

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION**

STERIGENICS U.S., LLC,)	
)	
Plaintiff,)	
v.)	Civil Action
)	No.
)	
COBB COUNTY, GEORGIA;)	
NICHOLAS DAWE, Fire Marshal of)	
Cobb County, Georgia, in his Individual)	
Capacity; and KEVIN GOBBLE,)	
Development and Inspections Division)	
Manager and Chief Building Official of)	
Cobb County, Georgia, in his Individual)	
Capacity,)	
)	
Defendants.)	
_____)	

**COMPLAINT FOR
DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF**

Plaintiff Sterigenics U.S., LLC (“Sterigenics”) files this Complaint against Defendant Cobb County, Georgia (“Cobb County” or the “County”), and Defendants Nicholas Dawe (“Dawe”) and Kevin Gobble (“Gobble”) in their individual capacities for their official acts that are unlawful and unconstitutional, and which are depriving health care providers and patients of essential medical products that are in critical need.

Sterigenics shows the Court as follows:

INTRODUCTION

1. Defendants Dawe and Gobble are unlawfully precluding Sterigenics' longstanding operation of its medical products sterilization facility in Cobb County, Georgia. They have done so by manufacturing a sham claim that Sterigenics needs a new "certificate of occupancy" as a pretext to close the facility for political purposes, in response to activists' unfounded environmental claims the County and its officials have no authority to regulate. They are thereby preventing millions of essential and lifesaving medical products Sterigenics' facility is responsible for sterilizing from reaching healthcare providers who need them for patient care.

2. Gobble's and Dawe's unlawful preclusion of Sterigenics' operations is contributing to a shortage of crucial medical products that health care providers need, and is causing immediate irreparable harm to Sterigenics. Sterigenics therefore files this Complaint to declare unlawful and enjoin their conduct in order for Sterigenics to resume operations and enable essential medical products to reach doctors, nurses and patients who critically need them.

PARTIES, JURISDICTION, AND VENUE

3. Sterigenics, formerly known as Griffith Laboratories and Griffith Micro Science, Inc., is a medical product sterilization company whose facilities are registered with and regulated by the U.S. Food and Drug Administration ("FDA").

4. Sterigenics operates a medical product sterilization facility in Cobb County, Georgia, at a location presently identified by the address 2971 Olympic Industrial Drive, SE, Suite 116, Atlanta, Georgia (the “Facility”).

5. Sterigenics is a Delaware limited liability company whose sole member is Sotera Health LLC. Sotera Health LLC is a Delaware limited liability company whose sole member is Sotera Health Holdings, LLC. Sotera Health Holdings, LLC is a Delaware limited liability company whose sole member is Sotera Health Topco, Inc. Sotera Health Topco, Inc. is a Delaware corporation with its headquarters and principal place of business in Broadview Heights, Ohio. Consequently, Sterigenics is a citizen of Delaware and Ohio for the purposes of diversity jurisdiction under 28 U.S.C. § 1332.

6. Defendant Dawe is the Cobb County Fire Marshal.

7. Defendant Gobble is the Cobb County Development and Inspections Division Manager and Chief Building Official.

8. Defendants Dawe and Gobble are residents of Georgia.

9. Defendants Dawe and Gobble, in their individual capacities, are proper parties to this case because of their official acts that are unauthorized by law, unconstitutional and in violation of Sterigenics’ legal and equitable rights, as set forth in this Complaint. *Lathrop v. Deal*, 301 Ga. 408 (2017).

10. Defendant Cobb County is a corporate body with the power to sue and be sued in any court.

11. Defendant Cobb County is a resident of Georgia for purposes of diversity of citizenship.

12. Defendant Cobb County is a proper party to this action because of its legislative violations of Sterigenics' due process rights in violation of the Fifth and Fourteenth Amendments of the United States Constitution.

13. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332(a) because the parties are citizens of different states and the amount in controversy exceeds \$75,000, exclusive of interest and costs.

14. Defendants' unconstitutional and unlawful actions have caused more than \$75,000 in losses to Sterigenics and will continue to result in such losses greater than \$75,000. These losses include revenue from lost business with existing Sterigenics customers; lost goodwill and reputation with current and potential customers, in turn putting Sterigenics at a substantial risk of losing contracts and business with existing and prospective customers; and the substantial investments Sterigenics has made in the Facility to perform the specific FDA-approved sterilization processes required under its contracts with its customers.

15. The Court also has original and supplemental jurisdiction in this action under 28 U.S.C. §§ 1331 and 1367 because the action presents claims arising under

the Constitution and laws of the United States and state law claims that are so related to those federal claims that they form part of the same case or controversy under Article III of the United States Constitution.

16. There is no available administrative remedy for Sterigenics' claims and injury in this case. Also, Sterigenics would not be required to exhaust such an administrative remedy (which does not exist) because Defendants' actions are causing Sterigenics irreparable harm, administrative action would not resolve the merits of Sterigenics' claims, and no administrative remedy would be adequate. *Panola Land Buyers Ass'n v. Shuman*, 762 F.2d 1550, 1556 (11th Cir. 1985) ("Courts will not require exhaustion when the administrative remedy is inadequate because it does not exist, or would not provide relief commensurate with the claim, or would unreasonably delay the action and thereby create a serious risk of irreparable injury."); *Georgia v. United States*, 398 F. Supp. 3d 1330, 1343 (S.D. Ga. 2019).

17. The Court has personal jurisdiction over Defendants because they are residents of Georgia, and because the events giving rise to the claims in this Complaint occurred in Georgia.

18. Venue is proper in this Court pursuant to 28 U.S.C. § 1391, because Defendants are residents of Georgia and this Judicial District, and the events giving

rise to the claims in this Complaint occurred in Cobb County within this Judicial District.

FACTS

I. The Facility Performs Safe and Essential Sterilizations of Medical Products.

19. The Facility is one of only five FDA-registered medical product sterilization facilities in Georgia.

20. The Facility is responsible for performing essential sterilizations of over one million medical products a day, including medical personal protective equipment, intravenous (IV) tube sets, blood bags, catheters, labor and delivery kits, anesthesia trays, bioprocessing bags, blood transfusion sets, trocar devices, sutures, and general surgery trays, among other critical medical products and devices.

21. Sterigenics uses ethylene oxide (“EO”) in gas form to sterilize products at the Facility.

22. Sterigenics’ use of EO to sterilize medical products is mandated by specifically-defined sterilization processes for each product.

23. In late 2019, the FDA recognized, “there are no readily available processes or facilities that can serve as viable alternatives to those that use ethylene oxide to sterilize these devices. In short: this method is critical to our health care system and to the continued availability of safe, effective and high-quality medical devices.” **Exhibit 1** at p. 3.

24. The FDA has further recognized that “[m]edical devices that are sterilized to remove potentially harmful germs and other microorganisms prior to use are critical to our health care system and a shortage – especially of life-saving, life-sustaining, or other critical devices – can be a detriment to public health.” *Id.*

25. Environmental air quality matters related to Sterigenics’ use of EO at the Facility are regulated by the United States Environmental Protection Agency and the Environmental Protection Division of the Georgia Department of Natural Resources (the “EPD”). O.C.G.A. §§ 12-9-3(12) and 12-9-4.

26. The Facility is also regulated by the Occupational Safety and Health Administration, the U.S. Department of Transportation (the “DOT”), and the United States Department of Homeland Security, among other regulatory bodies.

27. EO at the Facility is stored in double wall all-welded stainless-steel drums in accordance with DOT safety requirements under 49 CFR 173.323.

28. The Facility is equipped with multiple fire safety systems, including but not limited to multiple wet-system fire sprinkler systems, storage of EO drums in a secured isolated outdoor area, protection of EO drums by a foam/water deluge system in accordance with NFPA 55 requirements, an air sampling gas chromatograph EO vapor detection system throughout the Facility, a Lower Explosion Limit (LEL) gas monitoring system, off-site central station monitoring of

the sprinkler systems, local audible fire alarm system, and a mechanical ventilation system.

II. The County Has Approved Sterigenics’ Use, Development and Expansion of the Facility for Decades.

29. The Facility is located in an area that the County’s zoning ordinance has designated as a “Heavy Industrial” district, which the County “established to provide locations for heavy industrial uses such as . . . heavy manufacturing, chemical manufacturing and storage” Sec. 134-231(1), Cobb County Ord.

30. The County first issued a business license to Sterigenics for its medical product sterilization business at the Facility in the early 1970s. **Exhibit 2.**

31. In 1984, the County lawfully issued Sterigenics a certificate of occupancy for its use of the Facility for its EO sterilization operations. That certificate of occupancy certified Sterigenics’ lawful occupancy of the Facility as an “Industrial” occupancy, and certified the Facility’s compliance “with the minimum standards required by the Cobb County Fire Prevention Code and Life Safety Code on the date issued.” **Exhibit 3.**

32. In 1994, the County Planning Commission and the Board of Commissioners unanimously approved and granted Sterigenics a Special Land Use Permit to use the Facility “for the purpose of a Sterilization Facility” and “subject to the Air Quality Permit issued by the State of Georgia, Department of Natural Resources, Environmental Protection Division.” **Exhibits 59** (p. 10) and **60** (p. 12).

33. Throughout the 1990s, the County also lawfully issued building permits for and approved multiple expansions and developments of the Facility. Among those expansions and developments were the construction of an additional sterilization chamber; installation of an EO emissions control system, an acid scrubber system, and recovery tanks; and the additions and development of adjacent office, storage and industrial spaces. *See, e.g., Exhibits 4 – 9.*

34. In connection with each approved expansion, the County inspected the Facility and lawfully issued the certificates of occupancy included in **Exhibits 4 – 9** hereto for expanded areas of the Facility.

35. The County also consistently certified that the Facility complied with applicable County fire and building codes in connection with the approved expansions and developments. **Exhibits 4 – 9.** For example, the County repeatedly certified the following with respect to the Facility:

- a. “to the best of the Fire Department’s knowledge, [the Facility] complies with the minimum standards as required by the Georgia Safety Fire Laws which includes NFPA 101, NFPA 13 and, where applicable, NFPA 13D, NFPA 13R, NFPA 13R Modified and the Standard Fire Code” (**Exhibits 4, 5, 7, 8 and 9**);

- b. “to the best of the County’s knowledge and belief at the time of issuance the structure has been erected in substantial compliance with applicable county codes” (**Exhibits 4 – 9**); and
- c. “to the best of the County’s knowledge [the Facility] complies with the minimum standards required by Georgia Safety Fire Laws as enforced by the Governing Authority and the 101 Life Safety Code and Cobb County Fire Prevention Code on the date issued.” (**Exhibits 4 – 9**).

36. During that time, the County knew Sterigenics used EO for its sterilization operations at the Facility and knew the fire and combustibility information for EO. For example, among the information Sterigenics provided the County in the 1990s was material safety data that included the Hazardous Component Information and Fire and Explosion Data for EO that Sterigenics provided the County Fire Marshal’s office. *See, e.g., Exhibit 9* at p. 15.

37. By the end of the 1990s, the County had lawfully approved Sterigenics’ use, occupancy and development of approximately 47,000 square feet of the Facility for its EO sterilization operations. In good-faith reliance on those approvals, Sterigenics made substantial expenditures for the expansion and development of the Facility.

38. The County thereafter continued to approve, permit and certify Sterigenics' substantial investment in the expansion and development of the Facility during the 2000s.

39. For example, in 2007 the County lawfully issued a valid building permit and certificate of occupancy for Sterigenics' expansion into and development of approximately 25,000 square feet of adjacent warehouse space at the Facility used for the storage and transportation of customer's medical products after sterilization.

Exhibit 10.

40. Indeed, as recently as 2014 and 2015, the County lawfully issued Sterigenics valid building permits for the Facility under its Industrial occupancy to construct preconditioning rooms, an aeration room and two additional, 30-pallet EO sterilization chambers at the Facility. **Exhibits 11 and 12.**

41. In lawfully approving the building permit plans for these construction projects at the Facility, the County Fire Marshal's office and Community Development Department certified that "[e]very effort has been made to ensure that these plans comply with all applicable codes and ordinances." *See, e.g., Exhibit 11* at p. 4.

42. In good-faith reliance on the County's issuance of these building permits, Sterigenics expended substantial money and resources for the construction of these projects.

43. The building permits issued by the County for this 2014 and 2015 construction reflected estimated construction costs of approximately \$1,200,000 and \$1,361,334, respectively, compared to the Facility's tax assessment building values of \$999,452 and \$1,069,492 in 2014 and 2015, respectively. **Exhibits 11 – 13.**

44. After each construction project in 2014 and 2015, the County Fire Marshal's office lawfully issued "Fire Safety Code Release[s]" for the Facility under its Industrial occupancy classification, which certified that the Facility "complies with the State Minimum Fire Safety Standards and Cobb County Codes as adopted and amended by the State of Georgia and Cobb County, Georgia." **Exhibit 11** (p. 12) and **Exhibit 12** (p. 11).

45. The County Fire Marshal and Chief Building Official did not require a new certificate of occupancy for the Facility in connection with any of the construction work at the Facility in 2014 and 2015. **Exhibit 11** (p. 2) and **Exhibit 12** (p. 2).

46. Rather, upon Sterigenics' completion of each construction project in 2014 and 2015, the County lawfully issued Sterigenics a "Letter of Completion," which certified that "to the best of the county's knowledge and belief the structure/tenant space listed above has been erected/renovated in substantial compliance with applicable county codes." **Exhibit 11** (p. 13) and **Exhibit 12** (p.

12). The Letter of Completion for the construction in 2015 was signed and provided by Gobble on August 28, 2019.¹ **Exhibit 12** at p. 12.

47. Before issuing the building permits and Letters of Completion for the 2014 and 2015 construction projects, the County had reports from Sterigenics stating that it had a daily average of 6000 lbs. of EO and a daily maximum of 11,200 lbs. of EO at the Facility. *E.g.*, **Exhibits 14** and **15**.

48. The County Fire Department also toured the Facility in 2011, 2013 and 2015. **Exhibit 16**.

49. In addition, prior to approving the 2015 construction project, the County Fire Marshal's office required Sterigenics to provide a report of a third-party Fire Protection Engineer ("FPE") assessing fire safety matters at the Facility. **Exhibit 17**. In response to that requirement, Sterigenics provided the County Fire Marshal's office an FPE's "Facility Hazard Evaluation Report" from the global engineering firm SSOE Group. **Exhibit 18**.

50. The Facility Hazard Evaluation Report stated the following:

- a. "The facility uses a controlled process of ethylene oxide (EO) fumigation to sterilize medical linens and surgical equipment."

¹ Gobble started with the County in June 2018. *Kevin Gobble Named Cobb Development & Inspections Manager*, Cobb County Courier, available at <https://cobbcountycourier.com/2018/06/kevin-gobble-inspections-manager/>

- b. “Fumigation with EO occurs in specialized fumigation chambers (10 total chambers) using a mixture of nitrogen and EO.”
- c. “EO is received in 400 lb. 1A1 drums and stored in an exterior attached shed at the west/southwest corner of the building.”
- d. Up to 20 drums of ethylene oxide are kept in the exterior storage shed, and up to 40 drums (16,000 lbs.) of ethylene oxide are allowed at the Facility.
- e. “Ethylene oxide is a colorless flammable gas at atmospheric pressure and room temperature (boiling point = 55 degrees F).”

Id. The Facility Hazard Evaluation Report found that “[s]pecialized equipment and safeguards are in-place at this facility to minimize the risk of fire/explosion and exposure to the environment.” *Id.* at 1.

51. Applying the building and fire codes applicable in Cobb County at the time and in 2019, the Facility Hazard Evaluation Report further stated:

This plant facility is well-suited for fumigation/sterilization using ethylene oxide. Efforts have clearly been made to provide equipment, components and procedures to minimize the risk of fire/explosion or environmental exposure to employees and the surrounding community. The facility arrangement, equipment

procedures and training appear to be in compliance with NFPA 55 as referenced by the Georgia State Fire Code Amendments with the exception of the foam-water deluge protection for the EO storage area.

Id. at 4, 6.

52. Sterigenics installed the recommended foam-water deluge system in the Facility's ethylene oxide storage area in early 2016. **Exhibit 19.**

53. The Fire Marshal's office documented its knowledge that the Facility was a "High Hazard" subclassification of an Industrial occupancy in 2015 and 2016 and certified that the Facility "to the best of the Fire Inspector's knowledge, complies with the State Minimum Fire Safety Standards and Cobb County Codes as adopted and amended by the State of Georgia and Cobb County, Georgia." *See* **Exhibit 20** and **Exhibit 12** (p. 11).

III. Defendants Gobble and Dawe Issue a Building Permit for Emissions Control Enhancements at the Facility Pursuant to a Consent Order with the Georgia EPD.

54. On August 7, 2019, Sterigenics entered into a Consent Order with the EPD (the "EPD Consent Order"). **Exhibit 21.**

55. The EPD Consent Order expressly provided, "To the extent the Division can ascertain, [Sterigenics] is currently operating the Facility in compliance

with [its EPD-approved Air Quality Permit] and all applicable Federal and State air regulations.” *Id.* at p. 2.

56. In fact, the Facility’s EO emissions controls in place at that time consistently outperformed regulatory requirements.

57. Despite that compliance, Sterigenics agreed to voluntarily make certain enhancements to its emissions control system at the Facility to further reduce EO emissions (the “EPD System Enhancements”). *Id.* at pp. 2-3.

58. The EPD System Enhancements provide the Facility with the best available technology to further reduce EO emissions beyond their already safe levels. With the EPD System Enhancements, the Facility’s emissions controls system is state-of-the-art among all other sterilization facilities in the United States and will capture more than 99.99% of EO emissions, including indoor fugitive emissions.

59. The EPD Consent Order does not prohibit or limit Sterigenics’ operation of the Facility. Nor does it require Sterigenics to obtain a new Air Quality Permit from the EPD in order to operate its Facility with the EPD System Enhancements. *Id.*

60. On August 12, 2019 Sterigenics, through its contractor Pond Constructors, Inc. (“Pond”), submitted engineering plans and an application for a building permit to the County for approval to install the EPD System Enhancements.

A true and correct copy of the engineering plans Sterigenics submitted to the County for the EPD System Enhancements (the “EPD System Enhancement Plans”) is attached hereto as **Exhibit 22**.

61. After Gobble and the Fire Marshal’s office reviewed and approved the EPD System Enhancement Plans, Gobble, under his authority as the County Development and Inspections Division Manager and Chief Building Official, lawfully issued a valid building permit for Sterigenics to install the EPD System Enhancements on August 15, 2019 (the “2019 Building Permit”). **Exhibit 23**.

62. Gobble and the Fire Marshal’s office approved the 2019 Building Permit for the Facility as an “Industrial-High Hazard” occupancy. *Id.*

63. The 2019 Building Permit issued by Gobble classified the EPD System Enhancements work as another “remodel” at the Facility, and acknowledged the following limited scope of the work involved:

This work involves altering the existing building mechanical systems to improve air exhaust quality being released to atmosphere. Miscellaneous architecture, electrical, and structural modifications will be required to support the mechanical scope.

Id.

64. The County Fire Marshal's office approved the EPD System Enhancement Plans and determined that the work involved constituted a "REMODEL – minor construction" with no change in occupancy level. *Id.* at p. 3. The County Fire Marshal's office also specified that a letter of completion, rather than a certificate of occupancy, was required upon completion of the work. *Id.*

65. The County's official instructions for commercial building permits provide that a certificate of occupancy is required only if the applicant is moving into a new space or is reducing or expanding the amount of space the applicant is occupying in a building. **Exhibit 24.**

66. The EPD System Enhancements did not involve Sterigenics moving into a new space or reducing or expanding the amount of space it occupied in the Facility.

67. The EPD System Enhancements also did not change Sterigenics' longstanding occupancy at the Facility.

68. Relying in good faith on Gobble's lawful issuance of the 2019 Building Permit, Sterigenics commenced installation of the EPD System Enhancements at the Facility at a cost of over \$2 million while continuing to operate at the Facility.

IV. Defendants Claim that Sterigenics Needs a New “Certificate of Occupancy” to Operate as a Pretext to Unlawfully Close the Facility in Response to Pressure from Local Activists.

69. At the time Gobble issued the 2019 Building Permit, a local activist group called “Stop Sterigenics” had been protesting and calling for the Facility’s closure because of its use of EO, based on unfounded environmental claims.

70. At that time, Stop Sterigenics and the Facility were receiving significant attention from the local media and local politicians. *See, e.g., Exhibit 25.* This political and media attention resulted in multiple town hall meetings with Cobb County and Atlanta-area residents in July and August 2019. *See id.; see also, e.g., Exhibit 26; https://www.youtube.com/watch?v=C2tvmfKox_4.* County Commissioners and other local politicians participated in these town hall meetings and addressed the attendees, who confronted the politicians, demanded closure of the Facility for alleged environmental reasons, and blamed Cobb County for allowing the Facility to operate. *See, e.g., https://www.youtube.com/watch?v=C2tvmfKox_4.* Commissioner Bob Ott also was being attacked by activists over environmental claims the activists were making about this Facility. *E.g., Exhibit 27.*

71. On September 6, 2019, Sterigenics publicly announced that the EPD System Enhancements were ahead of schedule and should be completed at the beginning of October. **Exhibit 28.** Sterigenics also announced a voluntary

temporary suspension of the Facility's sterilization operations in order to accelerate completion of the EPD System Enhancements. *Id.*

72. Days later, Pond (Sterigenics' contractor) emailed Gobble and Dawe certain minor changes to the approved EPD Enhancement Plans to further enhance the emission control system at the Facility. **Exhibit 29**. Pond and Sterigenics had discussed these minor changes with Gobble and Dawe at a September 3, 2019 meeting. At that meeting, Dawe and Gobble had told Pond and Sterigenics that these minor changes should be sent to them by email and could be performed as revisions under the 2019 Building Permit.

73. Shortly thereafter, the president of Stop Sterigenics sent an email bearing the subject line, "Serious concerns regarding permits of Sterigenics," to County Commissioners Bob Ott and Lisa Cupid on September 20, 2019. **Exhibit 30** (the "Stop Sterigenics Email"). Commissioners Ott and Cupid had both been active in the July and August town hall meetings, and the media and community events concerning the Facility.

74. The Stop Sterigenics Email stated, "Our group, Stop Sterigenics GA, has serious concerns regarding the current permits for the construction at the Sterigenics facility." *Id.* The Stop Sterigenics email then made the false claim that the Facility only had a 2007 "storage" certificate of occupancy, and asserted that the County Fire Marshal's office and Community Development Department (which

includes Defendant Gobble's Development and Inspections Department) had improperly issued the 2019 Building Permit "knowing that the use of the facility is a high-hazard facility" under the County's current code. *See id.* The email also falsely claimed that a "high hazard facility" under the County's code required an EPD environmental review in order for the County to issue a building permit. *Id.*

75. The president of Stop Sterigenics forwarded the Stop Sterigenics Email to the local press the same day. **Exhibit 31.**

76. Defendants knew that the referenced 2007 "storage" certificate of occupancy was only for the approximately 25,000 square feet of adjacent warehouse space at the Facility used for product storage that Sterigenics began leasing in 2007. *See Exhibit 10.* No EO is used or stored in that warehouse space.

77. Also, Defendants have no authority to regulate any environmental air quality matters related to the Facility. That authority rests solely with and is exercised by the EPD. O.C.G.A. §§ 12-9-3(a)(12), 12-9-4.

78. Nevertheless, upon receiving the Stop Sterigenics Email, Defendants began taking the false position that Sterigenics had changed its occupancy from "Storage" to "Industrial-High Hazard," and stated it had placed a "hold" on the 2019 Building Permit issued six weeks before. *See Exhibit 32, available at https://www.mdjonline.com/news/cobb-investigates-sterigenics-plant-s-change-in-occupancy-status/article_b2b2997c-dbbd-11e9-9e27-37d002bf02ca.html*).

79. Sterigenics' longstanding occupancy clearly had not changed. Under the County's adopted Building Code, a "High Hazard" type of Industrial occupancy exists if as little as 15 lbs. of EO are stored in a building. **Exhibit 33**. With the County's knowing approval, Sterigenics' had occupied the Facility for years using far more than 15 lbs. of EO for its medical product sterilization operations. *E.g.*, **Exhibits 14, 15 and 18**. In fact, the County Fire Marshal's office had previously documented its knowledge of the Facility's "High Hazard" subclassification of an Industrial occupancy in 2015 and 2016 and certified that the Facility was in compliance with the County's fire safety standards and codes. *E.g.*, **Exhibits 20 and 12** (p. 11).

80. The next business day (September 23, 2019), Gobble "locked" the 2019 Building Permit.

81. On September 26, 2019, Commissioner Ott told reporters the County "is basically going to keep [Sterigenics] closed until we are certain they have met all of the County code requirements and the fire marshal requirements." *See* <https://www.youtube.com/watch?v=Ijv9xLSW2Og>. He repeated the demonstrably false claim that Sterigenics' certificate of occupancy "back in 1982" listed the Facility as "storage," and asserted the County was unaware of Sterigenics' purported "storage" occupancy because it "really had not made any renovations that had made them come in front of the County" before the 2019 EPD System Enhancements. *Id.*

82. Commissioner Ott acknowledged that Sterigenics was “totally legal in what they were doing by what Cobb County had issued to them.” *Id.* However, he stated, “We’ll not allow them to restart operations until the county is comfortable that they’ve met all the county code and fire marshal requirements.” **Exhibit 34**, https://www.mdjonline.com/news/comply-or-stay-closed-cobb-forces-safety-upgrades-at-sterigenics/article_8fd52cdc-e075-11e9-be73-c7a164d2bb32.html.

83. Stop Sterigenics’ president “applaud[ed]” the County’s actions and stated that Stop Sterigenics does not believe the Facility “will be able to be modified sufficiently to meet those requirements.” *Id.*

84. Defendants Dawe and Gobble took these new and unfounded positions as an improper pretext for closing the Facility in response to political pressure the County was receiving because of unfounded environmental claims that are not even within their authority to regulate.

85. Sterigenics met with Defendants on October 1, 2019 to address Defendants’ unfounded position on Sterigenics’ occupancy and Gobble’s “lock” of the 2019 Building Permit. At the beginning of that meeting, Defendants handed Sterigenics’ legal counsel a letter (the “October 1 Letter”) making various unfounded claims, including that “Sterigenics currently maintains a Certificate of Occupancy for only ‘Storage.’” **Exhibit 35**. The October 1 Letter asserted, “For this reason, and because of the substantial renovations occurring on the premises,

Sterigenics must acquire a new Certificate of Occupancy to operate.” *Id.* The October 1 Letter also claimed that the County would require and secure a “third-party technical expert” review of the Facility before it would issue the new certificate of occupancy that the County claimed was required for Sterigenics to resume its longstanding sterilization operations at the Facility. *Id.*

86. The County gave a copy of the October 1 Letter to the local press the same day.

87. Gobble subsequently asserted that he had “revoked” the 2019 Building Permit, and Defendants maintained their unlawful and unfounded position that Sterigenics could not operate the Facility unless the County issued it a new certificate of occupancy after a review by the County’s third-party technical expert. **Exhibit 36.**

V. Sterigenics Submits to Defendants’ Third-Party Review in an Effort to Resolve the Dispute.

88. At the October 1 Meeting, Defendants represented to Sterigenics that the County’s third-party technical expert review of the Facility would take about a month to complete.

89. Defendants identified a consulting firm called “Q-Dot Engineering” (“Q-Dot”) in York, Pennsylvania, and, specifically Dr. James Munger, a Certified Fire Protection Specialist at Q-Dot, as their third-party technical expert to conduct the Facility review they demanded.

90. Defendants represented to Sterigenics that they would follow their third-party technical expert's findings and recommendations and allow Sterigenics to resume its operations at the Facility if the expert made that recommendation.

91. Gobble and Dawe's claim that the review and a new certificate of occupancy were required for Sterigenics to reopen the Facility was unfounded and unlawful. There is no legal basis for the Defendants to require this third-party review or a new certificate of occupancy. However, in reliance on Defendants' representations that Gobble and Dawe would follow their expert's recommendations and that the review would take about a month, Sterigenics agreed to submit the Facility to Dr. Munger's review in October 2019 in an effort to quickly resolve this dispute with Defendants and resume operations.

VI. Defendants Reject the Review Findings and Recommendations and Continue to Preclude the Facility's Operation.

92. Sterigenics expeditiously provided Dr. Munger with materials concerning the Facility that he requested and flew him to Atlanta to inspect the Facility when he was first available to do so on November 8, 2019.

93. On December 12, 2019, after delays not caused by Sterigenics, Dr. Munger issued a draft report of his opinions regarding the Facility's compliance with fire and building safety codes and his recommendations allowing the Facility to resume operations immediately before the Christmas holiday. **Exhibit 37.**

94. Despite agreeing to follow Dr. Munger's report and recommendations, Defendants rejected Dr. Munger's report. **Exhibit 38.** Without Sterigenics' knowledge, Gobble and Dawe (through County Assistant Fire Chief Jay Westbrook) also caused Dr. Munger's withdrawal from the review and instructed Patsy Warnick, a certified Fire Safety Engineer at Q-Dot, to write a different report based on instructions they gave her. **Exhibits 39 and 40.**

95. Defendants were trying to obtain a report that would support Gobble and Dawe's unlawful closure of the Facility. In an effort to do this, Dawe (through County Assistant Fire Chief Jay Westbrook) and Gobble instructed Ms. Warnick to ignore the Facility's existing building status and treat the Facility as if its longstanding occupancy had changed to a High Hazard occupancy in order to apply new-building High Hazard occupancy code requirements.

96. At that time, Sterigenics was expecting Q-Dot to distribute another draft report from Dr. Munger early the week of December 23, 2019 before Christmas.

97. However, unbeknownst to Sterigenics, on December 23, 2019 Ms. Warnick—who had not visited the Facility and did not understand its operations—issued a draft report that she—not Dr. Munger—had written. **Exhibits 41.**

98. Shortly after Ms. Warnick issued her report, Dr. Munger emailed Sterigenics' counsel explaining that “[t]he county rejected my report as it was

written,” and Ms. Warnick “rewrote the report after the call with the county officials.” **Exhibit 39.**

99. Ms. Warnick’s report, which was supposed to be a draft of *Dr. Munger’s* report, contained erroneous findings and recommendations based on the Defendants’ improper instructions, her unfamiliarity with the Facility and its operations, and her failure to apply fire code provisions specific to those operations. Those erroneous recommendations required the Facility to operate at less than half of its normal operating capacity and to undergo renovations that would take substantial time before Sterigenics could resume its operations.

100. In an effort to salvage a possible resolution with Defendants for the Facility to reopen, over the course of the next month Sterigenics provided Ms. Warnick the materials concerning the Facility that it had provided Dr. Munger and attempted to educate her on the Facility and its operations for her to issue a revised, accurate report.

101. At a meeting with the County and its counsel on January 24, 2020, Sterigenics also emphasized the need for Ms. Warnick to visit and tour the Facility before issuing a revised report. At Sterigenics’ request, the County therefore asked Ms. Warnick to visit the Facility, which she did on January 31, 2020.

102. On March 23, 2020, almost two months later, and after repeated requests by Sterigenics, Ms. Warnick issued her revised, final report (the “March 23 Report”). **Exhibit 42.**

103. In the March 23 Report, Ms. Warnick confirmed that there had been no change of use or hazard present at the Facility to constitute a change in the Facility’s occupancy. *Id.* at 6. She therefore found that while conversion of the Facility’s multiple existing certificates of occupancy into a “unified Certificate of Occupancy” is “appropriate,” issuing one should be a simple “administrative matter.” *Id.* She also instructed that there was no reason to preclude Sterigenics from resuming its normal sterilization operations at the Facility on that ground. *Id.* at 6-7, 9-10.

104. She further explained:

The authority having jurisdiction is not permitted to retroactively enforce current adopted codes and regulations to existing, approved buildings that are not changing the space, use, or hazard. Imposing current standards on existing buildings creates undue hardships beyond the physical and structural impracticalities of applying current codes to buildings that were constructed decades ago. As seen with Sterigenics, the process can

create severe structural and financial hardships as well as an impact on societal needs.

Id. at 7.

105. She confirmed that the Facility is compliant with applicable code requirements for existing buildings, “has provided multiple safety measures beyond the minimum requirements,” and “has taken adequate measures to mitigate the risk presented by storing and handling EO.” *Id.* at 2, 4, 6, 7, 10.

106. Despite receipt of this report from the County’s third-party technical expert, Gobble and Dawe continue to preclude Sterigenics from resuming its medical product sterilization operations at the Facility.

VII. Closure of the Facility Is Depriving Healthcare Providers and Patients of Essential Medical Products.

107. Gobble’s and Dawe’s unlawful closure of the Facility is depriving healthcare providers and patients of essential medical products.

108. The Facility is responsible for performing essential sterilizations of over one million medical products a day, including medical personal protective equipment, intravenous tube sets, catheters, blood bags, blood transfusion and transfer sets, labor and delivery kits, trocar devices, surgical kits, anesthesia trays, and gastrointestinal endoscopic instruments, among other critical medical products and devices.

109. On October 25, 2019, the FDA issued a “Statement on concerns with medical device availability due to certain sterilization facility closures.” **Exhibit 1.** The FDA warned that “the number of ethylene oxide contract sterilization facilities in the U.S. is limited,” and the Facility’s closure “could affect the availability of some sterile medical devices used by health care delivery organizations and patients.” *Id.* The FDA further warned that patients’ “care could be negatively affected” by the closure of the Facility, and that “a shortage – especially of life-saving, life sustaining, or other critical devices can be a detriment to public health.” *Id.*

110. The FDA “alert[ed] the public to growing concerns about the future availability of sterile medical devices and impending medical device shortages.” *Id.* The FDA explained that “[w]ithout adequate availability of ethylene oxide sterilization, we anticipate a national shortage of these devices and other critical devices” *Id.* The FDA stated that the impact “will be difficult to reverse, and ultimately could result in years of spot or nationwide shortages of critical medical devices, which could compromise patient care.” *Id.*

111. The COVID-19 pandemic has intensified the critical need for medical products waiting to be sterilized at the Facility. There are already over 100,000 confirmed cases of COVID-19 in the United States. Over 2600 individuals in

Georgia already have been diagnosed with COVID-19. **Exhibit 43.** Already almost 700 of those Georgia COVID-19 patients are hospitalized. *Id.*

112. On March 13, 2020, President Donald Trump declared the pandemic a national emergency. **Exhibit 44.** A day later, Georgia Governor Brian Kemp declared the pandemic a state public health emergency. In his declaration, Governor Kemp stated that “[t]he uninterrupted supply of medical goods and other emergency related materials, supplies, goods, and services during this emergency is an essential need of the public and any perceived or actual shortage threatens public welfare[.]” **Exhibit 45.**

113. On March 18, 2020, the President issued an Executive Order pursuant to the Defense Production Act of 1950 (“DPA”), stating in part:

To ensure that our healthcare system is able to surge capacity and capability to respond to the spread of COVID-19, it is critical that all health and medical resources needed to respond to the spread of COVID-19 are properly distributed to the Nation’s healthcare system and others that need them most at this time.

Exhibit 46.

114. Further, the Department of Health and Human Services (“HHS”) has designated medical device sterilization services as a “scarce material” “needed to respond to the spread of COVID-19” under its DPA authority. **Exhibit 47.**

115. However, rather than allow Sterigenics to reopen the Facility to provide essential sterilizations of medical products for patient treatments, Gobble and Dawe continue their lawless closure of the Facility.

116. Even during this pandemic, the County would not intervene to allow the Facility to fully operate. In a March 25, 2020 Order the County Chairman issued under his Declaration of Emergency, the County would not override Gobble and Dawe’s unlawful closure of the Facility except to authorize the Facility to reopen temporarily for 21 days (through April 15, 2019, the termination of his Declaration of Emergency) and only for the sterilization of “Personal Protective Equipment (“PPE”).” **Exhibit 48.**

117. PPE, however, is not the only concern or category of medical products that is in tremendous need. *See, e.g., Health Chief: Georgia Seeking Out Medical Equipment Amid Shortages*, Atlanta Journal Constitution, **Exhibit 49**, available at <https://www.ajc.com/news/state--regional-govt--politics/health-chief-georgia-seeking-out-medical-equipment-amid-shortages/Q1HibGi68cXFJEbmEUd69O/>; *see also* **Exhibit 50**, March 21, 2020 letter to White House from AHA, AMA, and ANA.

118. Indeed, in response to Chairman Boyce's March 25 Order, the Secretary of HHS stated, "PPE was only about 20% of what was being sterilized at Sterigenics, and other items like catheters, syringes, IV sets and ventilator components like tubes, filters, and masks are critical to helping patients." **Exhibits 51 and 61.**

119. The United States Center for Disease Control ("CDC") has reported, "In the coming months, most of the U.S. Population will be exposed to this virus. Widespread transmission of COVID could translate into large numbers of people needing medical care at the same time Public health and healthcare systems may become overloaded, with elevated rates of hospitalizations and deaths." CDC, Coronavirus Disease 2019, Situation Summary, **Exhibit 52**, available at https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/summary.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fsummary.html.

120. The CDC reports that 20-30% of hospitalized patients with COVID-19 and pneumonia have required intensive care. *Interim Clinical Guidance for Management of Patients with Confirmed Coronavirus Disease (COVID-19)*, CDC, **Exhibit 53**, available at <https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html>. Also, COVID-19 complications requiring intensive medical care go beyond respiratory illnesses such as pneumonia and

include “cardiac injury, arrhythmia, septic shock, liver disfunction, acute kidneys injury, and multi-organ failure.” *E.g., id.; see also, e.g., Exhibit 54.* All of these complications require treatment.

121. IV tubing sets and catheters are among the essential medical products for providing intensive medical care. These devices are essential to providing patients with COVID-19 and other serious illnesses and conditions the controlled intravenous infusion of medications and fluids they need for treatment and recovery. The American Society of Health-System Pharmacists has warned that “tubing for administration of intravenous drugs ha[s] been affected by shortages [related to COVID-19].” ASHP, *Pharmacy Readiness for Coronavirus Disease 2019 (COVID-19): Recommendations for Federal Policymakers*, March 2020. **Exhibit 55.**

122. Moreover, numerous other medical products are facing supply shortages because of a lack of EO sterilization capacity in our healthcare system. As the FDA has stated, “the number of ethylene oxide contract sterilization facilities in the U.S. is limited.” **Exhibit 1.** In October, months before the COVID-19 outbreak, the FDA reported that “More than 20 billion devices sold in the U.S. every year” require EO sterilizations and are facing shortages:

These include surgical kits used in emergency procedures such as emergency Caesarean section (“C-Sections”) and in routine procedures such as cardiac surgery and hip or

knee replacement surgeries. Without adequate availability of ethylene oxide sterilization, we anticipate a national shortage of these and other critical devices including feed tube devices used in neonatal intensive care units, drug eluting cardiac stents, catheters, shunts and other implantable devices.

Exhibit 1.

123. Yet, the Facility remains closed for sterilizations of these and other essential products (including medical PPE beyond April 15) because of Gobble's and Dawe's unlawful actions. They are thereby preventing millions of essential and lifesaving medical products that would be sterilized at the Facility from reaching healthcare providers for use in patient care.

124. And the true reason for Gobble's and Dawe's actions has never been their baseless "certificate of occupancy" claim. That has always been a lawless pretext to close the Facility because of the unfounded political pressure the County is receiving from local activists regarding unfounded environmental claims related to the use of EO at the Facility.

125. Indeed, County Commissioner Lisa Cupid recently confirmed that the County's effort to keep the Facility closed has no relation to the Facility's certificate of occupancy. She has stated that the Facility should remain closed, even during the

COVID-19 crisis, unless she hears experts say that all public health concerns surrounding ethylene oxide have been eliminated. *Sterigenics CEO: Cobb Facility Should Reopen, Could Help in Coronavirus Fight*, Marietta Daily Journal, **Exhibit 56**, available at https://www.mdjonline.com/news/sterigenics-ceo-cobb-facility-should-reopen-could-help-in-coronavirus/article_ac5fe9a8-6853-11ea-a6ef-9b56ff1da342.html.

126. County Chairman Boyce also made clear that Gobble's and Dawe's preclusion of the Facility's operations is not related to the Facility's certificate of occupancy. Rather, it is based on unfounded environmental claims the County has no authority to regulate: "The only way we will issue the permit is when we believe they will meet the state standards' for ethylene oxide emissions." *Sterigenics: Cobb's order allowing it to reopen fails to protect public health*, Atlanta Journal Constitution, **Exhibit 57**, available at <https://www.ajc.com/news/local-govt--politics/sterigenics-cobb-order-allowing-reopen-fails-protect-public/nDo6AxiUvaZoeAu5Std7ZN/>.

127. Moreover, as the EPD has recognized, even before Sterigenics installed the EPD System Enhancements, it was "currently operating the Facility in compliance with the Permit and all applicable Federal and State air regulations." **Exhibit 21.**

128. The unlawful actions of Gobble and Dawe are precluding the Facility's sterilization of essential products doctors and nurses need to treat patients. They are also violating Sterigenics' vested legal right to use the Facility on unconstitutional grounds. And they are immediately and irreparably harming Sterigenics financially; irreparably damaging Sterigenics' goodwill, reputation and business relationships with current and potential customers; and putting Sterigenics at a substantial risk of irreparably losing the considerable investments it has made in the Facility (with the County's approvals) to perform the specific sterilization processes required under its contracts with its customers.

129. Dawe's and Gobble's baseless actions to close the Facility should be declared unlawful and enjoined.

**COUNT I – Declaratory Judgment: Vested Rights
(Against Defendants Gobble and Dawe)**

130. Sterigenics re-alleges and incorporates paragraphs 1 through 129 of this Complaint.

131. The County lawfully approved Sterigenics' occupancy, use and development of the Facility for decades, through the lawful issuance of certificates of occupancy, building permits and other approvals discussed above in this Complaint.

132. Sterigenics relied on those County certifications, permits and approvals in good faith to make substantial expenditures for the use, expansion and

development of the Facility during the decades it has occupied the Facility for its medical product sterilization operations, and to incur substantial obligations through contracts with its customers for sterilizations of their medical products at the Facility, pursuant to FDA-approved processes required by Sterigenics' customers.

133. In addition, Gobble lawfully issued the 2019 Building Permit to Sterigenics for the EPD System Enhancements at the Facility under his authority as the County Development and Inspections Division Manager and Chief Building Official.

134. Dawe also approved the 2019 Building Permit and EPD System Enhancements under his authority to act as the County Fire Marshal.

135. In good-faith reliance on the 2019 Building Permit, Sterigenics voluntarily installed the EPD System Enhancements at the Facility in accordance with the EPD Consent Order in connection with its continued use of the Facility, at a cost of more than \$2 million.

136. Based on each of the County certifications, permits and approvals for Sterigenics' continued use, expansion and development of the Facility for its medical product sterilization operations, and Sterigenics' reliance thereon in good faith to make substantial expenditures at the Facility and incur extensive obligations, Sterigenics has a vested right to continue its longstanding use of the Facility for providing EO sterilizations of medical products.

137. Gobble and Dawe's official actions to preclude Sterigenics' longstanding use of the Facility for providing EO sterilizations of medical products are arbitrary and capricious.

138. Sterigenics' longstanding occupancy at the Facility has not changed.

139. Gobble and Dawe have unlawfully divested Sterigenics' vested right by precluding Sterigenics' longstanding operations at the Facility based on their unfounded claim that Sterigenics must obtain a new certificate of occupancy to resume those operations at the Facility.

140. An actual and substantial continuing controversy exists between Sterigenics and Gobble and Dawe who have adverse legal interests concerning Sterigenics' vested right to continue its longstanding use of the Facility for providing EO sterilizations of medical products.

141. Because of the unlawful actions of Gobble and Dawe as alleged herein, Sterigenics has suffered injuries, and there is a substantial likelihood that Sterigenics will continue to suffer injuries in the future if Gobble and Dawe continue their unlawful actions to preclude Sterigenics' use and operation of the Facility.

142. Pursuant to the Uniform Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and Federal Rule of Civil Procedure 57, Sterigenics is entitled to a judgment declaring that Sterigenics has a vested right to continue its longstanding EO sterilization operations at the Facility, and that Sterigenics' vested right prohibits

Gobble and Dawe from precluding those operations based on their claim that Sterigenics must obtain a new certificate of occupancy to operate the Facility.

**COUNT II – Declaratory Judgment: Estoppel
(Against Defendants Gobble and Dawe)**

143. Sterigenics re-alleges and incorporates paragraphs 1 through 142 of this Complaint.

144. The County lawfully approved Sterigenics' occupancy, use and development of the Facility over the course of Sterigenics' occupancy of the Facility for decades, through the lawful issuance of certificates of occupancy, building permits and other approvals discussed above in this Complaint.

145. Sterigenics relied on those County certifications, permits and approvals in good faith to make substantial expenditures for the use, expansion and development of the Facility during the decades it has occupied the Facility for medical product sterilization operations, and to incur substantial obligations through contracts with its customers for sterilizations of their medical products at the Facility, pursuant to FDA-approved processes required by Sterigenics' customers.

146. In addition, Gobble lawfully issued the 2019 Building Permit to Sterigenics for the EPD System Enhancements at the Facility under his authority as the County Development and Inspections Division Manager and Chief Building Official.

147. Dawe also approved the 2019 Building Permit and EPD System Enhancements under his authority to act as the County Fire Marshal.

148. In good-faith reliance on the 2019 Building Permit, Sterigenics voluntarily installed the EPD System Enhancements at the Facility in accordance with the EPD Consent Order in connection with its continued use of the Facility, at a cost of more than \$2 million.

149. Because of Defendants' prior approvals and certifications of Sterigenics' longstanding occupancy and development of the Facility for its EO sterilization operations as discussed herein, and Sterigenics' good-faith reliance thereon to make substantial investments in the Facility during the decades it has occupied the Facility, Gobble and Dawe are estopped from claiming that Sterigenics must obtain a new certificate of occupancy to continue its longstanding operations at the Facility.

150. An actual and substantial continuing controversy exists between Sterigenics and Gobble and Dawe who have adverse legal interests concerning whether Gobble and Dawe are estopped from claiming that Sterigenics must obtain a new certificate of occupancy to continue its longstanding use of the Facility for providing EO sterilizations of medical products.

151. Because of the actions of Gobble and Dawe as alleged herein, Sterigenics has suffered injuries, and there is a substantial likelihood that Sterigenics

will continue to suffer injuries in the future if Gobble and Dawe continue their unlawful actions to obstruct Sterigenics' use and operation of the Facility.

152. Pursuant to the Uniform Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and Federal Rule of Civil Procedure 57, Sterigenics is entitled to a judgment declaring that Gobble and Dawe are estopped from claiming that Sterigenics must obtain a new certificate of occupancy to continue its longstanding use of the Facility for providing EO sterilizations of medical products.

**COUNT III – Declaratory Judgment:
Dawe and Gobble Have No Authority to Require a New Certificate of
Occupancy Under the Cobb County Ordinance
(Against Defendants Gobble and Dawe)**

153. Sterigenics re-alleges and reincorporates paragraphs 1 through 152 of this Complaint.

154. In addition, and in the alternative, Gobble and Dawe have no legal authority to require Sterigenics to obtain a new certificate of occupancy under the County's Ordinance.

**a) Dawe Has No Legal Authority Under the County's
Ordinance to Require a New Certificate of Occupancy.**

155. Defendant Dawe's only authority to require a certificate of occupancy for any building is governed by Sec. 54-51(c) of the Cobb County Ordinance.

156. Section 54-51(c) of the Cobb County Ordinance provides that "certificates of occupancy shall run for the life of the building structure or tenant

space, except where there is a change in the classification of occupancy, substantial renovation, reconstruction due to fire or other hazard of serious consequence, renovation or addition.” Sec. 54-51(c), Cobb County Ord.

157. Section 54-51(i) vaguely “defines” the term “substantial renovation” as follows:

any construction project involving exits or internal features of such building, or any structure costing more than the building’s or structure’s assessed value according to county tax records at the time of such renovation. Sec. 54-51(c), Cobb Cty. Ord.

158. The County issued Sterigenics an Industrial certificate of occupancy for the Facility in 1984 and thereafter issued Sterigenics additional certificates of occupancy for expanded areas of the Facility.

159. Sterigenics did not change its occupancy at the Facility by installing the EPD System Enhancements pursuant to the EPD Consent Order. Sterigenics’ occupancy remains the same as it has been throughout its longstanding occupancy of the Facility.

160. The EPD System Enhancements also were not a reconstruction of the Facility due to fire or other hazard of serious consequence, renovation or addition under Section 54-51(c) of the Cobb County Ordinance.

161. The EPD System Enhancements also were not a “substantial renovation” of the Facility under Section 54-51(c) of the Cobb County Ordinance.

162. Moreover, the definition of “substantial renovation” in Section 54-51(i) of the Cobb County Ordinance is unconstitutionally vague, because it fails to provide people of ordinary intelligence a reasonable opportunity to understand the type of work which constitutes a “substantial renovation” requiring a new certificate of occupancy, and because it authorizes and encourages arbitrary and discriminatory enforcement of Section 54-51(c).

163. The requirement that a building occupant obtain a new certificate of occupancy if there is a “substantial renovation” under Section 54-51(c) of the Cobb County Ordinance also is unconstitutionally arbitrary and capricious.

164. Section 54-51(c)’s requirement that a new certificate of occupancy is required if there has been a “substantial renovation” is therefore void under the due process requirements of the Fifth and Fourteenth Amendments of the United States Constitution.

165. In addition, Georgia law requires such an ordinance which restricts Sterigenics’ right to freely use its property for a lawful purpose to be strictly construed in favor of Sterigenics, and any ambiguity therein must be resolved in favor of Sterigenics’ free use of the Facility. *E.g., Fayette County v. Seagraves*, 245 Ga. 196 (1980).

166. Pursuant to that Georgia law, Section 54-51(c) and (i)'s vague and ambiguous provisions for requiring a new certificate of occupancy if there has been a "substantial renovation" cannot be construed to require Sterigenics to obtain a new certificate of occupancy in order to continue its longstanding operations at the Facility. For this additional reason, Dawe had no legal authority under Sections 54-51(c) and (i) to require Sterigenics to obtain a new certificate of occupancy in order to continue its longstanding operations at the Facility.

167. An actual and substantial continuing controversy exists between Sterigenics and Gobble and Dawe who have adverse legal interests concerning Dawe's legal authority to require Sterigenics to obtain a new certificate of occupancy to continue its longstanding operations at the Facility.

168. Because of the unlawful actions of Dawe to preclude Sterigenics' longstanding operation of the Facility, Sterigenics has suffered injuries, and there is a substantial likelihood that Sterigenics will continue to suffer injuries in the future if Dawe continues his unlawful actions to preclude Sterigenics' use and operation of the Facility.

169. Pursuant to the Uniform Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and Federal Rule of Civil Procedure 57, Sterigenics is entitled to a judgment declaring that Dawe has no legal authority to require that Sterigenics

obtain a new certificate of occupancy in order to continue its longstanding operations at the Facility.

b) Gobble Has No Legal Authority Under the County's Ordinance to Require a New Certificate of Occupancy.

170. Gobble also has no authority to require a new certificate of occupancy for a tenant or landowner's use of a building under the County's Ordinance unless there has been a change of occupancy at the building.

171. Sterigenics has not changed its longstanding occupancy at the Facility.

172. Gobble therefore has no authority to require Sterigenics to obtain a new certificate of occupancy in order to continue its longstanding operations at the Facility.

173. An actual and substantial continuing controversy exists between Sterigenics and Gobble and Dawe who have adverse legal interests concerning Gobble's legal authority to require Sterigenics to obtain a new certificate of occupancy to continue its longstanding operations at the Facility.

174. Because of the unlawful actions of Gobble and Dawe to preclude Sterigenics' longstanding operation of the Facility, Sterigenics has suffered injuries, and there is a substantial likelihood that Sterigenics will continue to suffer injuries in the future if Gobble continues his unlawful actions to preclude Sterigenics' use and operation of the Facility.

175. Pursuant to the Uniform Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and Federal Rule of Civil Procedure 57, Sterigenics is entitled to a judgment declaring that Gobble has no authority to require Sterigenics to obtain a new certificate of occupancy from the County in order to operate its Facility for this additional and alternative reason.

**COUNT IV – Declaratory Judgment:
Legislative Violation of the United States Constitution
(Against Defendant Cobb County)**

176. Sterigenics re-alleges and reincorporates paragraphs 1 through 175 of this Complaint.

177. Section 54-51(c) of the Cobb County Ordinance provides that “certificates of occupancy shall run for the life of the building structure or tenant space, except where there is a change in the classification of occupancy, substantial renovation, reconstruction due to fire or other hazard of serious consequence, renovation or addition.” Sec. 54-51(c), Cobb County Ord.

178. The definition of “substantial renovation” in Section 54-51(i) of the Cobb County Ordinance is unconstitutionally vague, because it fails to provide people of ordinary intelligence a reasonable opportunity to understand the type of work which constitutes a “substantial renovation” requiring a new certificate of occupancy, and because it authorizes and encourages arbitrary and discriminatory enforcement of Section 54-51(c).

179. The requirement that a building occupant obtain a new certificate of occupancy if there is a “substantial renovation” under Section 54-51(c) of the Cobb County Ordinance also is unconstitutionally arbitrary and capricious.

180. Section 54-51(c)’s requirement that a new certificate of occupancy is required if there has been a “substantial renovation” is therefore void and in violation of Sterigenics’ rights under the due process requirements of the Fifth and Fourteenth Amendments of the United States Constitution.

181. An actual and substantial continuing controversy exists between Sterigenics and Defendants who have adverse legal interests concerning the unconstitutionality of Section 54-51(c)’s requirement of a new certificate of occupancy if there has been a “substantial renovation.”

182. Because of the unconstitutionality of Sections 54-51 (c) and (i) of the County’s Ordinance, Sterigenics has suffered injuries, and there is a substantial likelihood that Sterigenics will continue to suffer injuries in the future if Section 54-51(c)’s requirement of a new certificate of occupancy if there has been a “substantial renovation” is not declared unconstitutional and void.

183. Pursuant to the Uniform Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and Federal Rule of Civil Procedure 57, Sterigenics is entitled to a

judgment declaring Section 54-51(c)'s requirement for a new certificate of occupancy if there has been a "substantial renovation" is unconstitutional and void.

**COUNT V – Temporary Restraining Order and Preliminary Injunction
(Against Defendants Gobble and Dawe)**

184. Sterigenics re-alleges and reincorporates paragraphs 1 through 183 of this Complaint.

185. The unlawful conduct of Gobble and Dawe to preclude Sterigenics' longstanding operations at the Facility should be temporarily restrained and preliminarily enjoined pending the final adjudication of Sterigenics' right to permanent declaratory relief in Counts I-IV of this Complaint.

186. Sterigenics is substantially likely to succeed on the merits of its claims in Counts I-IV of this Complaint.

187. The public interest overwhelmingly necessitates granting the temporary restraining order and preliminary injunction. The Facility would be sterilizing more than a million essential and life-saving medical products each day if Sterigenics were able to resume its operations. Such products cannot be used, and safe and vital medical care is at risk of not occurring, if the products are not sterilized in accordance with FDA requirements. Such products are in critical need, particularly during the coronavirus pandemic affecting our country. The public interest could not weigh more heavily in favor of granting a temporary restraining order and preliminary injunction.

188. Indeed, the FDA warned months before the pandemic that patients’ “care could be negatively affected” by the closure of the Facility, and that “a shortage – especially of life-saving, life sustaining, or other critical devices can be a detriment to public health.” **Exhibit 1.** The FDA “alert[ed] the public to growing concerns about the future availability of sterile medical devices and impending medical device shortages.” *Id.* The FDA explained that “[w]ithout adequate availability of ethylene oxide sterilization, we anticipate a national shortage of these devices and other critical devices including feeding tube devices used in neonatal intensive care units, drug-eluting cardiac stents, catheters, shunts, and other implantable devices.” *Id.* The FDA stated that the impact resulting from the temporary closure of the Facility along with other sterilization facilities “will be difficult to reverse, and ultimately could result in years of spot or nationwide shortages of critical medical devices, which could compromise patient care.” *Id.*

189. The COVID-19 pandemic has only escalated the critical need for medical products waiting to be sterilized at the Facility.

190. Granting emergency and preliminary injunctive relief to allow Sterigenics’ Facility to resume its operations and serve these critical needs is undeniably in the public’s interest.

191. Conversely, there is no harm to Gobble and Dawe by enjoining their unlawful conduct pending the adjudication of the declaratory judgment claims in

Counts I-IV of this Complaint. Indeed, none of the reports from Dr. Munger or Ms. Warnick found any fire or life safety problem at the Facility. And any alleged harm to them (there is none) is substantially outweighed by the risk of harm to Sterigenics, its customers, health care providers and patients their actions are causing.

192. Gobble's and Dawe's unlawful preclusion of the Facility's operations also is irreparably harming Sterigenics and its customers.

193. Gobble's and Dawe's closure of the Facility is preventing crucial medical products manufactured by Sterigenics' customers from getting to market for use by health care providers. The customers' inability to supply health care providers with their products is causing the customers to lose substantial revenue necessary to support their businesses. *E.g.*, **Exhibit 58**. It also puts Sterigenics' customers at a substantial risk of losing healthcare providers as customers.

194. Also, Sterigenics has substantial contracts with medical product manufacturers to provide sterilizations of their products at the Facility according to very specific sterilization processes to meet FDA requirements.

195. Sterigenics has made substantial investments in the Facility in order to provide those approved sterilization processes at the Facility under those contracts.

196. Sterigenics has a reputation as a reliable, safe, and innovative sterilization company. That reputation has been built up over decades of superior performance in the field.

197. Gobble's and Dawe's unlawful acts to preclude Sterigenics' longstanding operation of the Facility are causing and will continue to cause immediate and substantial irreparable losses to Sterigenics' operations, including lost revenue from unfilled contracts and lost business with existing customers; lost goodwill and reputation with current and potential customers, which is putting Sterigenics at a substantial risk of losing contracts and future business with existing and prospective customers; and the loss of its substantial investments in the Facility to perform the specific sterilization processes required to meet FDA standards under contracts with customers.

198. That harm to Sterigenics is immediate and irreparable, as Sterigenics has no legal recourse against Defendants to recover for that harm.

199. For these reasons, the Court should grant a temporary restraining order and a preliminary injunction pursuant to Federal Rule of Civil Procedure 65(a) to enjoin the unlawful actions of Gobble and Dawe precluding Sterigenics' longstanding use of the Facility pending the final adjudication of Sterigenics' right to permanent declaratory relief in Counts I-IV of this Complaint.

PRAYER FOR RELIEF

WHEREFORE, Sterigenics respectfully requests the following:

- a. That process issue according to law;

b. That the Court declare that Sterigenics has a vested right to use the Facility for its EO sterilization operations, and that Gobble and Dawe are precluded from obstructing Sterigenics' use of its Facility based on their claim that Sterigenics cannot continue its operations at the Facility without a new certificate of occupancy;

c. That the Court declare that Gobble and Dawe are estopped from claiming that Sterigenics cannot continue its operations at the Facility without a new certificate of occupancy;

d. That the Court declare that Gobble and Dawe have no authority under the Cobb County Ordinance to require that Sterigenics obtain a new certificate of occupancy in order to continue its operations at the Facility;

e. That the Court declare Cobb County Ordinance Section 54-51(c)'s provision that a new certificate of occupancy is required if there has been a "substantial renovation" unconstitutional and void under the Fifth and Fourteenth Amendments of the United States Constitution;

f. That the Court enter a temporary restraining order and a preliminary injunction enjoining the unlawful actions of Gobble and Dawe precluding Sterigenics' longstanding use of the Facility pending the final adjudication of Sterigenics' right to permanent declaratory relief in Counts I-IV of this Complaint;

g. That the Court award Sterigenics its attorneys' fees and costs incurred in this case; and

h. Any other relief this Court should deem just and appropriate.

Respectfully submitted this 30th day of March, 2020.

ALSTON & BIRD LLP
1201 West Peachtree Street
Atlanta, GA 30309
Telephone: (404) 881-7000
Facsimile: (404) 881-7777

/s/ W. Clay Massey
W. Clay Massey
Georgia Bar No. 476133
Daniel F. Diffley
Georgia Bar No. 221703
Kathryn C. Klorfein
Georgia Bar No. 236173
Thomas P. Grantham
Georgia Bar No. 116523

*Attorneys for Plaintiff Sterigenics U.S.,
LLC*