

SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT
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B. BRAUN US PHARMACEUTICAL MANUFACTURING LLC South Coast Air Quality Management District

BEFORE THE HEARING BOARD OF THE
SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT

In the Matter of

Case No. 4780-5

B. BRAUN US PHARMACEUTICAL MANUFACTURING LLC MEDICAL INC.
[Facility ID No. 117290]

[PROPOSED] FINDINGS AND DECISION

Petitioner,

South Coast AQMD Rule 1134

vs.

SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT,

Hearing Date: October 24 ~~December 19,~~ 2023

Time: 9:30 a.m.

Respondent.

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

FINDINGS AND DECISION OF THE HEARING BOARD

~~This On December 19, 2023,~~ a Petition for a Regular Variance (“Petition”) was heard ~~on~~ December 19, 2023, pursuant to notice and in accordance with the provisions of the California Health and Safety Code section 40826 and South Coast AQMD Rule 510. The Petition was subsequently granted, and a regular variance was issued by the Hearing Board on December 21, 2023. On May 29,

2024, B. Braun Medical Inc. (“BMI”) notified the Hearing Board that ownership and operation of its pharmaceutical manufacturing facility located at 2525 McGaw Avenue in Irvine, California (the “Irvine Facility”), which is subject to the variance, was transferred to an affiliate entity, B. Braun US Pharmaceutical Manufacturing LLC (“Petitioner” or “Pharma”). Pharma is now responsible for compliance with the variance. On August 30, 2024, Pharma filed a Petition for Extension of a Final Compliance Deadline, in connection with the variance (the “Extension Petition”). On October 24, 2024, the Hearing Board held a hearing pursuant to California Health and Safety Code section 40826 and South Coast AQMD Rule 510, to consider an extension of the variance compliance deadlines, as requested in the Extension Petition. The following members of the Hearing Board were present: Micah Ali Cynthia Verdugo Peralta, Chair; Robert Pearman, Vice-Chair; Mohan Balagopalan; Jerry P. Abraham, MD; and Cynthia Verdugo Peralta Micah Ali. Petitioner ~~B. Braun Medical Inc.~~ (“Petitioner” or “B. Braun”), was represented by J. Tom Boer, Esq., and Maia Jorgensen, Esq., Hogan Lovells US LLP, did not appear. Respondent, Executive Officer of the South Coast Air Quality Management District (“South Coast AQMD” or “Respondent”), ~~was~~ represented by Mary Reichert, Senior Deputy District Counsel, did not appear. The parties have stipulated to the issuance of this Order. The public was given the opportunity to testify. Evidence was received and the matter was submitted. The Hearing Board finds and decides as follows:

Nature of Business and Location of Facility

Petitioner ~~Pharma B. Braun~~ is a medical equipment manufacturing company operating the Irvine Facility, which is a modernized, 710,000 sq. ft. pharmaceutical manufacturing facility located ~~at 2525 McGaw Avenue~~ in Irvine, California ~~(the “Irvine Facility”)~~, within the jurisdiction of the South Coast AQMD. The Facility ID Number is 117290.

Equipment and Permit to Construct/Operate

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

South Coast AQMD Rule 1134 requires an emission standard of 2 ppm NOx @ 15% O2

1 for all stationary Natural Gas-Fueled Cogeneration Single Cycle Turbines effective January 1, 2024.

2 **SUMMARY**

3 Petitioner ~~is will be~~ in violation of District Rule 1134 because Turbines No. 1 and 2 do not
4 meet the Rule 1134 2 ppm NOx limitation that ~~took will be in~~ effect ~~on as of~~ January 1, 2024.
5 Petitioner must continue to operate Turbines No. 1 and 2 because delivery and installation of the
6 replacement technology ~~was ill~~ not ~~be~~ completed in time to meet the January 1, 2024 deadline.
7 Despite an initial estimate of completion that would have met the January 1, 2024 deadline,
8 Petitioner’s contractor ~~has~~ notified them that they ~~would ill~~ be unable to complete delivery and
9 installation of compliant equipment until October 2024. This resulted in a final compliance deadline
10 for the variance of October 31, 2024. Since issuance of the regular variance on December 21, 2023,
11 BMI and Petitioner have diligently pursued installation of replacement technology that will bring
12 the facility into compliance with District rules and allow for the decommissioning of the Turbines.
13 Nevertheless, for reasons outside of Petitioner’s control, Pharma has been made aware that certain
14 required upgrades to the Southern California Edison (“SCE”) electrical yard at the Irvine Facility
15 will delay operationalization of replacement technology until January 2025.

16 **FINDINGS OF FACT AND CONCLUSIONS**

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

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

22 Petitioner ~~is will be~~ in violation of District Rule 1134 because Turbines No. 1 and 2 do not
23 meet the Rule 1134 2 ppm NOx limitation that ~~took will be in~~ effect ~~on as of~~ January 1, 2024.
24 Petitioner must continue to operate Turbines No. 1 and 2 because delivery and installation of the
25 replacement technology ~~was ill~~ not ~~be~~ completed in time to meet the January 1, 2024 deadline.

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

1 ~~BMI~~~~Petitioner~~ began a process in late 2018 to identify a feasible alternative for power
2 generation at the Irvine Facility as required to meet the Rule 1134 deadline. ~~Petitioner~~~~BMI~~ signed
3 an Energy Services Agreement (“ESA”) with Bloom Energy (“Bloom”) to replace Turbines No. 1
4 and 2 with two natural gas fuel cell systems (the “Fuel Cells”) to comply with the Rule 1134 2 ppm
5 limit. When signing the contract in December 2022, Bloom agreed to a penalties provision in the
6 ESA in the event the Fuel Cells are not operational within 18 months. However, in the second
7 quarter of 2023, it became evident to ~~Petitioner~~~~BMI~~ that Bloom would not meet the January 1, 2024
8 deadline. The project delay was driven by a number of converging factors including unexpected
9 complications with the City of Irvine permitting process (due to the City changing its position by
10 requiring a City Master Plan modification process before issuing otherwise required permits for the
11 project), longer than expected procurement lead times for electrical switchgears necessary for the
12 project, and unanticipated challenges with various aspects of the project design including gas supply
13 engineering.

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

1 January 31, 2025.

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

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

12
13 **c. The closing or taking would be without a corresponding benefit in reducing air contaminants.**

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

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

1 project as recognized in the original variance.

2
3 **d. The Petitioner for the variance has given consideration to curtailing operations of the**
4 **source in lieu of obtaining a variance.**

5 Curtailing or terminating operations at the Irvine Facility would have serious medical supply
6 chain implications, result in breach of customer contracts, and have severe financial repercussions
7 for PharmaB. Braun. Several of the products Petitioner manufacturers at the Irvine Facility are or
8 have recently been on the FDA drug shortages list. Curtailing operations would have a negative
9 impact on millions of patients across California and the United States.

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

12 The Turbines have a permitted, maximum rated capacity of 6MW. During the variance
13 period, B. BraunPharma ~~has will~~ reduced its reliance on the Turbines to 4.5MW as measured on a
14 weekly average basis. This represents a 25% reduction below the Turbines' maximum rated capacity
15 (and a further 10% reduction below the Petitioner's original estimation of power needed from the
16 Turbines during the variance). This is the maximum reduction PharmaB. Braun can achieve during
17 the variance period without compromising its manufacturing operations and its ability to maintain
18 sufficient catalyst temperature to meet emissions requirements for air contaminants (e.g., carbon
19 monoxide). Petitioner will also continue to operate the Turbines in compliance with all other
20 applicable permit conditions and keep the Turbines in proper working condition.

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

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

26 ORDER

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

28 A. Petitioner is granted a regular variance from District Rule 1134 for Turbine No. 1
(D28) operating pursuant to Permit to Operate No. 432956 and Turbine No. 2 (D35) operating

1 pursuant to Permit to Operate No. 542242, for the period commencing ~~January~~ November 1, 2024
2 and continuing through January 31, 2025~~October 31, 2024~~, the final compliance date.

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

4 1. Petitioner shall maintain records of NOx emissions in pounds per day, and
5 fuel usage records in million cubic feet per day, for each Turbine Device ID D28 and D35 starting
6 01/01/24. These records shall be emailed to Air Quality Inspector Paolo
7 Longoni(plongoni@aqmd.gov) on a quarterly basis, no later than close of business (COB) on the
8 5th day of the month following the end of each quarter.

9 2. Petitioner shall calculate NOx excessive emissions, in pounds per day, for
10 each Turbine Device ID D28 and D35 starting 01/01/24 using the difference between the current
11 NOx limit of 9 ppm (as set by Permit to Operate condition no. A99.1) and the future NOX limit of
12 2 ppm (as set by Rule 1134). These records shall be emailed to Air Quality Inspector Paolo Longoni
13 (plongoni@aqmd.gov) on a quarterly basis, no later than COB on the 5th day of the month following
14 the end of each quarter.

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

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

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

24 6. Petitioner shall report the progress of this project to South Coast AQMD on a
25 quarterly basis, which includes the status of all design, demolition, and construction activities related
26 to the replacement of Turbines Device ID D28 and D35 with two new Fuel Cells. Petitioner shall
27 include, with each quarterly report, a Gantt chart showing the status of the Fuel Cells project. These

1 reports shall be emailed to Air Quality Inspector Paolo Longoni (plongoni@aqmd.gov) and Air
2 Quality Engineer Faye Ganser (fganser@aqmd.gov) no later than COB on the 5th day of the month
3 following the end of each quarter.

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

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

10 a. November 28, 2024: Outage to prepare SCE onsite yard for upgrades.

11 b. December 24, 2024: SCE yard upgrades complete.

12 c. December 30, 2024: Commencement of Fuel Cells operation.

13 d. January 29, 2025: Fuel Cells microgrid transfer complete.

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

17 8.9. Petitioner shall install and begin initial operation of the two new Fuel Cells
18 no later than COB ~~January~~ ~~October~~ 4, 202~~5~~4.

19 9.10. Petitioner shall achieve final compliance no later than COB ~~January~~ ~~October~~
20 31, 202~~5~~4. Petitioner shall notify by email Air Quality Inspector Paolo Longoni
21 (plongoni@aqmd.gov) of the following events as they occur:

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

24 b. Achieving final compliance.

25 ~~10.11.~~ Petitioner shall notify the Clerk of the Hearing Board at
26 clerkofboard@aqmd.gov when final compliance is achieved.

27 ~~11.12.~~ Petitioner shall pay any excess emissions fees to the Clerk of the Board on a

1 quarterly basis no later than COB on the 30th day of the month following the end of each quarter or
2 this variance shall be invalidated pursuant to Rule 303(k). The first payment will be due be due on
3 April 30, 2024.

4 **FOR THE BOARD:** _____

5 **DATE SIGNED:** _____

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