

**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
[Facility ID No. 117290]**

Petition for Modification of a Final
Compliance Date and Extension of a
Variance

Section 42357 of the California Health
and Safety Code

[PROPOSED] FINDINGS AND DECISION OF THE HEARING BOARD

This petition for a modification of a final compliance date and extension of a variance was heard on the consent calendar on **January 30, 2025**, pursuant to notice in accordance with the provisions of California Health and Safety Code Section 40826 and South Coast AQMD Rule 510. The following members of the Hearing Board were present: Micah Ali, Chair; Robert Pearman, Vice-Chair; Mohan Balagopalan; Jerry P. Abraham, MD; and Cynthia Verdugo-Peralta. Petitioner, B. Braun US Pharmaceutical Manufacturing LLC (Pharma) represented by J. Tom Boer, Esq., and Maia H. 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”), represented by

Mary Reichert, Senior Deputy District Counsel, did not appear. The joint Stipulation to Place Matter on Consent Calendar, the Declarations of Peter Klaes, Aniekan Udobot, Tim Hellem, and Maia H. Jorgensen, and the Proposed Findings and Decision were received as evidence, and the case submitted. The public was given the opportunity to testify. The Hearing Board finds and decides as follows:

FINDINGS OF FACT

1. Petitioner is a medical equipment manufacturing company operating the Irvine Facility, which is a modernized, 710,000 sq. ft. pharmaceutical manufacturing facility located in Irvine, California, within the jurisdiction of the South Coast AQMD. In addition to other products, the Irvine Facility is the largest manufacturer of intravenous (“IV”) solution on the West Coast. The Facility ID Number is 117290.

2. On December 19, 2023, petitioner was granted a regular variance from South Coast AQMD Rules 203(b), 1134, 2004(f)(1), and 3002(c)(1) to allow petitioner to operate two non-compliant natural gas cogeneration turbines (the “Cogens” or “Turbines”) within the timeframes set forth in the variance. The variance specified a final compliance date of December 31, 2024. (Reference is made to the Findings and Decision of the Hearing Board dated December 21, 2023.)

3. On October 24, 2024, petitioner was granted an extension to the variance, to allow petitioner to continue operating the Cogens through January 31, 2025. (Reference is made to the Findings and Decision of the Hearing Board dated November 15, 2024.)

4. Petitioner is unable to comply with the initial operation and final compliance deadlines in the variance. Petitioner is also unable to comply with the increments of progress and Gantt chart requirements in Condition Nos. 6 and 8 of the Amended Variance. Petitioner cannot proceed with permanent shut down of the Cogens until the replacement Fuel Cells are fully installed and progress on the Fuel Cells project has been stalled by an unexpected crisis in the U.S. IV solution market.

5. Domestic IV solution manufacturing capacity in the United States was

reduced due to damage from Hurricane Helene to pharmaceutical facilities on the East Coast. In early October, the U.S. Department of Health and Human Services Administration for Strategic Preparedness and Response (“ASPR”) requested that the Irvine Facility maximize its production of IV solution to abate shortages caused by Hurricane Helene and to begin rebuilding stockpiles nationwide. By letter dated December 6, 2024, Ms. Paige Ezernack, Director at ASPR, informed Mr. Wayne Nastri, Executive Officer of the South Coast Air Quality Management District, that ASPR was concerned that even a temporary shutdown of the Irvine Facility “would likely have significant impacts on the U.S. marketplace and further exacerbate an already dire situation.”

6. The inability to complete the Fuel Cells transition is beyond Petitioner’s control. Permanently shutting down the Cogens and replacing them with the Fuel Cells would disrupt the Facility’s ability to maximize production of IV solution. Petitioner is currently assisting with the federal government’s response to a domestic IV solution shortage crisis caused by severe weather events. Any outage would be contrary to the federal government’s request that Petitioner maximize IV solution production at the Irvine Facility through the second quarter of 2025 and, if such an outage occurred, the Facility’s output would be reduced by at least several million units of IV solution.

7. Petitioner has acted diligently to advance the Fuel Cells project during the variance. Physical construction of the Fuel Cells at the Irvine Facility began in the Spring of 2024. As of October 3, 2024, physical on-site construction of the Fuel Cells was materially complete. A portion of the Fuel Cells, servicing parts of the Facility not including the IV solution manufacturing line, is already operational and has offset the amount of power the Facility draws from the Southern California Edison electrical grid to operate.

8. Petitioner explored various options to expedite the timeline for completion of the project and thereby avoid the need for a further extension of the variance. However,

alternatives – other than delaying completion of the Fuel Cells project until the third quarter of 2025 – would be contrary to Petitioner’s commitment to maximize production of IV solution in response to ASPR’s request and would threaten the timely recovery of the domestic IV solution market.

9. Petitioner is acting in the public interest in supporting the recovery of the domestic IV solution market. Doing so comes at an economic cost to Petitioner because the delay in completing the Fuel Cell project required renegotiation of its contract with the installer, Bloom. As a result, Petitioner will incur increased operations costs, for the life of the Fuel Cells, as a result of the project delay caused by the IV solution shortage crisis.

10. Petitioner can reasonably be expected to achieve compliance by September 30, 2025.

11. The estimated excess NOx emissions from the subject equipment during the variance period are expected to be approximately 9.77 pounds per day. This is not a significant amount of emissions when weighed against the significant impacts of a potential shutdown of the Facility.

12. Failure to grant an extension to the variance will cause economic harm to petitioner of approximately \$2 million dollars per day in economic losses. More critically, an interruption to petitioner’s operations during the first two quarters of 2025 would exacerbate the IV solution crisis and delay recovery of the U.S. IV solution market.

CONCLUSION AND ORDER

The Findings of Fact and the Conclusions made by the Hearing Board on December 19, 2023 and October 24, 2024, are incorporated herein by reference. (Reference is made to the Findings and Decision of the Hearing Board dated December 21, 2023 and November 15, 2024, respectively.)

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

A. The variance from South Coast AQMD Rules 203(b), 1134, 2004(f)(1), and

3002(c)(1) granted to petitioner on December 19, 2023 and extended on October 24, 2024 is hereby modified as follows: The variance and final compliance date which extended through January 31, 2025, are extended through September 30, 2025.

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

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

2. Petitioner shall calculate NO_x excessive emissions, in pounds per day, for each Turbine Device ID D28 and D35 starting 01/01/24 using the difference between the current NO_x limit of 9 ppm (as set by Permit to Operate condition no. A99.1) and the future NO_x limit of 2 ppm (as set by Rule 1134). These records shall be emailed to Air Quality Inspector Paolo Longoni (plongoni@aqmd.gov) and Air Quality Engineer Faye Ganser (fganser@aqmd.gov) on a quarterly basis, no later than COB on the 5th day of the month (or first business day following the 5th day, if the 5th day is a holiday or weekend) following the end of each quarter.

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

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

5. Petitioner shall perform a full service per the manufacturer's

specifications of Turbines Device ID D28 and D35 at least once every two calendar quarters.

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

7. Petitioner shall achieve final compliance no later than EOD September 30, 2025. Petitioner shall notify by email Air Quality Inspector Paolo Longoni (plongoni@aqmd.gov) of the following events as they occur:

- a. Switchyard A Fuel Cells becomes operational; and
- b. Petitioner achieves final compliance by permanently shutting down the Turbines.

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

9. Petitioner shall pay any excess emissions fees to the Clerk of the Board on a quarterly basis no later than COB on the 30th day of the month following the end of each quarter or this variance shall be invalidated pursuant to Rule 303(k).

C. Petitioner shall comply with the following schedule of increments of progress as adopted by the Board pursuant to California Health and Safety Code §42358:

1. September 2, 2025: Outage to prepare SCE onsite yard for upgrades complete.
2. September 30, 2025: SCE yard upgrades complete, commencement of

operations of Switchyard A Fuel Cell, and permanent shutdown of
Turbines.

FOR THE BOARD: _____

DATED: _____