HOGAN LOVELLS US LLP
J. Tom Boer (State Bar No. 199563)
tom.boer@hoganlovells.com
Maia H. Jorgensen (State Bar No. 344980)
maia.jorgensen@hoganlovells.com
4 Embarcadero Center, Suite 3500
San Francisco, California 94111
Telephone: (415) 374-2300
Facsimile: (415) 374-2499

Attorneys for Petitioner
B. BRAUN US PHARMACEUTICAL MANUFACTURING LLC.

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

In the Matter of B. BRAUN US PHARMACEUTICAL MANUFACTURING LLC, Petitioner, v. SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT, Respondent.	CASE NO. 4780-5 FACILITY ID NO. 117290 **DECLARATION OF PETER KLAES IN SUPPORT OF B. BRAUN US PHARMACEUTICAL MANUFACTURING LLC'S PETITION FOR MODIFICATION / EXTENSION OF A FINAL COMPLIANCE DATE** **Date:** January 30, 2025 **Time:** 9:30 AM **Location:** 21865 Copley Drive Diamond Bar, CA 91765

I, Peter Klaes, declare:

1. This declaration is made, pursuant to Rule 4 of the SCAQMD Hearing Board Rules and Procedures, in support of B. Braun US Pharmaceutical Manufacturing LLC's ("Pharma" or the "Company") second Petition for Modification of an Existing Variance filed with the South Coast Air Quality Management District ("SCAQMD" or the "District") Hearing Board in Case No. 4870-5 on December 13, 2024.

2. As outlined in my prior declarations in Case No. 4780-5, I am the President of Pharma and the General Manager of the Company's manufacturing facility located at 2525 McGaw Avenue in Irvine, California (the "Irvine Facility" or "Facility"). As stated in my December 7, 2023, declaration, which was filed as Petitioner's Exhibit No. 9, I have been the General Manager of the Irvine Facility since December 2017. In my role as General Manager, I am responsible for and oversee all operations at the Facility. I am also kept apprised of market disruptions and other demands that may impact the Irvine Facility's operations and am responsible for any changes to Facility operations that may be needed to respond to shifts in the market for Pharma's products.

Disruption of the U.S. IV Solution Market by Hurricane Helene

3. In late September, Hurricane Helene struck the mainland United States, causing extensive flooding in western North Carolina. The flooding disrupted operations, and resulted in infrastructure damage, at the Baxter International Inc. ("Baxter") facility located in Marion, North Carolina (the "North Cove Facility"). Until its operations were disrupted by Hurricane Helene, the North Cove Facility was the largest domestic manufacturer of IV solution, producing approximately 1.5 million bags of IV solution per day.

4. Baxter was forced to close its North Cove Facility for repairs due to damage caused by Hurricane Helene. And, although Baxter has restarted the majority of its IV fluid manufacturing lines, as of January 22, 2025, the North Cove Facility still has not announced a full return to normal operations. Temporary closure of the North Cove Facility has had a dramatic impact on domestic IV solution production and availability.

5. The decrease in availability of solutions has caused the health care industry to substantially draw-down fluid stockpiles maintained for use in case of emergency situations (e.g., major storms). The substantial draw-down and lack of stockpiles raises significant risk in the event of a national emergency or if future events further restrict the industry's ability to manufacturer IV solution at existing facilities.

6. Prior to the damage caused by Hurricane Helene, Pharma's Irvine Facility was the largest manufacturer of IV solution on the West Coast. Now, with Baxter's North Cove Facility damaged, Pharma's Irvine Facility is operating as one of the largest suppliers of IV solution nationally.

7. Upon information and belief, the U.S. Department of Health and Human Services Administration for Strategic Preparedness and Response ("ASPR") is the federal agency responsible for leading the nation's medical and public health preparedness for, response to, and recovery from disasters and public health emergencies. Due to the damage caused to IV solution manufacturing capacity by Hurricane Helene, in early October ASPR requested that Pharma maximize production of IV solution units in an effort to abate the daily IV solution shortage and to begin rebuilding stockpiles nationwide. In response to this request, Pharma agreed to increase crewing and to operate all IV solution production lines at the Irvine Facility 24/7.

8. Since October 2024, Pharma, through its affiliate B. Braun Medical Inc. ("BMI"), has been in regular contact with the ASPR to discuss, among other topics, options to increase the supply of domestic IV solution. In the immediate aftermath of Hurricane Helene these meetings took place weekly. They now occur on an *ad hoc* basis, whenever requested by either BMI or ASPR – for example, following the fires in Los Angeles, ASPR contacted BMI to ask whether Pharma needed any assistance maintaining operations. I am a regular participant of these meetings.

9. Pharma has also been in regular communication with the U.S. Federal Drug Administration's Center for Drug Evaluation and Research ("CDER") and Drug Shortage Staff ("DSS") since Hurricane Helene. As with meetings between BMI and ASPR, these meetings began weekly and dropped to *ad hoc* once production at the Irvine Facility was ramped up and stable. The

focus of these meetings has been to identify ways in which the federal government can support Pharma in its efforts to maximize IV solution production.

10. Through Pharma's meetings with ASPR and CDER, the Company notified federal authorities about the Fuel Cells project and the potential need for a shutdown of the Irvine Facility to complete upgrades required by Southern California Edison ("SCE") before January 31, 2025.

11. As discussions with the government continued, I recognized that completion of the Fuel Cells project, underway at the Irvine Facility, would prevent Pharma from meeting ASPR's request to maximize IV solution production. This is because the Switchyard A Fuel Cells, which power the critical utilities and many of the IV solution manufacturing lines, cannot be switched on without a facility-wide shut down, during which no manufacturing could occur. Therefore, after receiving the request from ASPR, I directed the Irvine Facility's Project Management Department to contact SCE to discuss options to modify the electrical work at SCE's onsite yard adjacent to Switchyard A – then scheduled to occur between Thanksgiving and Christmas of 2024 – to limit short-term downtime and off-grid operation at the Irvine Facility. This direction represented a change in Pharma's prior position on performance of the work, i.e., at the time the yard upgrade work was originally planned and scheduled with SCE, Pharma was prepared to proceed with a Facility shutdown and accept the other risks associated with performance of the work. However, after receiving the request from ASPR to maximize production of IV solution to support the domestic supply, the Facility faced a new situation. At that point, Pharma could no longer accommodate the shutdown and increased risk of operational delays without failing in its commitment to ASPR to maximize production.

12. Pharma and SCE staff explored options for several weeks. However, by mid-November, it was clear that Pharma would not be able to identify a workable alternative allowing for the start-up of the Switchyard A Fuel Cells before January 31, 2025 without a Facility shutdown that would disrupt IV solution production. Specifically, all options explored with SCE, which would have allowed the Irvine Facility to comply with the existing final compliance deadline, required the Facility to experience two power outages (one to disconnect from SCE and the other to reconnect) and to operate off-grid for at least four days. During this off-grid period, the Irvine Facility would be required

to operate using a single source of power. This would place the Facility at heightened risk of shutdown; even a short disruption would result in a minimum of 12 to 24 hours of production downtime while the Facility reboots (potentially more, if equipment is damaged during the hard power down). I, and other members of Pharma's leadership, determined that two power outages and the risks associated with operating off-grid during an IV solution crisis were too great. Any outage would be contrary to the request from ASPR to maximize IV solution production at the Irvine Facility and, if such an outage occurred, the Facility's output would be reduced by at least several million units of IV solution.

13. ASPR was aware of the potential shutdown of the Irvine Facility for completion of the Fuel Cells project. As represented in a letter from Ms. Paige Ezernack, a Director at ASPR, to Mr. Wayne Nastri, Executive Officer of the South Coast Air Quality Management District, 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." As a result, ASPR asked that the District support an extension of the variance period, which would preclude a facility-wide shutdown disrupting IV production, until September 2025. A copy of Ms. Ezernack's letter has been filed in connection with Pharma's present petition as Petitioner's Exhibit No. 26.

14. Recognizing the need for the Irvine Facility to maximize production of IV solution in response to ASPR's request, and the lack of alternatives to complete work on Switchyard A without a facility-wide shut down, Pharma made the decision to file the present petition for a further extension of the variance.

Continued Operation of the Cogens is Vital to Market Recovery

15. Based on the information available to me through discussions with my staff, the federal government, and other IV solution market stakeholders, the U.S. IV solution market is projected to recover to normal levels by the end of the second quarter of 2025, assuming no other major disruptions occur in the interim. These projections anticipate uninterrupted, elevated production levels at the Irvine Facility, which are essential to ensuring timely recovery of the domestic IV solution market, including rebuilding national emergency stockpiles. Continued operation of the Cogens is critical to

operation of the Irvine Facility's IV solution production lines and, as such, critical to meeting domestic demand for IV solution and rebuilding domestic stockpiles.

16. If the Hearing Board declines to extend the variance, Pharma would have to proceed with an immediate Facility shutdown as required to implement the SCE yard upgrades for Switchyard A as soon as possible. Given the passage of time, and SCE's disapproval of Pharma's proposed two-phase approach to yard upgrades (see paragraphs 19-21 of the declaration of Aniekan Udobot filed concurrently with this declaration) the SCE yard upgrade work cannot be completed by the current final compliance deadline of January 31, 2025. As a result, the Irvine Facility would require a power outage to disconnect from the utility grid, operate for an extended time with no back-up electrical source while the SCE yard is upgraded, then require another power outage to reconnect to the utility grid during a time where national IV solution stocks need to be restored.

17. As discussed above in Paragraph 12, any shutdown of the IV solution manufacturing lines at the Irvine Facility would be contrary to the request to maximize production made by ASPR and delay the projected schedule for a timely recovery of the domestic IV solution market.

18. In addition, temporarily shutting down the Facility would have a substantial economic impact on Pharma. Specifically, economic harm to the Irvine Facility and Pharma if the variance is not extended would amount to daily economic losses of $2 million for each day the Facility did not operate.

19. However, the driving factor for the requested extension is not the avoidance of economic costs and losses associated with downtime at the Irvine Facility but, rather, meeting the federal government's request to operate at maximum capacity, 24/7, in response to the nationwide IV solution shortage. Pharma is not a public entity, but in this particular instance it is a performing a critical public service by supporting the federal government's response to the IV solution shortage.

20. In fact, continuing to operate the Cogens under a further amended variance will result in additional cost to Pharma. For example, the delay in the start-up of the Switchyard A Fuel Cells has required the Company to renegotiate certain contractual terms with the Fuel Cells contractor, Bloom. As a result, Pharma has agreed to pay a higher price, per-kilowatt-hour, for energy generated

by the Fuel Cells. This will increase Pharma's costs of operating the Fuel Cells by approximately 6 percent, for the life of the Company's current agreement with Bloom.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct. Executed this 22nd day of January, 2025, at Irvine, California.

PETE KLAES
President/General Manager
Pharma