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12 **BEFORE THE HEARING BOARD OF THE**  
13 **SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT**

14 **In the Matter of**

15 B. BRAUN US PHARMACEUTICAL  
16 MANUFACTURING LLC [Facility ID No.  
17 117290]

18 Petitioner,

19 vs.

20 SOUTH COAST AIR QUALITY  
21 MANAGEMENT DISTRICT,

22 Respondent.

23 **Case No. 4780-5**

24 **[PROPOSED] FINDINGS AND**  
25 **DECISION**

26 South Coast AQMD Rule 1134

27 Hearing Date: October 24, 2024

28 Time: 9:30 a.m.

Place: Hearing Board  
South Coast Air Quality  
Management District  
21865 Copley Drive  
Diamond Bar, CA 91765

29 **FINDINGS AND DECISION OF THE HEARING BOARD**

30 On December 19, 2023, a Petition for a Regular Variance (“Petition”) was heard, pursuant to  
31 notice and in accordance with the provisions of the California Health and Safety Code section 40826  
32 and South Coast AQMD Rule 510. The Petition was subsequently granted, and a regular variance  
33 was issued by the Hearing Board on December 21, 2023. On May 29, 2024, B. Braun Medical Inc.  
34 (“BMI”) notified the Hearing Board that ownership and operation of its pharmaceutical  
35 manufacturing facility located at 2525 McGaw Avenue in Irvine, California (the “Irvine Facility”),  
36 which is subject to the variance, was transferred to an affiliate entity, B. Braun US Pharmaceutical  
37 Manufacturing LLC (“Petitioner” or “Pharma”). Pharma is now responsible for compliance with the

1 variance. On August 30, 2024, Pharma filed a Petition for Extension of a Final Compliance Deadline,  
2 in connection with the variance (the “Extension Petition”). On October 24, 2024, the Hearing Board  
3 held a hearing pursuant to California Health and Safety Code section 40826 and South Coast AQMD  
4 Rule 510, to consider an extension of the variance compliance deadlines, as requested in the  
5 Extension Petition. The following members of the Hearing Board were present: Micah Ali, Chair;  
6 Robert Pearman, Vice-Chair; Mohan Balagopalan; Jerry P. Abraham, MD; and Cynthia Verdugo-  
7 Peralta. Petitioner, represented by J. Tom Boer, Esq., and Maia Jorgensen, Esq., Hogan Lovells US  
8 LLP, did not appear. Respondent, Executive Officer of the South Coast Air Quality Management  
9 District (“South Coast AQMD” or “Respondent”), represented by Mary Reichert, Senior Deputy  
10 District Counsel, did not appear. The parties have stipulated to the issuance of this Order. The public  
11 was given the opportunity to testify. Evidence was received and the matter was submitted. The  
12 Hearing Board finds and decides as follows:

13 **Nature of Business and Location of Facility**

14 Petitioner Pharma is a medical equipment manufacturing company operating the Irvine  
15 Facility, which is a modernized, 710,000 sq. ft. pharmaceutical manufacturing facility located in  
16 Irvine, California, within the jurisdiction of the South Coast AQMD. The Facility ID Number is  
17 117290.

18 **Equipment and Permit to Construct/Operate**

19 The equipment that is the subject of the variance consists of Turbine No. 1 (Device D28)  
20 operated pursuant to Permit to Operate No. 432956 and Turbine No. 2 (Device D35) operated  
21 pursuant to Permit to Operate No. 542242 (collectively, the “Turbines”).

22 **South Coast AQMD Rule 1134** requires an emission standard of 2 ppm NOx @ 15% O2  
23 for all stationary Natural Gas-Fueled Cogeneration Single Cycle Turbines effective January 1, 2024.

24 **SUMMARY**

25 Petitioner is in violation of District Rule 1134 because Turbines No. 1 and 2 do not meet the  
26 Rule 1134 2 ppm NOx limitation that took effect on January 1, 2024. Petitioner must continue to  
27 operate Turbines No. 1 and 2 because delivery and installation of the replacement technology was  
28 not completed in time to meet the January 1, 2024 deadline. Despite an initial estimate of completion

1 that would have met the January 1, 2024 deadline, Petitioner’s contractor notified them that they  
2 would be unable to complete delivery and installation of compliant equipment until October 2024.  
3 This resulted in a final compliance deadline for the variance of October 31, 2024. Since issuance of  
4 the regular variance on December 21, 2023, BMI and Petitioner have diligently pursued installation  
5 of replacement technology that will bring the facility into compliance with District rules and allow  
6 for the decommissioning of the Turbines. Nevertheless, for reasons outside of Petitioner’s control,  
7 Pharma has been made aware that certain required upgrades to the Southern California Edison  
8 (“SCE”) electrical yard at the Irvine Facility will delay operationalization of replacement technology  
9 until January 2025.

### 10 FINDINGS OF FACT AND CONCLUSIONS

11 Following are the facts and conclusions supporting the findings set forth in Health and Safety  
12 Code Section 42352 necessary to grant the variance. The Executive Officer did not oppose the  
13 granting of the regular variance.

14 **a. The Petitioner for a variance is or will be in violation of Section 41701, or of any rule,  
15 regulation, or order of the South Coast AQMD.**

16 Petitioner is in violation of District Rule 1134 because Turbines No. 1 and 2 do not meet the  
17 Rule 1134 2 ppm NOx limitation that took effect on January 1, 2024. Petitioner must continue to  
18 operate Turbines No. 1 and 2 because delivery and installation of the replacement technology was  
19 not completed in time to meet the January 1, 2024 deadline.

20 **b(1). Non-compliance with District Rule(s) is due to conditions beyond the reasonable  
21 control of the Petitioner.**

22 BMI began a process in late 2018 to identify a feasible alternative for power generation at  
23 the Irvine Facility as required to meet the Rule 1134 deadline. BMI signed an Energy Services  
24 Agreement (“ESA”) with Bloom Energy (“Bloom”) to replace Turbines No. 1 and 2 with two natural  
25 gas fuel cell systems (the “Fuel Cells”) to comply with the Rule 1134 2 ppm limit. When signing  
26 the contract in December 2022, Bloom agreed to a penalties provision in the ESA in the event the  
27 Fuel Cells are not operational within 18 months. However, in the second quarter of 2023, it became  
28 evident to BMI that Bloom would not meet the January 1, 2024 deadline. The project delay was

1 driven by a number of converging factors including unexpected complications with the City of Irvine  
2 permitting process (due to the City changing its position by requiring a City Master Plan  
3 modification process before issuing otherwise required permits for the project), longer than expected  
4 procurement lead times for electrical switchgears necessary for the project, and unanticipated  
5 challenges with various aspects of the project design including gas supply engineering.

6 Since issuance of the regular variance on December 21, 2023, BMI and Petitioner have  
7 diligently pursued installation of replacement technology that will bring the Irvine Facility into  
8 compliance with District rules and allow for the decommissioning of the Turbines. Certain aspects  
9 of the project, however, rely upon work performed by SCE. Such work is performed based upon the  
10 availability of SCE personnel and resources and is outside the direct control of Petitioner. Despite  
11 Petitioner's best efforts, in May of 2024, SCE notified Petitioner that certain structural and electrical  
12 upgrades must be completed at the SCE yard located adjacent to the Irvine Facility's Switchyard A  
13 before SCE will allow tie-in of the Fuel Cells into the electrical grid, which is an essential step to  
14 operationalizing the Fuel Cells. Based on estimates provided by SCE, it is contemplated that the  
15 necessary upgrades will be completed by the end of December 2024, after which the Fuel Cells can  
16 be energized. Bloom estimates a month will be required after energization of the Fuel Cells to  
17 complete the project. These unexpected project delays, which were outside Petitioner's control,  
18 form the basis of Petitioner's request for an extension of the final variance compliance deadline to  
19 January 31, 2025.

20 **b(2). Requiring compliance would result in either (1) an arbitrary or unreasonable taking of**  
21 **property, or (2) the practical closing and elimination of a lawful business.**

22 Petitioner's Irvine Facility produces over 100 medical products including premixed  
23 intravenous (IV) solutions, generic drugs, antibiotics, and nutrition therapy formulations. The  
24 Facility plays a critical role in the health care sector, as it produces approximately 20 percent of the  
25 IV solutions used in the United States. The Facility operates twenty-four hours a day, seven days a  
26 week, relying heavily on consistent energy generated by its two natural gas-fueled Turbines. These  
27 turbines are essential for the operation of the Facility. Shutting down of the Turbines without  
28 alternative power could result in \$2 million per day of lost revenues and significant disruption to the

1 healthcare system.

2 **c. The closing or taking would be without a corresponding benefit in reducing air**  
3 **contaminants.**

4 Estimated excess emissions are 9.77 pounds of NOx per day. This is not a significant amount  
5 of emissions when weighed against the significant impacts of a potential shutdown of the Facility.

6 There are also long-term benefits to the Facility’s decision to replace its natural gas-fueled  
7 Turbines with the Fuel Cells as compared to installing replacement cogeneration turbines. Once  
8 installed, NOx emissions for the Fuel Cells will be approximately 0.0017 lbs/MWh, which will  
9 result in annual emissions that are significantly below the Rule 1134 limit. Within a year of the  
10 installation and start-up of the Fuel Cells, emissions saving from the conversion to the Fuel Cells  
11 will effectively cancel out the excess NOx emissions expected to be generated by the Turbines  
12 during the original 10-month variance period. After that one-year period, NOx emissions associated  
13 with the Fuel Cells will continue to be orders of magnitude less than the annual NOx emissions that  
14 would have occurred if Pharma had instead installed cogeneration turbines compliant with the  
15 newly effective January 1, 2024, NOx emission limitations for cogeneration turbines. The limited,  
16 additional excess NOx emissions generated during a three-month extension of the variance through  
17 January 31, 2025, will not materially change the benefits of the Fuel Cell project as recognized in  
18 the original variance.

19 **d. The Petitioner for the variance has given consideration to curtailing operations of the**  
20 **source in lieu of obtaining a variance.**

21 Curtailing or terminating operations at the Irvine Facility would have serious medical supply  
22 chain implications, result in breach of customer contracts, and have severe financial repercussions  
23 for Pharma. Several of the products Petitioner manufacturers at the Irvine Facility are or have  
24 recently been on the FDA drug shortages list. Curtailing operations would have a negative impact  
25 on millions of patients across California and the United States.

26 **e. During the period the variance is in effect, the Petitioner will reduce excess emissions to**  
27 **the maximum extent feasible.**

28 The Turbines have a permitted, maximum rated capacity of 6MW. During the variance

1 period, Pharma has reduced its reliance on the Turbines to 4.5MW as measured on a weekly average  
2 basis. This represents a 25% reduction below the Turbines' maximum rated capacity (and a further  
3 10% reduction below the Petitioner's original estimation of power needed from the Turbines during  
4 the variance). This is the maximum reduction Pharma can achieve during the variance period  
5 without compromising its manufacturing operations and its ability to maintain sufficient catalyst  
6 temperature to meet emissions requirements for air contaminants (e.g., carbon monoxide). Petitioner  
7 will also continue to operate the Turbines in compliance with all other applicable permit conditions  
8 and keep the Turbines in proper working condition.

9 **f. During the period the variance is in effect, the Petitioner will monitor or otherwise**  
10 **quantify emission levels from the source, if requested to do so by the District, and report**  
11 **these emission levels to the District pursuant to a schedule established by the District.**

12 Petitioner will continue to operate the CEMS units and report emissions as required under  
RECLAIM and the conditions under this Order.

### 13 ORDER

14 THEREFORE, good cause appearing, the Hearing Board orders as follows:

15 A. Petitioner is granted a regular variance from District Rule 1134 for Turbine No. 1  
16 (D28) operating pursuant to Permit to Operate No. 432956 and Turbine No. 2 (D35) operating  
17 pursuant to Permit to Operate No. 542242, for the period commencing November 1, 2024 and  
18 continuing through January 31, 2025, the final compliance date.

19 B. The variance granted herein is subject to the following conditions:

20 1. Petitioner shall maintain records of NOx emissions in pounds per day, and  
21 fuel usage records in million cubic feet per day, for each Turbine Device ID D28 and D35 starting  
22 01/01/24. These records shall be emailed to Air Quality Inspector Paolo  
23 Longoni(plongoni@aqmd.gov) on a quarterly basis, no later than close of business (COB) on the  
24 5th day of the month following the end of each quarter.

25 2. Petitioner shall calculate NOx excessive emissions, in pounds per day, for  
26 each Turbine Device ID D28 and D35 starting 01/01/24 using the difference between the current  
27 NOx limit of 9 ppm (as set by Permit to Operate condition no. A99.1) and the future NOX limit of  
28 2 ppm (as set by Rule 1134). These records shall be emailed to Air Quality Inspector Paolo Longoni

1 (plongoni@aqmd.gov) on a quarterly basis, no later than COB on the 5th day of the month following  
2 the end of each quarter.

3 3. Petitioner shall not operate the Turbines, in combination, to exceed 4.5MW  
4 of power as measured by the Petitioner on an average weekly basis. Petitioner shall record the  
5 weekly average power generation from the Turbines, which shall be included in Petitioner's  
6 quarterly report to Air Quality Inspector Paolo Longoni.

7 4. Petitioner shall maintain the existing Relative Accuracy Test Audits (RATAs)  
8 schedule for once every six months (or every twelve months if the incentive is met) for each Turbine  
9 Device ID D28 and D35 as required by Rule 2012.

10 5. Petitioner shall perform a full service per the manufacturer's specifications of  
11 Turbines Device ID D28 and D35 at least once every two calendar quarters.

12 6. Petitioner shall report the progress of this project to South Coast AQMD on a  
13 quarterly basis, which includes the status of all design, demolition, and construction activities related  
14 to the replacement of Turbines Device ID D28 and D35 with two new Fuel Cells. Petitioner shall  
15 include, with each quarterly report, a Gantt chart showing the status of the Fuel Cells project. These  
16 reports shall be emailed to Air Quality Inspector Paolo Longoni (plongoni@aqmd.gov) and Air  
17 Quality Engineer Faye Ganser (fganser@aqmd.gov) no later than COB on the 5th day of the month  
18 following the end of each quarter.

19 7. Petitioner shall timely submit complete information for the two new Fuel  
20 Cells, consistent with Rule 222, in a format determined by the Executive Officer. Information for  
21 the Fuel Cells submitted pursuant to Rule 222 should be submitted online to  
22 PermitServicesOnline@aqmd.gov and confirmation of the application submittals shall be provided  
23 to Air Quality Engineer Faye Ganser (fganser@aqmd.gov) by email.

24 8. Petitioner shall comply with the following Increments of Progress:

- 25 a. November 28, 2024: Outage to prepare SCE onsite yard for upgrades.
- 26 b. December 24, 2024: SCE yard upgrades complete.
- 27 c. December 30, 2024: Commencement of Fuel Cells operation.
- 28 d. January 29, 2025: Fuel Cells microgrid transfer complete.

1 Within two business days of the deadline for the completion of each Increment of Progress,  
2 Petitioner shall submit via email to Air Quality Inspector Paolo Longoni (plongoni@aqmd.gov) an  
3 updated Gantt chart for the Fuel Cells project.

4 9. Petitioner shall install and begin initial operation of the two new Fuel Cells  
5 no later than COB January 4, 2025.

6 10. Petitioner shall achieve final compliance no later than COB January 31, 2025.  
7 Petitioner shall notify by email Air Quality Inspector Paolo Longoni (plongoni@aqmd.gov) of the  
8 following events as they occur:

9 a. The construction start date, the installation completion date, and the date  
10 each new Fuel Cell becomes operational; and

11 b. Achieving final compliance.

12 11. Petitioner shall notify the Clerk of the Hearing Board at  
13 clerkofboard@aqmd.gov when final compliance is achieved.

14 12. Petitioner shall pay any excess emissions fees to the Clerk of the Board on a  
15 quarterly basis no later than COB on the 30th day of the month following the end of each quarter or  
16 this variance shall be invalidated pursuant to Rule 303(k). The first payment will be due be due on  
17 April 30, 2024.

18  
19 **FOR THE BOARD:** \_\_\_\_\_

20 **DATE SIGNED:** \_\_\_\_\_

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