

Item No.1

(Pune Bench)

**BEFORE THE NATIONAL GREEN TRIBUNAL
WESTERN ZONE BENCH, PUNE**

[THROUGH PHYSICAL HEARING (WITH HYBRID OPTION)]

ORIGINAL APPLICATION NO.31 OF 2023 (WZ)

Prasad M. Mulye

.... Applicant

Versus

M/s Bharat Serums and Vaccines Ltd. & Os.

.... Respondents

Date of Hearing : 03.08.2023

**CORAM: HON'BLE MR. JUSTICE DINESH KUMAR SINGH, JUDICIAL MEMBER
HON'BLE DR. VIJAY KULKARNI, EXPERT MEMBER**

Applicant : ----

Respondents : Mr. T. Subramanian, Senior Advocate, i/b and
with Mr. Bhash H. Mankad, Advocate for R-1
Ms. Manasi Joshi, Advocate for R-2
Mr. Prashant Chavan, Advocate representing
Navdeep Vora & Co., for R-3
Mr. Aditya Bapat, Advocate for R-4
Mr. Vilas Ghogare, Advocates for R-5
Mr. Aniruddha Kulkarni, Advocate for R-6

ORDER

1. From the side of the applicant, none has appeared today, although an e-mail dated 02.08.2023 has been received by us stating therein that Mr. Asim Sarode, learned counsel, who is one of the Advocates appearing in this matter, is unwell. We find that in vakalatnama filed from the side of the applicant, there are names of as many as eight Advocates, who are supposed to represent the applicant. We are of the view that if one of them is sick, the others could have appeared today and the proceedings could have been held easily.

2. In pursuance of our previous order dated 21.07.2023, from the side of respondent No.1 – Project Proponent, reply-affidavit has been filed, wherein it is submitted by him that this application has been filed with

ulterior motive. The answering respondent is engaged in manufacturing of life saving pharmaceutical formulations at its Ambernath plant and also operates a Research and Development (R&D) facility at Airoli. The applicant Mr. Prasad M. Mulye is not authorized agent, who is not a person who has sustained any injury or damage. Therefore, he is not aggrieved person as per the provisions of Section 18(1) read with Sections 14 and 15 of the National Green Tribunal Act. Several case-laws have also been relied upon by him which lay down that when a person approaches the Court/Tribunal, his credentials and motives must be ascertained before proceeding. The applicant resides 25 kms. away from Airoli and 52 kms. from Ambernath. The answering respondent has obtained valid Consent to Operate for both facilities, which is valid upto 30.06.2026 (annexed at page 403 of the paper-book) while the R&D facility at Airoli does not require Consent to Operate. The monitoring is being done by the MPCB through its server for effluent and there is zero liquid discharge being maintained by the answering respondent. The monitoring results of the air emissions and effluent generated during April, 2022 and May, 2023 have been annexed to the reply-affidavit at Annexure R-1/1, which would reflect that the effluent generated during the abovesaid period was within permissible limits. The annual environment statement for the year 2021-2022 related to hazardous waste and biomedical waste is annexed at Annexure-R-1/2 (Colly) at pages 260 to 274. Besides that, some other statements and documents are also attached by the answering respondent with the reply-affidavit.

3. The learned Senior Counsel has also raised an issue that this Tribunal does not have jurisdiction because no substantial question relating to the environment is raised, which is alleged to have arisen due to enforcement of the acts mentioned in Schedule-I of the National Green Tribunal Act. The answering respondent ensures recycling and complete

reuse of the effluent generated from its Ambernath plant within the premises. The trade and sewage waste water generated is not discharged outside the premises, rather the same is reused for various purposes. All the test reports which have been annexed by him, indicate that there is no pollution beyond limits. Respondent No.2 – MPCB had carried out inspection on 12.01.2023 and finding nothing adverse against the Project Proponent, renewed Consent to Operate (CTO) on 13.01.2023. There has been repeated visits and inspections by the MPCB officers and that the plant of the answering respondent was not found any high pollution index at any point of time. Ambernath plant has installed the online monitoring system connected to MPCB server for continuous monitoring of effluent generated and discharged, which ensures zero liquid discharge.

4. With respect to the allegation of the applicant that the hazardous waste is generated out of the plant of the answering respondent – Project Proponent, which is in close proximity of Chikholi dam and the Project Proponent is depositing the garbage, which is resulting in generation of effluent which has capacity to pollute the ground-water. In this regard, it is submitted by respondent No.1 that the Irrigation Department of the State of Maharashtra has not found any potential threat of pollution to the dam water because the location of the plant of the answering respondent does not fall under the submerged area (appears to be catchment area) due to increase in height of the Chikholi dam. A report of the Department in this regard is also annexed at pages 421 to 422 of the paper-book. Therefore, it is prayed that the application should be dismissed as it has no substance.

5. The stand taken from the side of respondent No.2 – MPCB, vide their affidavit dated 25.07.2023, is that respondent No.1's industry is categorized as Orange category based on the CPCB guidelines. The

schedule of renewal of Consent to Operate (CTO) has been given in tabular form, which is as follows:

<i>Sr. No.</i>	<i>Date of Consent to Operate</i>	<i>Manufacturing activity</i>	<i>Valid upto</i>
1.	27/9/2002	For manufacture of INJ Propavan, INJ Anpholp, INJ Fruseuide I. P. (only formulation activity)	29/9/2004
2	Amendment to Consent dated 26.06.2023 for condition No.3- For daily quantity of effluent from the factory shall not exceed 35 M ³ and the daily quantity of sewage effluent from the factory shall not exceed 12 M ³ .	--	--
3.	21/07/2004	For manufacture of Injections & Vaccines (Only formulation)	30/06/2014
4.	30/01/2015	For manufacture of Injections & Vaccines (Only formulation)	30/06/2016
5.	23/1/2017	For manufacture of Injections & Vaccines (Only formulation)	30/06/2022
6.	6/4/2018	For Manufacture of : 1. Injections & Vaccines (Only formulation) 2. Analytical Testing and R & D Activity	30/06/2022
7.	1 st Consent to Operate for expansion dated 8/4/2021	For the manufacturing of : 1. Injection & Vaccines 2. r-FSH (Recombinant-Follicle Stimulating Hormone), 3. r-HCG (Recombinant-Human Chronic Gonadotropin, 4. mAnti-D (Monoclonal Anti Rho-D Immunoglobulin), 5. rAnti-D (Recombinant Anti Rho-D immunoglobulin), 6. Analytical Testing and R & D activity	30/06/2022
8	Combined Consent to Operate and BMW Authorization for Bio-Pharmaceuticals & small animal testing facility dated	For the manufacturing of : 1. Injection & Vaccines, 2. r-FSH (Recombinant-Follicle Stimulating Hormone),	30/06/2022

	28.01.2022	3. <i>r-HCG (Recombinant-Human Chronic Gonadotropin,</i> 4. <i>mAnti-D (Monoclonal Anti Rho-D Immunoglobulin),</i> 5. <i>rAnti-D (Recombinant Anti Rho-D Immunoglobulin),</i> 6. <i>Analytical Testing and R & D Activity.</i>	
9	<i>Renewal of Consent dated 13/1/2023</i>	<i>For manufacture of :</i> 1. <i>Analytical Testing and R & D Activity.</i> 2. <i>r-FSH (Recombinant Follicle Stimulating Hormone),</i> 3. <i>r-HCG (Recombinant-Human Chronic Gonadotropin,</i> 4. <i>mAnti-D (Monoclonal Anti Rho-D Immunoglobulin)</i> 5. <i>rAnti-D (Recombinant Anti Rho-D Immunoglobulin),</i> 6. <i>Injection & Vaccines.</i>	30/6/2026

6. In paragraph No.8 of the affidavit of respondent No.2 – MPCB, the observations made during the visit by the answering respondent, which was conducted on 19.06.2023, are noted against the Project Proponent and it was found to be compliant unit.

7. From the side of respondent No.6 – CPCB, by its affidavit dated 28.07.2023, the position of law has been given and the learned counsel for respondent No.6 submits that the categorization of respondent No.1's industry as Orange category is rightly done as per the CPCB guidelines.

8. From the side of respondent No.4, Irrigation Department, learned counsel submits that respondent No.4 should be deleted from the array of the parties as no relief is claimed against them.

9. From the side of respondent No. 5 – Director, Industrial Safety and Health, reply-affidavit has been filed wherein it is stated that the R&D facility of respondent No.1 at Airoli requires license under Section 2(k)(i)

of the Factories Act, 1948 because the said unit is used for manufacturing process even if it is R&D facility employing 63 workers and more than 20 workers are required to qualify the said industry to fall in the category being called “industry”. In this regard, it is also apprised to us by mentioning that the prosecution has been launched against respondent No.1 in the Court of Chief Judicial Magistrate, Thane by filing Case (S.C.C. No.6284/2023), which is pending.

10. The learned counsel for respondent No.1 has rebutted the said averments of respondent No.5 saying that the R&D unit of respondent No.1 is not manufacturing any drugs. Hence, the same does not require any license to be obtained. This has been stated by respondent No.1 in their rejoinder dated 01.08.2023.

11. In the interest of justice, we provide one last opportunity to the applicant to file rejoinder against the affidavits filed by respondents, note of which has been taken by us above, within two weeks from the date of uploading of this order positively. On the next date, no adjournment would be granted on the ground of illness as there are several Advocates who have been engaged to represent the applicant.

12. Put up this matter for final arguments on 09.10.2023.

Dinesh Kumar Singh, JM

Dr. Vijay Kulkarni, EM

August 03, 2023
O.A. No.31/2023 (WZ)
npj