SL. No.3

NATIONAL COMPANY LAW TRIBUNAL
HYDERABAD BENCH
COURT HALL NO: II

Hearing Through: VC and Physical (Hybrid) Mode

CORAM: SHRI. RAJEEV BHARDWAJ, HON'BLE MEMBER (J)
CORAM: SHRI. SANJAY PURI, - HON'BLE MEMBER (T)

ATTENDANCE-CUM-ORDER SHEET OF THE HEARING OF NATIONAL COMPANY LAW TRIBUNAL, HYDERABAD BENCH, HELD ON 23.02.2024 AT 10:30 AM

TRANSFER PETITION NO.	
COMPANY PETITION/APPLICATION NO.	**Company Petition IB/26/2023**
NAME OF THE COMPANY	**Airis Pharma Pvt Ltd**
NAME OF THE PETITIONER(S)	**Biocon Pharma Limited**
NAME OF THE RESPONDENT(S)	**Airis Pharma Pvt Ltd**
UNDER SECTION	**9 of IBC**

ORDER

Orders pronounced, recorded vide separate sheets. In the result, this petition is dismissed.

Sd/-
MEMBER (T)

Sd/-
MEMBER (J)

Apoorva

IN THE NATIONAL COMPANY LAW TRIBUNAL
HYDERABAD BENCH – II

CP (IB) No.26/09/HDB/2023
U/s. 9 of IB Code, 2016

Between:

M/s. Biocon Pharma Limited,
20th KM, Hosur Road,
Electronic City,
Bengaluru – 560 100.

....Operational Creditor

Vs

M/s. Airis Pharma Private Limited,
Plot No.64 & 65,
ALEAP Industrial Estate,
Gajularamaram,
Quthbullapur Mandal,
Hyderabad – 500 078.

....Corporate Debtor

Date of Order : 23.02.2024

CORAM:

Sri Rajeev Bhardwaj, Hon'ble Member (Judicial)

Sri Sanjay Puri, Hon'ble Member (Technical)

Counsels present:

For the Applicant	:	Mr. Perikal K Arjun, Advocate
	:	Mr. Shardul Amarchand, Advocate
For the Respondent	:	Mr. Avinash Desai, Senior Advocate
		Mr. L. Preetham Reddy, Advocate
Heard on	:	20.02.2024

Per : Sanjay Puri, Member (Technical)

O R D E R

1. This application has been filed by M/s Biocon Pharma Limited, the Operational Creditor (**OC**) against M/s Airis Pharma Private Limited, the Corporate Debtor (**CD**), seeking to initiate the CIRP[1] against the latter for the default committed in paying the operational debt to the former under section 9 of IBC[2].

2. The OC and the CD had entered into a Licensing and Supply Agreement[3] on 22.04.2021 for in-licensing of a pharmaceutical product[4]. As per the Agreement, the CD was to develop and obtain all necessary approvals for manufacturing and commercialisation of the product. This included a filing of Abbreviated New Drug Application (**ANDA**) with Food and Drug Administration (**FDA)** of the United States, and obtaining the regulatory approval for the commercialisation of the product. The OC was to provide the supporting documents to the CD including the Risk Evaluation and Mitigation Strategy (**REMS**) Authorization. It is stated by the OC that 'pursuant to the same' the REMS Authorization letter[5] dated 20.04.2021 was issued to the FDA.

3. Under the Agreement, the OC was required to pay a Licensing Fees of USD 1,350,000 to the CD on a milestone basis, the details[6] of which are given in Article 1.5 of the Agreement. On

[1] Corporate Insolvency Resolution Process
[2] Insolvency & Bankruptcy Code, 2016
[3] Pg 29-53 of the Application.
[4] "Mycophenolate Mofetil suspension, oral suspension 200mg/ml, 225 ml in finished dosage form"
[5] Pg 54-55 of the Application.
[6] Pg 52 of the Application.

completion of the first three milestones under the Agreement, the OC disbursed 70% of the Licensing Fees of USD 950,000 to the CD besides paying IGST @18% of Rs.1,27,06,470.

4. The FDA however, did not approve the ANDA filing submitted by CD. One of the deficiencies highlighted by the FDA was about the REMS Authorization submitted by the OC, which did not grant the CD's necessary permissions required for approval of the product.

5. Since the CD was unable to obtain the FDA's approval within the stipulated time period, the OC terminated the Agreement on 21.04.2022 under Clause 3.2 of the Agreement and called upon the CD to refund the entire amount of Licensing Fees along with the IGST amount. Clause 3.2 of the Agreement provided as follows:

> "In the event that Airis does not obtain the Regulatory Approval from FDA for Product within ten (10) calendar months from REMS authorization from Biocon or its affiliates, Biocon shall have the right to terminate this Agreement immediately by providing Airis a notice of such termination in writing. In event of Biocon exercising its right to terminate the Agreement in terms of this Section 3.2. Airis shall refund to Biocon any and all payments, including but not limited to Licensing Fees, disbursed to Airis under this Agreement, and such refund will be done within thirty (30) business days from such termination."

6. Another notice dated 30.08.2022 was sent to the CD for refund of Rs 8,32,97,970, comprising of rupee equivalent of USD 950,000 and IGST of Rs 1,27,06,470. Since, no payment was forthcoming, The OC issued a Demand Notice under Section 8 of IBC on 21.10.2022.

7. In its reply dated 11.11.2022, the CD pointed out to the failure on part of the OC to provide proper REMS Authorization, which lead to rejection of ANDA by FDA and disputed the amount claimed by the OC. The CD also made a counter-claim on the OC of USD 500,000 on account of financial loss suffered by them and damage to its reputation. Moreover, the CD informed about their invoking arbitration Clause 27 of the Agreement to settle the disputes arising under the Agreements.

8. It is noted that, on a petition[7] made by the CD on 07.03.2023, the Hon'ble High Court of Karnataka in its Order[8] dated 27.09.2023 allowed the continuance of the arbitration proceedings and has appointed a former Judge of the High Court as the Sole Arbitrator in the matter. It has been however observed that the continuation of arbitral proceedings will be subject to the Order of NCLT on the present application.

9. The Respondent on the other hand, has pointed out towards E-mail exchanges between the OC and the CD before and after termination of Agreement by the OC to show that despite their repeated requests, the OC did not provide proper REMS authorisation which led to the CD not being able to obtain FDA's approval.

10. In the E-mail dated 09.02.2022 from the CD[9], the persons concerned at the OC were made aware of the discrepancy related to the REMS filings by the OC. After the OC had terminated the Agreement, vide an E-mail dated 01.08.2022, the CD raised the

[7] Petition No. 107 of 2023 : Page 124 to 136 of the Respondent's Counter
[8] Page 137 to 158 of the Respondent's Counter
[9] Page 79 of the Respondent's Counter

issue of REMS with the OC again and requested for Letter of Authority (LoA), so that a response can be sent to FDA and reviews could be started in relation to the complete response sent by the FDA.

11. We have heard the parties and gone through the records. On one hand, the OC has relied upon Article 3.2 of the Agreement to claim, that it was will within its right to terminate the Agreement in the event of CD not being able to obtain the FDA approval within the stipulated time and therefore, they are entitled to the refund of the money paid to the OC. It is claimed on their part that the un-paid debt is undisputed and therefore, their Application under Section 9 of IBC be allowed. The Respondent CD on the other hand has also referred the same Article 3.2 and claimed that; obtaining of FDA approval was contingent upon REMS Authorization issued by the OC. It is contended that, the OC did not provide the proper REMS Authorization which resulted in the non-approval of ANDA by FDA. It is argued on behalf of the Respondent that, there were pre-existing disputes with regard to the REMS Authorization which have bearing on the OC's claim of refund of money paid by them under the Agreement.

12. Learned Counsel for the Respondent referred to the decision in the case of ***Mobilox***[10] wherein, the Hon'ble Supreme Court has held in relation to Section 9 proceedings that;

> *"all that the adjudicating authority is to see at this stage is whether there is* ***a plausible contention which requires further investigation*** *and that the "dispute" is not a patently feeble legal argument or an assertion of*

[10] Mobilox Innovations Private Limited vs. Kirusa Software Private Limited in Civil Appeal No. 9405 o 2017

fact unsupported by evidence. It is important to separate the grain from the chaff and to reject a spurious defence which is mere bluster. However, in doing so, the Court does not need to be satisfied that the defence is likely to succeed. The Court does not at this stage examine the merits of the dispute except to the extent indicated above. So long as a dispute truly exists in fact and is not spurious, hypothetical or illusory, the adjudicating authority has to reject the application."

13. We are in agreement with the contention of the Learned Counsel of the Respondent. This view has been reiterated by Hon'ble Supreme Court in the cases of ***Sabarmati Gas Ltd***[11] and ***Rajratan B Agarwal***[12] also, where again it has been unequivocally held that any "plausible contention requiring investigation" will constitute a dispute and if raised prior to the issue of section 8 notice, will result in rejection of Application under section 9 of the IBC.

14. In this case it is clear that, while the OC had the right to terminate the Licensing Agreement in case of the CD not having obtained regulatory approval from FDA, obtaining the approval itself was contingent upon REMS Authorisation from the OC or its affiliates. From the Complete Response (CR)[13] of the FDA, it is also apparent that one of the reasons why the approval could not be obtained was improper in the REMS issued by the OC. The same is also evident from the

[11] SABARMATI GAS LTD VS SHAH ALLOYS LTD (2023) 3 SCC 229 [p.256]

[12] RAJRATAN BABULAL AGARWAL VS SOLARTEX INDIA PVT LTD (2023) 1 SCC 115 [p.150]

[13] Page 56-61 of the Application (on p-58)

emails[14] of FDA Official Ms Jeniffer Sarchet sent on 19.01.2022 and 31.01.2022.

15. Be that as it may, the issue as to whether the Agreement was rightfully terminated by the OC and its entitlement to refund of Licensing Fees along with IGST amount paid are matters which are now in the arbitration.

16. That, before section 8 notice was sent on 21.10.2022 by the OC, the CD had engaged with the OC on the issue of improper REMS, that led to denial of FDA approval, which the CD was to obtain. After termination of the Agreement on 21.04.2022, but before issue of Section 8 notice also, this issue was raised on 01.08.2022 and conveyed that the CD was "in no position to refund the amount" Sought by the OC.

17. These exchanges suggest to us that there are plausible contentions in the matter which would require investigation and which are not feeble legal arguments or the facts unsupported by evidence. We are of the considered view that, these would constitute the disputes raised by the CD prior to issue of the Demand Notice under Section 8 of IBC. In these circumstances, the present application under Section 9 of IBC cannot be allowed to be proceeded with.

18. Moreover, it is essential to acknowledge that the principal objective of the Insolvency and Bankruptcy Code (IBC) is not intended to be a tool for recovery of the disputed amounts. Instead, its primary purpose is to facilitate the resolution of

[14] Page 74 and 76 of the Respondent's Counter

insolvency for corporate entities. Issues pertaining to refund of money on non-performance of any particular contract cannot be addressed through the initiation of insolvency proceedings under the IBC. This Authority with a summary jurisdiction is not competent to evaluate contesting positions requiring detail investigation.

19. In order to recover such contested dues, the Petitioner can pursue a legal recourse through the appropriate Civil Court, which possesses jurisdiction to determine the validity of the contested claims. In this case, the arbitration proceedings have already commenced, and the dispute arising from the terms of the Agreement can be resolved after thorough investigation of the issues involved.

Therefore, the application is dismissed with the above remarks.

Sd/-
(SANJAY PURI)
MEMBER (TECHNICAL)

Sd/-
(RAJEEV BHARDWAJ)
MEMBER (JUDICIAL)

VL