

IN THE SUPERIOR COURT OF NEWTON COUNTY  
STATE OF GEORGIA

RICHARD E. DUNN, DIRECTOR, )  
ENVIRONMENTAL PROTECTION DIVISION, )  
GEORGIA DEPARTMENT OF NATURAL )  
RESOURCES, )

Plaintiff, )

v. )

BECTON, DICKINSON and COMPANY, )

Defendant. )

Civil Action File Number:

**BRIEF IN SUPPORT OF DIRECTOR'S MOTION  
FOR A TEMPORARY RESTRAINING ORDER**

COMES NOW Richard E. Dunn, Director (Director) of the Environmental Protection Division of the Georgia Department of Natural Resources (EPD), Plaintiff in the above-styled matter, and submits the following Brief in Support of the Director's Motion for a Temporary Restraining Order, pursuant to O.C.G.A. § 12-9-12.

**I. INTRODUCTION**

Defendant Becton, Dickinson and Company, (BD) owns and operates a medical device sterilization facility in Covington, Georgia (the Facility).

BD has and continues to engage in unlawful actions under the Georgia Air Quality Act including negligently causing the release of 54.5 pounds of ethylene oxide into

the atmosphere over a recent eight-day period and allowing 555.7 pounds per year of fugitive emissions of ethylene oxide. The Director has applied to this Court for injunctive relief pursuant to O.C.G.A. § 12-9-12. This Court has jurisdiction to grant a temporary restraining to enjoin BD from violating the Act. *Id.*

## II. FACTUAL BACKGROUND<sup>1</sup>

BD is required to operate the Facility in compliance with the Georgia Air Quality Act O.C.G.A. §§ 12-9-1 through 12-9-25 (the Act), the Rules for Air Quality Control promulgated thereunder, Ga. Comp. R. & Regs. 391-3-1.01 through 391-3-1.15 (the Rules), and its EPD-issued Air Quality Permit Number 3841-217-0021-S-04-0 (the Permit). However, BD has operated and continues to operate the Facility in violation of the Permit, the Act, and the Rules.

BD's sterilization process at the Facility involves placing the medical devices in a vented sterilization chamber and introducing ethylene oxide gas to the sterilizer chamber to accomplish sterilization. Once sterilization is complete, a vacuum process pulls ethylene oxide from the sterilization chamber through the sterilizer chamber vent to the emission control device. Finally, the medical devices are aerated following sterilization.

On September 23, 2019, BD discovered that the exhaust valve on the chamber vent that is part of the vacuum process for sterilizer chamber number five was not fully closed as a result of operator error. That valve, while opened vented ethylene oxide into the atmosphere. As a result, BD negligently released 54.5

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<sup>1</sup> The Verified Complaint, filed contemporaneously with the Motion and this Brief, includes relevant exhibits.

pounds of ethylene oxide into the atmosphere from September 15, 2019 to September 23, 2019. That release caused BD to achieve only a 97.3% reduction of ethylene oxide in one of the sterilizer chamber vents at the Facility in violation of Permit Condition 2.3 which requires that, “the ethylene oxide emissions to the atmosphere from each sterilizer chamber vent shall be reduced by at least 99%.” In addition, BD is operating the facility in violation of Permit Condition 3.1 and Ga. Comp. R. & Regs. 391-3-1-.02(2)(a)(1) by willfully or negligently allowing 555.7 pounds per year of fugitive emissions of ethylene oxide.

In 2016, the United States Environmental Protection Agency (EPA) characterized ethylene oxide as a known carcinogen. EPA estimated a possible increased cancer risk from continuously inhaling a specified concentration of ethylene oxide over a lifetime. See <https://www.epa.gov/iris/iris-recent-additions> (last visited October 21, 2019) (containing the Integrated Risk Information System risk assessment characterizing ethylene oxide as carcinogenic to humans by the inhalation route of exposure). Accordingly, the fugitive emissions of ethylene oxide are injurious and unreasonably interfere with the enjoyment of life or use of property in the vicinity of the Facility. BD’s actions also violate O.C.G.A. §12-9-7(a) and Ga. Comp. R. & Regs. 391-3-1-.03(2)(g) which require BD to operate in compliance with the Permit.

### **III. ARGUMENT AND CITATION OF AUTHORITY**

#### **A. Legal Standard For Temporary Restraining Order**

A trial judge has broad discretion to grant injunctive relief. *Verner v. DeKalb Cnty.*, 207 Ga. 436, 436 (1950); *Mitchell v. Dekalb Cnty. Bank*, 139 Ga. Ct. App 562, 563 (1976). The Court's grant of injunctive relief will not be disturbed unless there is a manifest abuse of discretion or no evidence upon which to base the ruling. *Lee v. Envtl. Pest & Termite Control, Inc.*, 271 Ga. 371, 373 (1999). In exercising its discretion, a court should balance conveniences and consider whether more harm might come from refusing than from granting the injunction. *Mitchell*, 139 Ga. Ct. App. at 563 (citing *Maddox v. Willis*, 205 Ga. 596 (1949)). A court also must consider whether granting a preliminary injunction will maintain or disturb the status quo. *See Ga. Dept. of Agric. v. Ga. Crown Distrib. Co.*, 262 Ga. 761, 761 (1993). A court may restrain a defendant from engaging in further illegal acts for the protection of the public. *See, e.g., Jacobs v. Chatham Cnty.*, 295 Ga. App. 74, 76-77 (2008) (affirming injunction prohibiting defendant from future violations of county health ordinances); *Agri-Cycle, LLC v. Couch*, 284 Ga. 90, 92 (2008) (affirming interlocutory injunction granted to enjoin further violations of the Georgia Water Quality Control Act by defendant at its wastewater treatment plant).

Pursuant to O.C.G.A. § 12-9-1 this Court has authority to grant injunctive relief upon a showing by the Director that a person has engaged in or is about to engage in an unlawful action under the Act. Injunctive relief is available even where there is an adequate remedy at law. O.C.G.A. §12-9-12.

Where a request for TRO is concerned, the court should look to preserve the status quo. Here, the status quo favors a ruling in favor of the Director. BD admits that it negligently released 54.5 pounds of ethylene oxide into the atmosphere over the course of eight days. The release violated the Act, the Rules, and the Permit. Additionally the facts and scientific evidence, including EPD's June 7, 2019 Modeling Analysis for Ethylene Oxide Becton Dickinson (formerly C. R. Bard), Covington, Newton County, GA memo demonstrate that BD is not taking all necessary precautions to prevent fugitive emissions of ethylene oxide as required by the Permit and the Rules.

While the Director is charged with protecting the public, he needs the TRO to do so. In the absence of a TRO, the likelihood of harm to public health posed by BD under the facts and circumstances of this case will continue, given BD's negligence and lack of cooperation. It would seem therefore that the way to preserve the public interest in health is to enjoin BD from operating until it can operate lawfully. Because the Director seeks an injunction with the benefit of protecting the public, this factor weighs strongly in favor of granting the TRO. Accordingly, until the Director's claims can be heard on the merits, the Court should temporarily restrain BD from operating the Facility and conducting any sterilization of medical devices at the Facility.

Even if this case is decided under the standard applicable to preliminary injunctions, the Court should issue an order in favor of the Director. The Georgia Supreme Court has identified four factors a trial court should consider in

determining whether preliminary injunctive relief is appropriate: (1) the threat that the moving party will suffer irreparable injury if the injunction is not granted; (2) whether the threatened injury to the moving party outweighs the threatened harm to the party being enjoined; (3) the likelihood that the moving party will prevail on the merits of its claim at trial; and (4) whether granting the injunction will serve the public interest. *SRB Inv. Servs., LLLP v. Branch Banking & Trust Co.*, 289 Ga. 1, 5 (2011).

In balancing the equities between the parties, the Court may consider the plaintiff's likelihood of success on the merits, but the likelihood of ultimate success is not dispositive. *Garden Hills Civic Ass'n v. Metro. Atlanta Rapid Transit Auth.*, 273 Ga. 280, 281 (2000). While injury to the public will occur in this case if the requested injunction is not issued, such injury need not be proven as a prerequisite to a party seeking a preliminary injunction. *Jackson v. Delk*, 257 Ga. 541, 543-44 (1987).

Here, as discussed more fully below, all four factors weigh strongly in favor of granting injunctive relief.

**B. A Temporary Restraining Order Is Appropriate In This Case to Stop Unlawful Activities by BD and to Protect the Public**

**1. The Director is Likely to Succeed on the Merits of the Claim**

In this matter, the Director is likely to succeed on the merits because the law is clear and the factual allegations are supported by scientific evidence and BD's admissions in its Incident Report and in the fugitive emissions data BD provided to EPD. This factor weighs strongly in favor of granting preliminary injunctive relief.

A temporary restraining order is appropriate in this case due to BD's ongoing unlawful activities and the dangers its actions pose to the community in the vicinity of the Facility. The verified complaint establishes BD's negligence in causing a release of ethylene oxide and BD's lack of cooperation with EPD to protect the public by expediting the reduction of fugitive emissions at the Facility. The fugitive emissions of ethylene oxide can be controlled. EPD has engaged in repeated discussion with BD to try to convince BD to take steps to expedite installation of pollution control equipment to capture and control ethylene oxide before it is released to the atmosphere. But, BD has demonstrated an unwillingness to take the steps necessary to accomplish the reductions in a timely manner.

Despite public statements of being cooperative, BD has not been a cooperative partner with EPD. To date, BD has not submitted a permit modification application or any other substantive document to EPD indicating that it has made progress toward reducing ethylene oxide emissions at the Facility. In sum, based upon information that has come to EPD's attention, it appears that BD has taken few, if any, demonstrable steps to reduce emissions of ethylene oxide at the Facility.

The Director is likely to succeed on the merits by demonstrating that BD has violated the Act, the Rules, and the Permit. The violations will continue without the Court's intervention.

## **2. A Temporary Restraining Order Will Serve the Public Interest**

EPD is working diligently to reduce ethylene oxide emissions in Georgia in light of EPA's risk assessment characterizing ethylene oxide as carcinogenic to humans by the inhalation route of exposure over a lifetime. EPD had hoped to work with BD to accomplish reductions at the facility in a timely manner. But BD has not been cooperative and its actions in violating the Act, the Rules, and the Permit have proven contrary to the public interest.

BD's negligent release of 54.5 pounds of ethylene oxide from September 15, 2019 to September 23, 2019 was harmful to the public in the vicinity of the Facility. Likewise, the volume of BD's fugitive emissions of ethylene oxide from the facility – 555.7 pounds per year – is contrary to the public's interest. BD's failure to move quickly to remedy the failures in training and equipment that resulted in the negligent release and its failure to expedite the installation of necessary pollution control equipment to capture fugitive emissions of ethylene oxide at the Facility and route them to a control device with at least 99% efficiency demonstrate that a temporary restraining order is both justified and necessary.

## **3. The Injuries to the Public Outweigh BD's Interest in Continuing Its Unlawful Activity**

The injuries to the public if BD continues to operate unlawfully outweigh BD's interests in opposition to an injunction. The Director's requested injunction would not disrupt the status quo; rather, it would only halt BD's ongoing negligent activity and thereby restore the case to what it would be for the public under lawful operations. The public was adversely impacted by BD's negligent release of 54.5



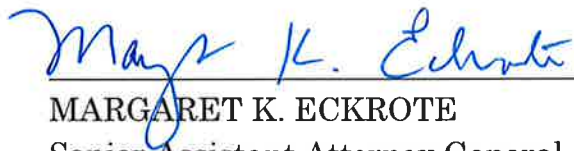
pounds of ethylene oxide in September of 2019. Likewise, the public is adversely impacted by BD's ongoing fugitive emissions of ethylene oxide which are injurious and unreasonably interfere with the enjoyment of life or use of property. The public cannot change the conditions to which it is subjected in the absence of relief from this Court. On the other hand, the impact of a TRO on BD is in BD's hands. BD can mitigate the impact on the public and return to normal operations quickly if it moves expeditiously to take corrective actions to preclude a recurrence of the negligent release of ethylene oxide and if it moves quickly to design, purchase, and install necessary pollution control equipment to capture fugitive emissions of ethylene oxide at the Facility and route them to a control device with at least 99% efficiency.

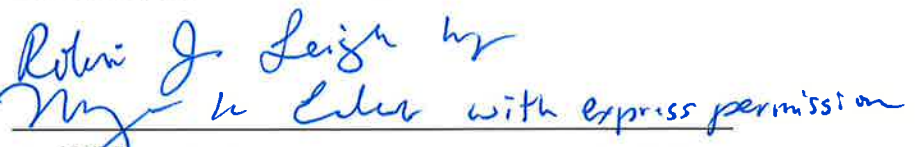
The Director therefore respectfully requests that the Motion for a Temporary Restraining Order be granted.

Respectfully submitted this 21<sup>st</sup> day of October, 2019.

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