAYO 100	STRIP	EZAY1003	48,280	16-02-21
5.	ZAYO 100	STRIP	EZAY1004	1,10,000	19-02-21
6.	ZAYO 100	STRIP	EZAY1004	12,600	20-02-21
7.	ZAYO 100	STRIP	EZAY1005	1,21,750	20-02-21
8.	Zayo 100	STRIP	EZAY1006	27,000	23-02-21
9.	ZAYO 100	STRIP	EZAY1006	1,000	08-03-21
10.	ZAYO 200	STRIP	EZAO1001	30,000	21-02-21
11.	ZAYO 200	STRIP	EZAO1001	19,180	23-02-21
12.	ZAYO 200	STRIP	EZAO1002	48,700	23-02-21
13.	ZAYO 50	STRIP	EZYO1001	47,330	04-02-21
14.	ZAYO 50	STRIP	EZYO1001	410	16-02-21



15.	ZAYO 50	STRIP	EZYO1002	48,000	16-02-21
16.	ZAYO 50	STRIP	EZYO1003	49,280	16-02-21
17.	ZAYO 50	STRIP	EZYO1004	49,080	16-02-21
18.	ZAYO 50	STRIP	EZYO1005	48,400	16-02-21
19.	ZAYO 50	STRIP	EZYO1006	48,730	16-02-21
20.	ZAYO 50	STRIP	EZYO1007	48,870	16-02-21
21.	ZAYO 50	STRIP	EZYO1008	30,000	16-02-21
22.	ZAYO 50	STRIP	EZYO1008	19,500	18-02-21
23.	ZAYO 50	STRIP	EZYO1009	90,000	18-02-21
24.	ZAYO 50	STRIP	EZYO1009	1,52,000	19-02-21
25.	ZAYO 50	STRIP	EZYO1009	2,660	21-02-21
26.	ZAYO 50	STRIP	EZYO1010	1,50,000	21-02-21
27.	ZAYO 50	STRIP	EZYO1010	89,850	23-02-21
28.	ZAYO 50	STRIP	EZYO1011	47,000	23-02-21
29.	ZAYO 50	STRIP	EZYO1011	1,460	01-03-21

4. *I state that Eris Lifesciences has sold all the products mentioned at para 3 to the distributors/stockists on a principal to principal basis. I submit that the stockists/distributors in turn sell the same to various hospitals and pharmacies across the country.*”

13. The above affidavit disclosed a total sale of 14,38,000 strips of 50mg, 100mg, and 200mg ‘ZAYO’ tablets, which would constitute over 1.43 crores tablets. The value of these drugs, as per the affidavit dated 5th July, 2021 placed on record by ERIS is as under:

“2. *The products manufactured by MSN Laboratories Pvt. Ltd. are sold in bottle of 30 tablets while the product obtained from Windlas Biotech Pvt. Ltd. is sold in strip of 10 tablets.*

3. *I further state that the value of the goods received from Defendant No.1 (valsartan-sacubitril tablets under the mark ZAYO) is Rs 43 crores (approximately). The amount received so far from the market is approximately Rs 25 crores.*



The total value of the goods on MRP basis as received from Windlas Biotech Private Limited is approximately Rs. 60.5 crores (of which only – Rs.43 crores would be realisable in the hands of the Defendant No.2 as it sells the goods concerned on wholesale basis and balance is the trade margin to distributors)”

14. The submission of Mr. Hemant Singh, Id. Counsel for the Plaintiffs is that an illegal *modus operandi* has been adopted by MSN Laboratories Pvt. Ltd., ERIS Lifesciences Limited and M/s. Windlas Biotech Ltd. only with an intent to circumvent the injunction order passed by the Telangana High Court as also the *status quo* orders in the present suits. He submits that the product information literature of the product ‘ZAYO’, which was available in the market, clearly showed that the product was manufactured by MSN Laboratories as the said literature refers to MSN Laboratories. If the products were manufactured by Windlas, the question of MSN Laboratories being mentioned in the product information literature, would not have arisen.

15. He further relies upon the affidavit dated 17th May, 2021 by Ms. Laboni Chatterjee, Business Franchise Head, Novartis in India, to argue that the information available from the market sources through IQVIA, which is a data analytics company in the pharmaceutical industry, would show that only a small percentage of the large stocks manufactured by Windlas has been sold in the market as of April, 2021.

16. He further submits that the Defendants ought not to be allowed to violate the *status quo* orders by selling such a huge quantum of products in violation of the Plaintiffs’ rights in the suit patent.

17. The fact that these products are available in the market, is also clear



from the suit being **CS (COMM) 68/2022** filed against M/s. Chhabra Healthcare Solutions Pvt. Ltd., which was selling the products bearing the trademark 'ZAYO', having the same pharmaceutical composition, which were marketed by ERIS. The stock statement dated 11th March, 2022 filed by M/s. Chhabra Healthcare Solutions Pvt. Ltd., pursuant to the order dated 2nd February, 2022 in the said suit, shows that a total of 19,820 units, including bottles and strips, have been sold by M/s. Chhabra Healthcare Solutions Pvt. Ltd. The market value of the said stock is Rs.55,81,207/-. As per the said stock statement dated 11th March, 2022, a stock worth Rs.25,34,590/- had already been sold or disposed of by M/s. Chhabra Healthcare Solutions Pvt. Ltd. prior to order dated 2nd February, 2022, by which the said distributor was enjoined.

18. Thus, the submission of Mr. Hemant Singh, Id. Counsel is that a large amount of stock is still available in the market and the main Defendant i.e., ERIS ought to be directed to withdraw the said stock from the distributors.

19. On the other hand, Mr. C.S. Vaidyanathan, Id. Senior Counsel appearing on behalf of ERIS Lifesciences Ltd. raises two submissions. The first submission is that the products being marketed by ERIS are supramolecular forms of the combination of Valsartan and Sacubitril, and the suit patent does not cover the supramolecular complexes of the combination of Sacubitril and Valsartan. Thus, there ought to be no injunction restraining ERIS as the injunction would not cover the said products.

20. Without prejudice to the above argument, he submits that the *status quo* order was passed against the ERIS on 21st December, 2020 in the ERIS suit only *qua* MSN products. The said order did not cover any products



manufactured by Windlas. The order against Windlas was passed only on 26th March, 2021. Thus, the products which are obtained from Windlas are not subject-matter of the *status quo* order dated 21st December, 2020. All the products which are available with ERIS are of February, 2021 i.e., prior to 26th March, 2021, and hence, there is no violation of the injunction.

21. He further submits that, in any event, products manufactured by Windlas are independent products and are not the products of MSN Laboratories as MSN Laboratories has a separate manufacturing license. Thus, the products that are being sold are not covered by the injunction. He further submits that the order dated 26th February, 2021 passed by the Telangana High Court permitted sale of all the products manufactured prior to order dated 11th December, 2020. In view of both of these orders, the products would not be covered by the injunction.

22. Heard Id. Counsels for the parties.

23. A perusal of the history of the litigation and various orders which have been passed by this Court as also the Telangana High Court, clearly shows that insofar as MSN Laboratories is concerned, it is only permitted to sell products which were manufactured prior to 11th December, 2020. The question as to whether the products manufactured by Windlas were those which were manufactured by MSN Laboratories or not, is a question which would have to be established at trial. However, at this stage, this Court only takes note of the fact that the product information literature of ZAYO states as under:

*“Reporting of suspected adverse reactions
Reporting suspected adverse reactions after
authorisation of the medicinal product is
important. It allows continued monitoring of the*



benefit/risk balance of the medicinal product. To report Suspected Adverse Reactions, contact MSN Laboratories Private Limited at pharmacovigilance@msnlabs.com or through company website www.msnlabs.com->Contact us->Medical Enquiry/ to report a side effect.”

Thus, the appearance of the name of MSN Laboratories Pvt Ltd in the product literature of Windlas, is inexplicable, at this stage.

24. The photographs of strips, which are placed on record, show that the products branded as ZAYO are marketed by ERIS, and the name of the manufacturer is shown as Windlas. The product literature shown is sufficient to create a doubt in the mind of the Court that there may be some connection between the said two companies - MSN and Windlas. However, at this stage, no concrete conclusion can be arrived at.

25. Various affidavits placed on record disclosing the stock of products, show that a large amount of goods have been supplied by Windlas to ERIS, and ERIS claims to be marketing the same. The injunction *qua* ERIS has been operating since 21st December, 2020. Thus, at this stage it is not clear as to how ERIS procured this huge quantity as of February, 2021, and how it could have marketed the same. The quantum which has been disclosed is also of very high value i.e., Rs.43 crores at the distributor level and Rs.60 crores at the retailer level.

26. Mr. Singh, Id. counsel for the Plaintiffs insists that all the products ought to be recalled at this stage and the details of the distributors ought to be disclosed to the Plaintiffs. However, almost one year has passed since the affidavit dated 17th May, 2021 by Ms. Laboni Chatterjee giving IQVIA data, was placed on record. This Court considers the following factors –



- a) The suit patent is itself due to expire in January, 2023.
- b) The affidavit giving the IQVIA data is more than ten months old;
- c) The medicines are for cardiovascular disease which may be needed by a large number of patients;
- d) Recall from distributors or retailers would be an extremely cumbersome exercise and may result in panic.
- e) Even if the exercise is undertaken, owing to the sheer number of distributors and chemists to whom the products may have been disbursed, directing recall is not a viable option.

27. The sealed cover containing the list of distributors has been opened by this Court. The said cover shows that the products have been distributed from various corners of the country by the C&F Agents of ERIS – ERIS Vijaywada CFA, ERIS Guwahati CFA, ERIS Bhiwandi CFA, ERIS Cuttack, ERIS Howrah, ERIS Jaipur, ERIS Kanpur, ERIS Trichur, ERIS Ambala, ERIS Bangalore, ERIS Chennai, ERIS Dehradun, ERIS Hyderabad, ERIS Indore, ERIS Madurai, ERIS New Delhi, ERIS Patna, ERIS Pune, ERIS Raipur, ERIS Ranchi, amongst others. Thus, directing recall would not be fully feasible as the products may have been sold to hundreds of dealers and distributors, in the downstream chain of distribution.

28. However, ERIS cannot be allowed to go completely scot-free. Some measures would have to be taken to secure the Plaintiffs' interest, especially since recall from distributors is not a viable option, at this stage.

29. Under these circumstances, the applications being ***I.As.6539/2021***, ***1516/2022*** and ***I.A.3014/2022*** seeking interim injunction and seeking access to the details of the distributors submitted to the Court in sealed cover, are disposed of with the following directions:



- i. There shall be an interim injunction restraining all the Defendants in these matters from manufacturing, selling, offering for sale any pharmaceutical preparations which are a combination of Sacubitril and Valsartan, either in tablet form or any other form, either packaged as strips or in bottles/containers, and from infringing the Patent IN'051 of the Plaintiffs, in any manner whatsoever.
 - ii. In respect of the stocks, as captured above, which were clearly marketed by Eris Lifesciences Limited post the passing of order dated 21st December, 2020 in *CS (COMM) 557/2020*, Eris Lifesciences Limited is directed to deposit a sum of Rs.5 crores with the worthy Registrar General of this Court. The said deposits shall be made within a period of six weeks and shall be subject to the outcome of the present suits.
 - iii. The amounts deposited shall be retained in a fixed deposit on auto-renewal mode.
30. Let the documents in the sealed cover be scanned and tagged along with the record. Copy of the same may be provided to counsel for the Plaintiffs, upon request.
31. On the next date, the application under Order XXXIX Rule 2A CPC being *I.A. No.5231/2021* shall be taken up for hearing.
32. List before Joint Registrar for marking of exhibits, on 20th May, 2022.
33. List before Court for framing of issues and case management, on 1st August, 2022.

PRATHIBA M. SINGH
JUDGE

MARCH 25, 2022/dk/ad