

**BEFORE THE NATIONAL GREEN TRIBUNAL
WESTERN ZONE BENCH, PUNE**
THROUGH PHYSICAL HEARING (WITH HYBRID OPTION)

Original Application No.31/2023(WZ)

IN THE MATTER OF:

Prasad M. Mulye

265/2015, Motilal Nagar No.1,
Road No. 7, Goregaon (West),
Mumbai - 400 104.

.....Applicant

Versus

- 1. Managing Director,
M/s. Bharat Serums and Vaccines Ltd.**
3rd Floor, Liberty Tower, K-10,
Kalwa Industrial Estate
Airoli, Navi Mumbai - 400 708.
- 2. Regional Officer,
Maharashtra Pollution Control Board**
Plot No P-30, 5th floor Office Complex Building,
Mulund Checknaka, Thane - 400 604.
- 3. Chief Executive Officer
Maharashtra Industrial Development Corporation**
Udyog Sarathi, Marol Industrial Estate,
Mahakali Caves Road, Andheri East,
Mumbai- 400 093.
- 4. Superintendent Engineer
Thane Irrigation Circle,**
Sinchan Bhavan, Krishna Borkar Marg,
Kopri, Thane East – 400 603.
- 5. Director,
Directorate of Industrial Safety & Health**
Kamgar Bhavan, 5th floor, C-20, E - Block,
Opp. R.B.I., Bandra Kurla Complex,
Bandra (E), Mumbai – 400 051.
- 6. Regional Directorate,
Central Pollution Control Board,**
Parivesh Bhawan, East Arjun Nagar,
Delhi -110 032.
- 7. Regional Officer,
Ministry of Forest, Environment & Climate Change**
Regional Office (WCZ), Ground Floor,

East Wing, New Secretariat Building,
Civil Lines, Nagpur – 440 001.

.....Respondent(s)

Counsel for Applicant:

Mr. Asim Sarode, Advocate along-with
Ms. Sughanshi Ropia, Advocate

Counsel for Respondent(s):

Mr. Bhash H. Mankad, Advocate for R-1/PP
Ms. Manasi Joshi, Advocate along-with
Ms. Pooja Natu, Advocate for R-2/MPCB
Mr. Prashant Chavan, Advocate along-with
Mr. Navdeep Vora, Advocate & Associates for R-3/MIDC
Mr. Vilas Ghogare, Director, DISH, for R-5
Mr. Aniruddha Kulkarni, Advocate for R-6/CPCB
Mr. Pushkal Mishra, Advocate for R-7/MoEF&CC

PRESENT:

Hon’ble Mr. Justice Dinesh Kumar Singh (Judicial Member)
Hon’ble Dr. Vijay Kulkarni (Expert Member)

Reserved on : 20.03.2024
Pronounced on : 01.07.2024

JUDGMENT

1. This Original Application has been preferred with the prayers that respondent No.1- Managing Director, M/s. Bharat Serums and Vaccines Ltd. be permanently directed to be shut down due to the violations of environmental laws at its end; respondent No.2- Regional Officer, Maharashtra Pollution Control Board; respondent No.3- Chief Executive Officer, Maharashtra Industrial Development Corporation; respondent No.4- Superintendent Engineer, Thane Irrigation Circle; and respondent No.5- Director, Directorate of Industrial Safety & Health be directed to cancel all the permissions related to respondent No.1 to run the activities in its plants at Ambernath and Airoli; respondent No.2- Regional Officer, Maharashtra Pollution Control Board be directed to review/set aside ‘Consent to Operate’ granted to the respondent No.1; and cost be imposed upon the respondent No.1’s Industry.

2. In the body of this application, it is submitted that the applicant has observed hazardous waste being generated by the respondent No.1's plant in a close proximity to the Chikhloli Dam, resulting in leachate being generated, which is having capacity to pollute the ground water table. This act is putting the population of Ambernath in jeopardy as the dam provides drinking water supply to the city.

3. It is further mentioned in this application that the respondent No.1- M/s. Bharat Serums and Vaccines Ltd. is a pharmaceutical company dealing in the business of manufacturing bio-pharmaceutical products, having its Plant at Plot No.K-27, K27/part, K27/1 Additional MIDC, Anand Nagar, Ambernath (East), Thane (hereinafter to be referred in short as "Ambernath Plant") and a research and development unit at Plot No.K-10, Kalwa Industrial Area, Airoli, Navi Mumbai (hereinafter to be referred in short as "R&D unit"). The Respondent No.1's industry falls under the "Red" Category as per the Central Pollution Control Board's (CPCB) directions dated 07th March, 2016. These are the modified directions, under Section 18(1)(b) of the Water (Prevention and Control of Pollution) Act, 1974 and the Air (Prevention and Control of Pollution) Act, 1981, regarding harmonization of classification of industrial sectors. As per the CPCB's directions, pharmaceuticals are mentioned at Sr. No.58, under the "Red" Category. But somehow the Respondent No.1's industry is operating in Orange Category instead of "Red" Category.

4. It is further mentioned in this application that the "Consent to Operate" issued to the respondent No.1 is not valid and it is also violating various conditions stipulated in the Consent to Operate. It is further mentioned that respondent No.1 operated its Ambernath Plant illegally without "Consent to Operate" for about 6.5 months as the "Consent to Operate" was issued on 28/01/2022, which expired on 30/06/2022. The

said Consent was renewed only in January 2023, for which the respondent No.1 had applied on 25/06/2022, i.e., 5 days prior to its expiry. It is further mentioned that given nature of the operations being carried out by the Respondent No.1's Ambernath Plant, its categorization under Orange Category is erroneous, as it should fall in Red Category because "isolated storage of hazardous chemicals" falls within the ambit of "Red" category, as per the directions provided by the CPCB in March 2016. Further, it is mentioned that pharmaceuticals as an **industrial** sector, on an individual level fall under the "Red" category. However, the industry has been categorized in the present case as "Orange" instead of "Red" erroneously. Given the nature of activities being carried out, involving massive investments and products, which are Active Pharmaceutical Ingredients (API), category of the industry should be "Red" instead of "Orange".

5. It is further mentioned in this application that the "Pharmaceuticals" has been identified as one, among all the 17 categories of 'Highly Polluting Industries', which generate all sorts of pollution. The liquid effluent of the industry should be treated as per the zero liquid discharge policy. But the plant uses the effluent, which is highly toxic, for gardening purposes. The plant is dangerously close to the Chikhloli dam, which is a primary source of water for the city of Ambernath. This effluent gets mixed in the groundwater through gardening and is likely to be polluting the water being used in households of Ambernath.

6. It is further mentioned in this application that the consent neither permits the usage of raw/fresh water for gardening nor the treated effluent water for gardening. The respondent No.2- MPCB had issued closure directions to the respondent No.1 for various violations, a copy of which is annexed as Annexure- C. It is further mentioned that the categorization of the industries, which are falling in different categories, made by the CPCB

is based on the concept of Pollution Index related to air pollutants, effluents, water pollutants, hazardous waste generated and consumption of resources. The industrial sectors having the Pollution Index Score of 60 and above fall under the category of "Red" industry. In the case in hand, the industry in question was kept in Red Category and in revised category also, the same fell in "Red" Category. Hence, there is no change made in the categorization of pharmaceutical industries. Further, it is mentioned that it is mandatory apply for a 'Joint Consent' i.e. normal Consent plus B Consent which automatically attracts "Red" category Consent .

7. It is further mentioned in this application that the Respondent No.2's officials did not even check the type of activities of respondent No.1 as it had not obtained environmental clearances and other specific licenses for manufacturing API drugs. In addition, the Respondent No.1's Ambernath Plant carried out testing on different types of animals and the dead animals were disposed off near the primary source of drinking water for Ambernath city, i.e., Chikhholi Dam. It is further mentioned that the Respondent No.1's manufacturing activities in Plant No.1 are divided into two units. Unit-I facility dedicated for manufacturing of general category, human biological, equine biological and GnRH analog products. Unit- II facility dedicated for the manufacturing of fertility and uterine stimulant hormonal products, recombinant API and monoclonal drug substances. A copy of the said Joint Inspection Report of Food & Drugs Administration Department dated 24/12/21 is annexed as Annexure- D.

8. It is further mentioned in this application that in the year 2020, the Respondent No.1 set up a new plant next to their earlier plant at Plot No.K-27/1 under the Survey No.25/2, which is close to the Chikhholi Water Dam, Ambernath, Thane. As per the Circular dated 08/03/2018 of Irrigation Department, Government of Maharashtra, from the High Flood

Line, there should be no construction upto 200 metres, a copy of which is annexed as Annexure-E. However, within 200 metres, the Respondent No.1 has constructed an animal house, which is very close to drinking water source. It is further mentioned that since the Respondent No.1's activities deal with hazardous chemicals, statutory licenses were required to be obtained from the Directorate of Industrial Safety & Health. However, the Respondent No.1 had not obtained the same.

9. It is further mentioned in this application that the premises of Reliable Plaza at Kalwa, where the Respondent No.1 was operating manufacturing activities, were reserved for "Development of Information Technology (IT) & Information Enabled Technology Park (ITES). The facilities that were permitted to operate include medical stores, convenience shopping outlets, travel agencies, dispensaries, etc., however, Maharashtra Industrial Development Corporation's documents would reveal that the Respondent No.1's industry had been incorrectly listed under the category of 'IT/ITES' and permitted to be carry out 'Back Office Operations'. Therefore, the Respondent No.1 was operating illegally at the premises reserved for IT/ITES industries, regarding which the complaint was made to the Chief Executive Officer of MIDC, Joint Directorate of Industries, Directorate of Industries (IT Branch) and the Regional Officer at Navi Mumbai. However, so far only a show cause notice has been given to the owner of the property by the MIDC.

10. This matter was first considered by us on 31.03.2023 when it was admitted and direction was issued to the Registry to issue notice to the respondents.

11. From the side of respondent No.5- Director, Directorate of Industrial Safety & Health, reply affidavit dated 20.06.2023 has been filed, wherein it

is submitted that the Regional Office of answering respondent is enforcing the Factories Act, 1948 and Rules made thereunder, as per which the answering respondent enquired about the accidents, fire, explosion or any dangerous occurrence occurring in the factories and found that respondent No.1's unit, having address 3rd Floor, Liberty Tower, Plot No. K-10, Behind Reliable Plaza, Kalwa Industrial Estate, Airoli, Navi Mumbai, Thane, is not registered under the Factories Act till date.

12. It is further mentioned in this affidavit by the respondent No.5 that pursuant to the complaint dated 16/11/2022 from the applicant, which was submitted to the Director, Industrial Safety and Health, Mumbai, a visit of the premises of respondent No.1 was made on 28/11/2022 and it was found that the activity of making of medicines was being carried out, which included products such as a. Luprodex 3.75 mg, 11.25 mg; b. Liposomal Amphotericin B injection 50 mg; c. Ceftaroline fosamil powder for infusion 600 mg; d. Certizidime 2 gm and avivactam 0.5 gm powder injection; e. Dydrogesterone tablets 10 gm; f. Anti-T Lymphocyte Immunoglobulin; g. Snake Venom Antiserum; h. Rabies Antiserum; i. Recombinant anti rho d immunoglobulin; j. Recombinant human follicle stimulating hormone; and k. Human chorionic gondtropin (recombinant). It is further mentioned that making of medicine is a "Manufacturing Process" as per Section 2(k)(i) of Factories Act, 1948. This was being carried out with the aid of power in the form of electricity and with employing 63 number of workers, hence this premise would be treated to be factory as the manufacturing process was being carried out in this premise with more than 20 workers and with the aid of power in the form of electricity. During visit, it was further observed that the occupier of the factory was using the premises as a factory without obtaining a valid

license from the Director, Directorate of Industrial Safety and Health, Maharashtra State, Mumbai.

13. It is further mentioned in this affidavit by the respondent No.5 that pursuant to the said visit, a Show Cause Notice was issued to the occupier for the contraventions of Rule 4(4) and Rule 4 (1) (a, b, c) of Maharashtra Factories Rules, 1963. But no compliance was secured by the occupier. Because of that reason, a prosecution has been initiated by the Directorate of Industrial Safety and Health, Thane office under provisions of Factories Act 1948 against the Occupier in the Court of Chief Judicial Magistrate Thane, bearing Court Case No S.C.C. 6284/23 on 18/01/2023 for not obtaining factory license for premises located at M/s. Bharat Serums and Vaccines Ltd. The said prosecution is still pending. Therefore, the allegation made against the answering respondent for not having initiated action against the respondent No.1 is erroneous.

14. With respect to the unit of respondent No.1 located at K-27, K-27/Part, K-27-1, Anand Nagar, MIDC, Ambernath, Dist-Thane, it is mentioned in this affidavit by the respondent No.5 that the same is registered under the Factories Act 1948 and having license under the said Act for the year 2023. The Occupier had complied with the statutory requirements for the issuance of license and renewal under Factory Act. Hence license cannot be canceled.

15. From the side of respondent No.1- Managing Director, Bharat Serums and Vaccines Ltd., reply affidavit dated 21.07.2023 has been filed, wherein it is submitted that the Answering Respondent is engaged in manufacturing of life saving pharmaceutical formulations, which are supplied to various distributors, stockiest, institutions in India as well as abroad including government and private health care institutions, armed

forces, etc. The Answering Respondent carried out manufacturing activities at Plot No.K-27, K-27-Part, K-27/1, Additional Ambernath MIDC, Ambernath, Thane, Maharashtra and also operated a Research And Development (R&D) facility at Plot No.K-10, Kalwa Industrial Area, Airoli, Navi Mumbai, Maharashtra (Airoli Office). The respondent No.1 is established in the year 1971 and is an environmentally conscious, law abiding company and has applied and procured all requisite approvals from relevant authorities included the permissions from the Maharashtra Pollution Control Board for operating Ambernath Plant and Airoli Office in a timely manner. The Answering Respondent has been regularly submitting compliance reports to the MPCB under the applicable environmental laws, which is evident through certifications by several international regulatory agencies like WHO-GMP, EU-GMP from Halmed and ANVISA, ISO 9001:2015 (Quality Management System), ISO 45001:2018 (Occupational Health and Safety Management System) and ISO 14001:2015 (Environmental Management System) etc.

16. With respect to the allegation of the applicant, he lacks *locus standi* in terms of Section 14 & 15 of the National Green Tribunal Act- 2010. It is further mentioned in this affidavit by the respondent No.1 that Section 18(2) of the NGT Act reads as follows:-

“(2) Without prejudice to the provisions contained in section 16, an application for grant of relief or compensation or settlement of dispute may be made to the Tribunal by-

- (a) the person, who has sustained the injury; or*
- (b) the owner of the property to which the damage has been caused; or*
- (c) where death has resulted from the environmental damage, by all or any of the legal representatives of the deceased; or*
- (d) any agent duly authorised by such person or owner of such property or all or any of the legal representatives of the deceased, as the case may be; or*
- (e) any person aggrieved, including any representative body or organisation; or*

(f) the Central Government or a State Government or a Union territory Administration or the Central Pollution Control Board or a State Pollution Control Board or a Pollution Control Committee or a local authority, or any environmental authority constituted or established under the Environment (Protection) Act, 1986 (29 of 1986) or any other law for the time being in force:.....”

17. It is further mentioned in this affidavit by the respondent No.1 that the present Original Application has been filed by Mr. Prasad M. Mulye, who is not a person, who has sustained the injury nor is the owner of the property, to which damage has been caused nor is an agent, who has been duly authorized by these persons to file an application. Therefore, he is not an ‘aggrieved person’ under the provisions of NGT Act and does not fit into any definition as per Section 18 (2) of the said Act. It is further mentioned that the Applicant is also not a resident of nor stays nearby Airoli or Ambernath, rather is a resident of Goregaon, which is about 25 kms. away from the Airoli and almost 52 kms. away from the Ambernath.

18. It is further mentioned in this affidavit by the respondent No.1 that the applicant has admitted in the present application that the cause of action first arose when CTO was issued to Ambernath Plant on 28.01.2022 under alleged wrong categorization as orange industry. Without prejudice to the merit-based averments against these allegations, it is submitted that the limitation period to file Application under Section 14 against operation of Ambernath Plant without valid CTO and its alleged wrong categorization as orange industry had expired after 6 months from 30.06.2022 (date of expiry of CTO which was subsequently renewed on 13.01.2023) and 28.01.2022 (date of issue of CTO to Ambernath Plant as orange industry) respectively. Accordingly, since the cause of action first arose on a specific date/event, limitation period would be computed from that date/event. In the present case, the limitation period for filing an application raising these issues had expired on 31.12.2022 and 28.07.2022 respectively. However, the present application was filed on

27.02.2023 without seeking condonation of such delay, as required under Section 14(3) of the National Green Tribunal Act, 2010.

19. It is further mentioned in this affidavit by the respondent No.1 that the cause of action for these issues first arose on specific scenarios, i.e., on the date of issue and expiry of CTO dated 28.01.2022 of Ambarnath Plant and therefore, is not continuing in nature and no sufficient cause has been shown by the Applicant to seek condonation of delay for a further period upto 60 days. It is further mentioned that the Answering Respondent is undertaking operations at Ambarnath Plant and R&D Centre at Airoli Office after obtaining and maintaining valid approvals under the applicable environmental laws. It has also undertaken testing of the water sample from Chikhholi dam, sewage treatment plant and effluent treatment plant. In that regard, a report dated 03.07.2023 has been prepared by Aditya Environmental Services Pvt. Ltd., which is an independent laboratory, recognized by the Ministry of Environment, Forest and Climate Change (MoEF&CC) and accredited by the National Accreditation Board for Testing and Calibration Laboratories (NABL), result of which is annexed as Annexure R-1/1 at page nos.257-259 of the paper book; true copies of annual environment statement (FY 2021-22), hazardous waste annual return (FY 2021-22) and biomedical waste annual return (calendar year 2021) are attached as Annexure R-1/2(Colly) at page nos.260-274 of the paper book; true copies of membership certificate for disposal of hazardous waste and biomedical waste are attached herewith as Annexure R-1/3(Colly) at page nos.275-276 of the paper book; true copies of the relevant documents for disposal of hazardous waste during April 2022 to June 2023 are attached as Annexure-R-1/4(Colly) at page nos.277-322 of the paper book; true copies of invoices for disposal of biomedical waste during April 2022 to May 2023 are attached herewith as Annexure R-

1/5(Colly) at page nos.323-345 of the paper book; true copies of water sample test reports dated 03.07.2023 along-with an excel sheet summarizing the data of these test reports are annexed as Annexure R-1/6(Colly) at page nos.346-368 of the paper book.

20. It is further mentioned in this affidavit by the respondent No.1 that the issues pertaining to proximity of Ambernath Plant to the Chikhholi dam and operation of Airoli Office in MIDC industrial area do not raise substantial question relating to environment or seek enforcement of any legal right relating to environment, arising out of implementation of enactments specified in Schedule- I of the National Green Tribunal Act, 2010. The answering Respondent has ensured operation of Airoli Office and Ambernath Plant in compliance with applicable environmental laws, including valid consents and authorizations and environmentally safe disposal of waste materials in accordance with terms and conditions prescribed therein. Hence, it is submitted by the answering respondent that these issues are beyond the jurisdiction of this Tribunal under Section 14 of the National Green Tribunal Act, 2010.

21. It is further mentioned in this affidavit by the respondent No.1 that answering Respondent has operated Ambernath Plant in compliance with the applicable environmental laws since its commencement in 2003. The Consent to Establish for this plant was obtained in 2003 followed by the first CTO in 27.07.2004 and these consents were renewed from time to time. The combined CTO and bio-medical and hazardous waste authorization for this plant was obtained on 28.01.2022 for operation of bio-pharmaceutical formulation and for small animal testing facility. The Answering Respondent applied for the renewal of this CTO and authorization on 25.06.2022, i.e., before expiry of its validity period i.e. on

30.06.2022. The requisite fee for renewal was paid to the MPCB on 30.06.2022.

22. It is further mentioned in this affidavit by the respondent No.1 that the MPCB found the responses furnished by the Answering Respondent in January 2023 to be satisfactory. The MPCB also inspected the Ambernath Plant on 12.01.2023 based on the Applicant's complaint but did not find anything untoward and in fact the said inspection was carried out at the behest of the complainant. Being satisfied with the operations at Ambernath Plant, MPCB issued the renewed CTO and authorization on 13.01.2023 and also dealt with all the issues raised by the Applicant in this Application. Therefore, it is submitted that the letter of renewal of CTO dated 13.01.2023 alone would suffice in dealing with all the contentions raised in this Original Application.

23. It is further mentioned in this affidavit by the respondent No.1 that the Central Pollution Control Board (CPCB) has issued the direction titled Categorization of Industrial Sectors under Red, Orange, Green and White Category, 2016 to classify the industries into different categories. The industries with pollution potential index score from 41 to 59 are categorized as orange industries and those with score of 60 and above are categorized as red industries. Based on these criteria, the CPCB has categorized "pharmaceutical formulation and for R&D purpose (for sustained release/ extended release of drugs only and not for commercial purpose)" under entry 74 in the orange category. It is pertinent to mention that the prerogative to categorize an industry is solely under the purview of the Respondent No.2 i.e. the MPCB and therefore, the allegations against the Answering Respondent are absolutely ill-founded. The allegation relating to proximity of Ambernath Plant to Chikholi dam is outside the

jurisdiction of this Tribunal in terms of Section 14 of National Green Tribunal Act, 2010.

24. It is further mentioned in this affidavit by the respondent No.1 that the Answering Respondent commenced operations of Airoli Office on 16.10.2019 after obtaining prior combined CTO and authorization from the MPCB. The allegation relating to allocation of plot in the MIDC industrial area to the Airoli Office for IT/ITES and back office operations activities is outside the jurisdiction of this Tribunal in terms of Section 14 of NGT Act. The letter dated 28.12.2018, which was issued by the Irrigation Department of the State of Maharashtra, clearly reveals that there is no potential threat of pollution to the dam water and the location of the plant of the Answering Respondent does not fall under the submerged area due to increase in height of the Chikholi dam and a letter to that effect is annexed as Annexure-R-1/12 at page nos.416-429 of the paper book.

25. It is further mentioned in this affidavit by the respondent No.1 that the Answering Respondent ensures recycling and complete re-use of the effluent generated from the Ambarnath Plant within the premises. The trade and sewage wastewater generated at the plant is not discharged outside the premises and is reused within the plant for various purposes. The biomedical and hazardous wastes generated at this plant are disposed in an environmentally safe manner through the MPCB authorized agency. The Answering Respondent also gets environmental monitoring tests at regular intervals and shares these results with the MPCB in compliance with the CTO conditions. Therefore, allegation of the Applicant is baseless. All the test reports regarding alleged water pollution have been annexed and all the allegations of water pollution have been completely debunked by a report of an independent agency.

26. It is further mentioned in this affidavit by the respondent No.1 that the Ambernath Plant was engaged in the pharmaceutical formulation activities, which were categorized as orange industry in the CPCB's 2016 Directions. Therefore, the Applicant has made the baseless claim pertaining to groundwater pollution due to the activities at Ambernath Plant without providing any specific evidence to justify this allegation. It is further mentioned that the Ambernath Plant has installed the online monitoring system and connected it to MPCB's server for continuous monitoring of effluent generation and discharge. The Ambernath Plant ensures zero liquid discharge in compliance with CTO conditions, which means that trade and sewage wastewater is not discharged outside the plant premises but treated, recycled and reused within the plant for various activities. The treated trade effluent is recycled and completely reused within the plant premises for cooling, scrubbing, process and utilities. Only the treated sewage water is reused for gardening purposes in compliance with the CTO conditions. Therefore, the allegations of the applicant are baseless without providing any specific evidence to justify this allegation. It reiterated that the Ambernath Plant is engaged in the pharmaceutical formulation activities, which are categorized as orange industry as per the CPCB's 2016 Directions. Therefore, the applicant has made the baseless claim pertaining to groundwater pollution by the activities at Ambernath Plant without providing any specific evidence to justify this allegation.

27. It is further mentioned in this affidavit by the respondent No.1 that the Ambernath Plant has installed the online monitoring system and connected it to MPCB's server for continuous monitoring of effluent generation and discharge and the Ambernath Plant ensures zero liquid discharge in compliance with CTO conditions, which means that trade and

sewage wastewater is not discharged outside the plant premises but treated, recycled and re-used within the plant for various activities. It is further mentioned that the Answering Respondent was earlier using highly purified treated effluent for gardening purposes in compliance with the CTO conditions. But pursuant to the MPCB's directions, it has stopped using such water for gardening and that the entire treated effluent is recycled and reused for activities like cooling, process, utilities and scrubbing. In view of above, it is prayed that the present Original Application may be dismissed.

28. From the side of respondent No.2-MPCB, reply affidavit dated 25.07.2023 has been filed, wherein it is submitted that Respondent Board had granted Consent to Operate to the Respondent No.1-M/s. Bharat Serums & Vaccines Ltd. under 'Orange' Category', details of which are given in tabular form in para no.3.

29. In this affidavit of respondent No.2, reference is made of the CPCB's Guidelines dated 07/03/2016 for categorization of industries into Green, Orange and Red category depending upon the pollution load. As per the said categorization, at Final Sr. No.74 and Original Sr. No.50, Pharmaceutical Formulation and for R & D purpose (for sustained release/extended release of drugs only and not for commercial purpose), the Respondent No.1-Industry falls under the 'Orange' Category.

30. It is further mentioned in this affidavit of respondent No.2 that on the basis of non-compliance of consent conditions, observed during the visit of the official of the Board at Kalyan on 06/06/2017, the Respondent Board had issued closure directions to the Respondent No.1 on 13/06/2017 with the directions to the Competent Authorities to disconnect water / electricity supply, a copy of which is annexed as

Annexure -C. After receipt of reply from the respondent No.1, the answering respondent granted Temporary Re-connection of water and electricity supply to Respondent No.1- Industry vide letter dated 20/06/2017, subject to the condition that they will not charge fresh batch of manufacturing till further orders. Thereafter, the answering respondent had extended an opportunity of personal hearing to the Respondent No.1- Industry on 03/08/2020. As decided in the said hearing, the Respondent Board had issued conditional restart directions on 21/08/2020 to the Respondent No.1-Industry, subject to certain terms & conditions. In order to verify the present status, the Officials of the Respondent Board at Kalyan again visited the industry of Respondent No.1 on 19/06/2023 and observed as under:-

- “
- (i). *During visit, the Industry was found operational, engaged in manufacture of bio-pharmaceuticals and small animal testing facility.*
 - (ii). *Production quantity found within consented limit.*
 - (iii). *The industry has provided primary, secondary & tertiary treatment facility for the treatment of trade effluent. During visit, the ETP was found in operation.*
 - (iv). *The industry is recycling the treated effluent to utilities i.e. cooling tower to achieve zero liquid discharge.*
 - (v). *The industry has provided STP for the treatment of sewage.*
 - (vi). *The treated domestic effluent is recycled for toilet flushing and remaining used on land for gardening.*
 - (vii). *During visit, no discharge of effluent observed outside the factory premises.*
 - (viii). *During visit, the representative of the Respondent- Industry informed they are manufacturing bio-pharmaceuticals products etc.*
 - (ix). *The industry is having PNG /LDO fired boiler, during visit, the boiler was found in operation on PNG.*
 - (x). *The industry has provided ladder, sampling point and platform to the stack.*
 - (xi). *The industry is a Member of CHWTSDf and is regularly disposing hazardous waste to MWML, Talaja etc.*
 - (xii). *The industry has also obtained membership of CBMWTDf and regularly disposing bio-medical to MWML-Talaja etc.”*

31. From the side of respondent No.6- Regional Directorate, Central Pollution Control Board, reply affidavit dated 28.07.2023 has been filed, in which we find that this affidavit contains only rule position.

32. Rejoinder affidavit dated 01.08.2023 against the reply affidavit of respondent No.5- Director, Directorate of Industrial Safety & Health has been filed by the respondent No.1, wherein it is submitted that the Research and Development unit of the Answering Respondent is registered under the Shops & Establishments Act and has a valid license. It is further mentioned that Show Cause Notices were issued by the respondent No.5 on various dates, which were responded to by the Answering Respondent.

33. From the side of respondent No.4- Superintendent Engineer, Thane Irrigation Circle, reply affidavit dated 01.08.2023 has been filed, wherein it is mentioned that answering respondent has not given NOC or permission for execution of the industry that forms the subject matter of the present Original Application.

34. Rejoinder affidavit dated 08.10.2023 has been filed by the applicant, wherein it is submitted that respondent No.1 had been given red category consent by the respondent No.2-MPCB for their Airoli R&D Centre, which were obtained in non-permitted zone for IT (Information Technology) & ITES (Information Technology Enable Services) sectors where Red category industry could not be allowed. The respondent No.1 is also not having permission under Factory Act. Therefore, the respondent No.1's industry may not be permitted to set up its Airoli R&D Centre at the present location and therefore, the same is illegal. The respondent No.1 is manufacturing the pilot batches of products using hazardous chemicals.

35. It is further mentioned in this rejoinder affidavit by the applicant that the respondent No.1 has not submitted any proof regarding its industry having achieved Zero Liquid Discharge (ZLD). There is no CETP for disposal of R&D effluent. Absence of any CETP is evident to show that the ZLD mandate is not being followed and it is a serious breach of the consent terms mentioned in CTO dated 13/01/2023. The R-1's Ambernath Factory unit-1 is having production unit for injectable pharmaceuticals products and names of such formulation chemical based products are mentioned in the Consent to Operate, which are API (Active Pharmaceutical Ingredients) and shall be certified as per the FDA (Food and Drug Administration). Regarding such products, requirement of EC is compulsory or Pre-EC product permission under Environment Clearance Notification 2006 amended vide S.O.1223 (E) dated 27th March 2020 and S.O. 3636 (E) dated 15th October 2020 and as such clearance has not been taken by the respondent No.1. Therefore, the same should be treated to be in violation and breach of environmental norms.

36. It is further mentioned in this rejoinder affidavit by the applicant that the Total Density (TDS- Total Dissolved Solids) data submitted on oath by the respondent No.1 in their reply affidavit dated 21/07/2023 is manipulated, which also amounts to misrepresentation to the NGT as well. It is a crystal clear case of perjury. Further, the said TDS data shows that the said water cannot be recycled. The effluent water is being used for gardening, which is not permitted as per the Consent to Operate issued by the MPCB and as per the mandatory provision of maintaining ZLD. There is no CETP in the nearby area available and CETP of MIDC is not operational, hence the water balancing of respondent No.1 needs to be verified considering the huge intake of water for manufacturing by the respondent No.1. Water and Soil testing of the surrounding land is

essential since it is already polluted because of previously discharged untreated water by the respondent No.1. For the same reason only, the MPCB had issued closure notices to the respondent No.1 earlier in the year 2017. The chemicals, which are using by respondent No.1, are hazardous and toxic, which may be observed from the list of chemicals in their statements submitted to the MPCB.

37. It is further mentioned in this rejoinder affidavit by the applicant that the respondent No.1 is having its Unit No.2 on MIDC Plot No K-27/1 where the respondent No.1- BSVL is having Animal Testing facility and other activities, which are also in non-permitted zone because the said plot falls under the High Flood Level Catchment Zone as declared by the Irrigation Department, related documents are already attached to the main Application. The Irrigation Department had also communicated to the Additional Ambarnath MIDC that they had not permitted or provided any Consent to do any construction activity in Plot K-27/1, Anand Nagar, Addl. MIDC, Ambernath (East), belonging to respondent No.1- BSVL. The facility at Unit No.2 on MIDC Plot No K-27/1 of respondent No.1 is built without any approval of the Irrigation Department, hence the same should be held to be illegal and no one is allowed to construct anything or to conduct any activity in the plot of Additional Ambernath MIDC.

38. It is further mentioned in this rejoinder affidavit by the applicant that it is surprising that the respondent No.1- BSVL has mentioned that they have checked the water quality of Chichloli dam and the same is found to be good. It is alleged that the said company by which the test was got conducted, was not having any authority to check the water quality of Chichloli Dam just because it was in the Vicinity of their MIDC Plot No.K-27/1 at Ambernath. The data of bio-medical waste and hazardous waste generation and disposal has no meaning for any illegal activities done in

the non-permissible zone by the respondent No.1. It is further mentioned that whenever there is combined Consent to Operate (CTO) and Bio-Medical Waste Authorization granted together, it automatically attracts the consent regime mentioned for Red Colour Industry and hence the consent by the MPCB was required. But the respondent No.1 has not taken any such legally required permission or consent.

39. It is further mentioned in this rejoinder affidavit by the applicant that the Pollution Score Index of respondent No.1- BSVL, which is given by the respondent No.1 in its reply dated 21/07/2023 in paragraph no.39, to be just 55 but it is actually more than 62 even though calculated without the Bio-Medical Waste. As per the said index, the unit of respondent No.1 falls under Red Category. It is further mentioned that without verifying the fact, the respondent No.2- MPCB has categorised respondent No.1's BSVL Ambernath factory as a Pharmaceutical industry referred under serial No. 74, which are manufacturing products only. Whereas BSVL Ambernath is manufacturing bio-pharmaceutical formulation products, active pharmaceutical ingredients (API) products, products by fermentation, bulk product etc. Therefore, the respondent No.1 is generating hazardous waste as well, in the form of bio-medical waste and even then the MPCB has given it the Consent to Operate under Orange Category instead of Red Category, erroneously.

40. It is further mentioned in this rejoinder affidavit by the applicant that the MPCB officials had visited the BSVL Ambernath on 19/06/2023 and had conducted inspection. From their inspection report, it can be clearly seen that the respondent No.1 manufactures Bio-Phanna products hence the same would also fall automatically under Red category. The Pollution Index, as declared by the respondent No.1 is 55, would automatically shoot up since 13MT waste is also generated by the

Industry. Also BSVL is generating sewage /effluent quantity more than 100 KLD Per day, which would also attract RED category. Respondent No.1 is having more than 100 Cages for small animals, wherein the small animals are housed, hence the same would also fall in Red Category. It is further mentioned that respondent No.1- BSVI has also submitted technically wrong information of pollution index - 55 instead of 62 under entry no.74, which is applicable only for Pharmaceutical Industry. The respondent No.1 needed to obtain prior Environmental Clearance. It is further mentioned that respondent No. 4- Irrigation Department has not given clearance to MIDC to build or construct industry like the one of respondent No.1 on plot no.K-27/1 belonging to BSVI, since it is coming under HFL Catchment Zone. The respondent No.3- MIDC is responsible for allowing the construction in No Permissible Zone at Ambernath.

41. From the side of respondent No.3-Chief Executive Officer, Maharashtra Industrial Development Corporation, reply affidavit dated 17.01.2024 has been filed, wherein it is submitted that the Respondent No.1 has already produced the Certificate of Irrigation Department dated 28.12.2018 that the Plot No.K-27/1 of Additional Ambernath Industrial Area does not fall under the submerged area of Chikhholi Dam. Therefore, the contentions of the applicant in respect of Plot No.K-27/I does not survive.

42. It is further mentioned in this affidavit by the respondent No.3 that the Respondent No.1 is one of the sub-lettee of Reliable Spaces Pvt. Ltd. for 2945.42 sq. mtrs. in respect of Plot No.K-10, TTC Industrial Area. One of the condition of the sub-letting is that the activity permitted in respect of the said plot shall not change and the plot holder and sub-lettee shall obtain all the required government permissions. In the instant case, the Respondent No.1 has submitted that the activities carried out by them are

back office operations, which fall under IT/ITES activities as specified under the IT Policy, 2015 of Government of Maharashtra. The Respondent No.1 has also obtained registration of ITES activities namely back office operations from the District Industrial Centre (DIC), Thane on 31.01.2020, which is annexed as Annexure-1 to this reply, which shows that the Respondent No 1 is using the said premises at Reliable Plaza, IT Park, Airoli for back office operations.

43. It is further mentioned in this affidavit by the respondent No.3 that the MIDC does not have any powers of either granting the consent to operate or monitoring the activities of industry from the environmental point of view.

44. Applicant has submitted its rejoinder affidavit dated 23.01.2024 with respect to the respondent No.1's plant situated at Airoli, in which we find that nothing new has been stated from their side, except what has been earlier stated by him and other respondents have been recapitulated.

45. We have heard the arguments of learned counsel for parties and perused the record.

46. For deciding the issue involved in this case, we have framed following points for determination:-

- (i). Whether Ambernath Plant of respondent No.1 caused any water pollution in Chikhholi Dam?;
- (ii). Whether the unit of respondent No.1 at Airoli is only R&D facility and is not involved in manufacturing activity? If yes, its effect?
- (iii). Is there any error in granting CTO to Airoli unit of respondent No.1 by changing the category of the same from red to orange?

(iv). As to what relief, applicant is entitled?

47. **Issue No.(i)**: With respect to this issue, we have to decide as to whether Ambernath Plant of respondent No.1 caused any water pollution in Chikhloli Dam. The burden to prove this issue lies on the applicant, who has made this allegation. The said allegation has been denied by the respondent No.1-Project Proponent saying that it ensures recycling and complete reuse of effluent generated from the Ambernath Plant within the premises. The trade and sewage wastewater generated at the plant is not discharged outside the premises and is reused within the plant for various purposes. The biomedical and hazardous wastes generated at this plant are disposed of in an environmentally safe manner through the MPCB authorized agency. The Answering Respondent also gets environmental monitoring tests **done** at regular intervals, which are also shared with the MPCB in compliance with the CTO conditions. The test reports have also been annexed, as per which there is no water pollution found.

48. Much emphasis has been laid by the learned counsel for respondent No.1 upon the communication dated 28.12.2018 made by the Executive Engineer, Thane Irrigation Department, Kalwa, Thane addressed to the Executive Engineer, Maharashtra Industrial Development Corporation (MIDC), Ambernath in respect of Jambhivali (Chikhloli), Minor Irrigation Scheme, Taluka: Ambernath, District: Thane, in which it is recorded that the height of the Dam of Jambhivali (Chikhloli), Minor Irrigation Department, Taluka: Ambernath, District: Thane is proposed to be increased by 2.50 mtrs. with a view to acquire land for that purpose and the work of land survey is being carried out by the Office of Land Records, Ambernath. Accordingly, boundaries have been marked in the Catchment Area and joint survey was in progress. Accordingly, on the basis of boundaries of the additional Catchment Area, Plot No.K-27/1 (land in

question where the Plant of respondent No.1 is located) of the Additional Ambernath Industrial Area does not fall in the Catchment Area of the Dam.

49. Having drawn our attention to the above-mentioned letter, it has been vociferously argued by the learned counsel for respondent No.1 that in no way the effluent could flow towards the dam in question because the said Plant is outside the catchment area of Chikhloli Dam. Hence, no apprehension of pollution could be there. Consequently, the allegation made by the applicant is only a figment of imagination, which has been made only in order to harass the respondent No.1.

50. We find force in the argument made by the learned counsel for respondent No.1, particularly, in view of the fact that there is no such evidence extended from the side of applicant showing that if any effluent did flow into the Chikhloli Dam and that the water of the said Dam was found to be contaminated, no such report of water, having been found to have been contaminated, has been placed on record by the applicant.

51. With the reply affidavit dated 21.07.2023 of respondent No.1, we find annexed Inspection Report of the MPCB of the Ambernath Plant of respondent No.1, which was conducted on 12.01.2023, wherein no pollution was found to have been caused by the Plant of respondent No.1 in the Chikhloli Dam's water.

52. We also find in the reply affidavit dated 25.07.2023 of the respondent No.2- MPCB, wherein it is mentioned that the Ambernath Plant of respondent No.1 was granted consent under Orange Category because the activity carried out by the respondent No.1- Project Proponent fell in that Category, which is placed at serial no.74 of the Guidelines dated 07.03.2016 issued by the Central Pollution Control Board, laid down

for categorization of industries into Green, Orange and Red category, depending upon the pollution load. It is also recorded that on the basis of certain non-compliances of the consent conditions being observed during the visit made on 06.06.2017, closure direction was issued to the respondent No.1 on 13.06.2017. But after having received the reply of the respondent No.1 and finding the compliances having been made, the temporary re-connection of water and electricity supply were ordered vide letter dated 20.06.2017, subject to condition that they shall not start fresh batch of manufacturing till further orders. Thereafter, inspection of the site in question was also made on 19.06.2023 and no non-compliances were noticed.

53. In view of the reply affidavit of respondent No.2- MPCB, though the same is being orally said to be biased in favour of the respondent No.1 by the learned counsel for applicant, we do not find any proof to hold that the respondent No.2- MPCB has shown any bias towards the respondent No.1- Project Proponent. Merely making such an oral allegation would not be sufficient for us to disbelieve what has been stated on an affidavit by the Government Authority unless there is a sound proof given in rebuttal. Therefore, in view of above analysis, we come to the conclusion that the Ambernath Plant of respondent No.1 is not found to have caused any pollution in Chikhholi Dam. This issue is decided accordingly.

54. **Issue No.(ii)**: As per this issue, we have to decide as to whether the unit of respondent No.1 at Airoli is only R & D facility and is not involved in manufacturing activity? If yes, its effect. The burden to prove this issue lies on the respondent No.1- Project Proponent because the allegation against the respondent No.1 is that the said unit is also indulging in manufacturing activity, which is causing pollution in the area in question.

55. The learned counsel for applicant has drawn our attention to page no.1069 of the paper book, which is a Combined Consent to Operate dated 16.10.2019 granted to the Airoli Unit of respondent No.1 under Red Category, which is valid till 31.12.2024, in which at point no.4, trade effluent of 4.5 CMD is expected to be generated by this Unit and hence it is argued that this Plant should be treated to be indulging in manufacturing of the drugs and not conducting only R & D facility. This Consent was given in Red Category but subsequently on 30.05.2023, the same was converted into Orange Category by the respondent No.2- MPCB erroneously/in collusion with the respondent No.1-Project Proponent, which could **not** have been done.

56. Thereafter, the learned counsel for applicant has drawn our attention to the Notification dated 14.09.2006 issued by the Ministry of Environment and Forests, which is annexed at page no.1110 of the paper book onwards and **read** its para no.2, which says “All new projects or activities listed in the Schedule to this Notification; (ii) Expansion and modernization of existing projects of activities listed in the Schedule to this notification with addition of capacity beyond the limits specified for the concerned sector, that is, projects or activities which cross the threshold limits given in the Schedule, after expansion or modernization; (iii)Any change in product- mix in an existing manufacturing unit included in Schedule beyond the specified range”.

57. Having drawn our attention to the above, it is argued by the learned counsel for applicant that since the consent was renewed, therefore, under the aforesaid Regulations/para of the EIA Notification 2006, the respondent No.1- Project Proponent required to obtain prior EC from the MoEF/SEIAA.

58. In rebuttal of the said argument, the learned counsel for respondent No.2- MPCB has brought to our notice that there was a mistake committed at their end in granting consent at the initial stage to the said unit of the respondent No.1- Project Proponent under Red Category because the said unit of respondent No.1 was involved only in R&D activity and not in manufacturing activity. Therefore, it should have been granted under Orange Category at the very initial stage. Therefore, the same was later on corrected through amendment on 30.05.2023.

59. We find force in the argument made by the learned counsel respondent No.2- MPCB in view of the fact that Notification dated 07.03.2016 issued by the Central Pollution Control Board modifying the directions under Section 18(1) (b) of the Water (Prevention and Control of Pollution) Act, 1974; and the Air (Prevention and Control of Pollution) Act, 1981 regarding harmonization of classification of industrial sectors under Red/Orange/Green/White Categories, in which serial no.74, in tabular form, relates to Pharmaceutical formulation and for R&D purpose (for sustained release/extended release of drugs only and not for commercial purpose) and therefore, the Airoli Unit of the respondent No.1 being found to be covered under Pharmaceutical formulation and for R & D purpose only, the same appears to have been rightly rectified/amended into the Orange Category by the respondent No.2- MPCB. Merely because at the initial stage, some error was committed by the respondent No.2- MPCB, would not mean that the said error should be allowed to remain there and that the same has rightly been amended. We do not have any reason to disbelieve the decision of the MPCB. Accordingly, we find that the Airoli Unit of the respondent No.1 has been rightly categorized under Orange Category and accordingly, it has been rightly granted Consent to Operate under the said Category.

60. We may also emphasize here that as per the “Classification of Industrial Sectors into Red, Orange, Green and White Categories: A Tool for Progressive Environmental Management”, there is no basic difference in the process of grant of consent under Red, Orange, Green Category, except that for the industries, which are falling in Red Category, the consent is granted for one year; for the Orange Category, the consent is granted for two years; and for Green Category, the consent is granted for three years respectively, which subsequently get renewed from time to time, if applied for by the industry. Hence, the applicant appears to have made huge issue of change in consent category from Red to Orange, which to us does not appear to be of much significance. We may further conclude from the above that the Airoli Unit of respondent No.1 also cannot be treated to have caused any pollution because it is found involved in R&D facility and not in actual manufacturing. Therefore, this issue is decided accordingly.

61. **Issue No.(iii)**: As per this issue, we have to decide as to whether the respondent No.2- MPCB has committed any error in granting CTO to Airoli unit of respondent No.1 by changing the category of the same from red to orange. In view of the analysis made by us while dealing with the issue no.(ii) above, we find that there was an error committed by the respondent No.2- MPCB at the initial stage while granting the Consent to Operate to the Airoli Unit of respondent No.1 under Red Category. But later on, the same was rectified and was placed under Orange Category. This issue is decided accordingly.

62. **Issue No.(iv)**: After having discussed as above, we are of the view that the applicant is not found entitled to be granted any relief.

63. With the above observations, we dispose of this Original Application accordingly.

64. Pending application, if any, also stands disposed of. No order as to cost.

Dinesh Kumar Singh, JM

Dr. Vijay Kulkarni, EM

July 01, 2024
Original Application No.31/2023(WZ)
P.Kr.