

RENDERED: FEBRUARY 9, 2024; 10:00 A.M.  
NOT TO BE PUBLISHED

**Commonwealth of Kentucky**  
**Court of Appeals**

NO. 2023-CA-0093-MR

RUSSELL M. COLEMAN,  
ATTORNEY GENERAL, ON BEHALF  
OF THE COMMONWEALTH OF  
KENTUCKY

APPELLANT

v. APPEAL FROM FRANKLIN CIRCUIT COURT  
HONORABLE PHILLIP J. SHEPHERD, JUDGE  
ACTION NO. 22-CI-00560

CORNEAGEN, INC.; ADAM  
MATHER, INSPECTOR GENERAL,  
OFFICE OF THE INSPECTOR  
GENERAL, IN HIS OFFICIAL  
CAPACITY; AURION BIOTECH,  
INC.; EDWARD HOLLAND, M.D.;  
ERIC FRIEDLANDER, SECRETARY,  
CABINET FOR HEALTH AND  
FAMILY SERVICES, IN HIS  
OFFICIAL CAPACITY; AND  
KENTUCKY CABINET FOR  
HEALTH AND FAMILY SERVICES,  
OFFICE OF THE INSPECTOR  
GENERAL

APPELLEES

OPINION  
AFFIRMING

\*\* \*\* \* \*\* \* \*\* \*

BEFORE: THOMPSON, CHIEF JUDGE; ECKERLE AND TAYLOR, JUDGES.

TAYLOR, JUDGE: Daniel Cameron, Attorney General on behalf of the Commonwealth of Kentucky, (Attorney General) brings this appeal from a December 28, 2022, Opinion and Order of the Franklin Circuit Court granting summary judgment that declared Kentucky Revised Statutes (KRS) 311.1939 unconstitutional as violative of Kentucky Constitution Sections 2, 3, 59, and 60.<sup>1</sup> We affirm.

The sole issue presented in this appeal is the constitutionality of KRS 311.1939. On July 15, 2022, CorneaGen, Inc., Aurion Biotech, Inc., and Edward Holland, M.D. (collectively referred to as plaintiffs) filed a Verified Complaint for Preliminary and Permanent Injunctive Relief and for Declaratory Judgment in the Franklin Circuit Court. Therein, it was alleged that KRS 311.1939 was amended effective June 9, 2021, and that the amended version of KRS 311.1939 was violative of Sections 2, 3, 59, and 60 of the Kentucky Constitution:

1. Plaintiff, CorneaGen, Inc., is a Delaware corporation with its principal office at 1200 6th Avenue, Suite 300, Seattle, Washington 98101-1128. It is the world's largest provider of corneal tissue for transplant and provides high-quality donor tissue and superior processing services and devices that have transformed how ophthalmologists treat and care for people impacted by corneal disease.

---

<sup>1</sup> Daniel Cameron was succeeded as Attorney General of Kentucky by Russell M. Coleman effective January 1, 2024. Attorney General Coleman has been substituted as the real party in interest.

2. Plaintiff, Aurion Biotech, Inc., is a Delaware corporation with its principal office at 701 Pike Street, Suite 2225, Seattle, Washington 98101. It specializes in advanced cell therapy and utilizes proprietary processes to treat patients with corneal endothelial disease.

3. Plaintiff, Edward Holland, M.D., a resident of Boone County, Kentucky, is a pioneering ophthalmologist practicing in Kentucky. He is also the Director of Cornea Services at the Cincinnati Eye Institute and a Professor of Ophthalmology at the University of Cincinnati.

....

13. CorneaGen has its origins as a non-profit eye bank that was founded in Seattle in 1969. However, by 2016, it became clear that the mission of eliminating corneal blindness by 2040 could not be achieved without investor capital. For that reason, CorneaGen was spun out of the non-profit eye bank and changed its tax status to for-profit.

....

17. In 2018, CorneaGen introduced the pre-loaded, pre-stamped tissue in the Geuder Glass Cannula, which is an innovative tissue delivery system used for Descemet's Membrane Endothelial Keratoplasty ("DMEK").

18. In 2018, CorneaGen began processing Nano-Thin Descemet Stripping Automated Endothelial Keratoplasty ("DSAEK") tissue. This is currently the thinnest DSAEK available at 50 microns or less. This processing has greatly improved corneal transplant outcomes for surgeons and patients and is the preferred tissue of Dr. Holland.

19. In 2018, CorneaGen became the exclusive U.S. distributor of INTACS Corneal Implants, a device to improve vision in patients with keratoconus, which is a condition causing blurred vision and sensitivity to light and glare and can be quite painful.

20. In 2019, CorneaGen began offering VisionGraft, a premier sterile tissue, which is used to treat patients with Glaucoma.

21. In 2022, CorneaGen launched the EndoSerter-PL, which is a very innovative delivery system for tissue used in DSAEK surgery and the only FDA-approved system available.

22. CorneaGen also offers Keratolimbal allograft tissue for use in Limbal Stem Cell transplantations. Very few eye banks offer this type of tissue which is used to treat severe corneal blindness.

23. Aurion Biotech, Inc., is a for-profit company that spun off from CorneaGen in April 2022.

.....

25. Aurion's focus is curing patients with Corneal Endothelial Disease, a sight-threatening and debilitating condition affecting millions of people throughout the world.

.....

29. Using its patented technology, Aurion extracts healthy endothelial cells from a mature donor cornea supplied by CorneaGen and propagates it in a proprietary solution.

30. Once the donor endothelial cells are extracted and propagated, the cells undergo a series of

culturing passages. Cultured cells are preserved in an injectable solution.

31. The injectable solution of endothelial cells allows ophthalmologists to perform corneal transplants more efficiently and reduces patient recovery time.

....

34. Aurion is also working toward FDA approval for corneal endothelial cell treatments. Currently, there are no FDA-approved corneal endothelial cell treatments available.

....

36. Aurion will commence clinical trials under an FDA investigational new drug (IND) application to support FDA approval of corneal endothelial cell treatment.

....

51. In 2021, Dr. Woodford Van Meter, Medical Director of The Eye Bank of Kentucky, convinced the Kentucky General Assembly to pass Senate Bill 12 (hereinafter “SB 12”) for the purpose of preventing CorneaGen from providing any corneal tissue to any ophthalmologists or patients in Kentucky.

....

53. KRS 311.1939(2) irrationally prohibits a for-profit entity from engaging directly or indirectly in the procurement, transfer, or distribution of any eye tissue, while permitting for-profit entities to procure, transfer, and distribute all other human tissue (e.g., skin, bone, heart valves, ligaments, etc.). These other human tissues have been handled by for-profit entities for over 20 years.

....

61. But, CorneaGen and Aurion do not sell human tissue and have no intent to ever do so.

62. In fact, KRS 311.1939, prior to being amended by SB 12, already made it illegal for any person to knowingly acquire, receive, or otherwise transfer any human organ or tissue for valuable consideration for use in human transplantation.

63. Likewise, 42 [United States Code [(U.S.C.)]§ 274e, which was enacted long before SB 12, makes it illegal under federal law for any person to knowingly acquire, receive, or otherwise transfer any human organ or tissue for valuable consideration for use in human transplantation.

....

65. Just like all non-profit eye banks and many other organizations involved in human tissue transplantation, CorneaGen is reimbursed for the costs of screening, processing, preparing, or distributing tissue for transplant. Such fees are not payment for the tissue itself and are explicitly permitted by 42 U.S.C. § 274e.

....

89. The plain language of KRS 311.1939(4) prohibits any for-profit entity from charging a fee for the removal, processing, preservation, quality control, storage, transportation, implantation, or disposal of any human organ or tissue in Kentucky.

....

93. CorneaGen provided tissue to ophthalmologists in Kentucky prior to the enactment of SB 12. CorneaGen would be currently providing tissue

to ophthalmologists in Kentucky if SB 12 had not made it illegal for CorneaGen to do so.

94. Likewise, Aurion is barred by SB 12 from providing endothelial cells to patients and ophthalmologists who need them in Kentucky. Aurion would provide cells to ophthalmologists under an open FDA IND application to support clinical trials in Kentucky if SB 12 had not made it illegal for Aurion to do so.

95. Dr. Holland is an ophthalmologist who specializes in treating patients with cornea problems. He performs over 2,000 ophthalmic surgeries annually, including over 200 corneal transplants each year. He regularly performs corneal transplants in Northern Kentucky.

....

106. Prior to the enactment of SB 12, Dr. Holland regularly used CorneaGen tissue for corneal tissue transplants that he performed on patients in Kentucky.

107. Dr. Holland's other source for corneal tissue has been the Lions Gift of Sight (formerly known as the Minnesota Lions Eye Bank) at the University of Minnesota.

108. However, CorneaGen, and now Aurion as well, offer specialized corneal tissue that the Lions Gift of Sight does not provide.

109. In Dr. Holland's experience, The Eye Bank of Kentucky has been unable to provide the type, quality, and quantity of tissue that Dr. Holland needs for his patients in Kentucky.

110. As a result of SB 12, Dr. Holland has not been able to perform all of the procedures needed by his patients in Kentucky since SB 12 became effective.

111. Due to Dr. Holland's inability to access tissue from CorneaGen in Kentucky, many of Dr. Holland's patients' vision has worsened. As a result of their worsened vision, these patients are unable to perform many of the activities of everyday life such as driving a vehicle. Additionally, these patients are at risk of incidental harm, such as falls, because of their poor vision.

....

113. Furthermore, Dr. Holland is planning a clinical trial at St. Elizabeth Healthcare in Edgewood, Kentucky, which is scheduled to start in the fourth quarter of 2022. This unique, groundbreaking clinical trial involves cultured endothelial cells.

114. For the clinical trial, Dr. Holland will need large quantities of cultured endothelial cells, which Aurion can provide as an FDA IND.

115. Aurion is a for-profit company and cannot provide Dr. Holland with the cells necessary for his clinical trial because of KRS 311.1939(2).

116. Neither the Lions Gift of Sight Eye Bank nor any other non-profit eye bank can provide the type of cells that are needed for the clinical trial.

117. If Dr. Holland is unable to obtain corneal endothelial cells from Aurion for his clinical trial, his clinical trial will have to be postponed indefinitely, and the trial will not occur in Kentucky.

....

121. Sections 59 and 60 of the Kentucky Constitution prohibit special legislation.

....



125. As amended, KRS 311.1939(2) singles out for-profit entities for discriminatory treatment: “A for-profit entity shall not engage, directly or indirectly, in the procurement, transfer, or distribution of any human eye, cornea, eye tissue, corneal tissue, or portions of eyes.”

....

128. Thus, KRS 311.1939 is Special Legislation in violation of Sections 59 and 60 of the Kentucky Constitution.

....

130. Section 2 of the Kentucky Constitution provides that: “[a]bsolute and arbitrary power over the lives, liberty and property of freemen exists nowhere in a republic, not even in the largest majority.”

131. There are no legitimate, reasonable public purposes for prohibiting for-profit entities from the procurement, transfer, or distribution of human eye tissue in Kentucky.

132. There are no legitimate, reasonable public purposes for prohibiting CorneaGen and Aurion from providing corneal tissue and cells to ophthalmologists in Kentucky.

133. There are no legitimate, reasonable public purposes for prohibiting Dr. Holland from deciding which eye banks to utilize for his corneal transplantations. Prior to SB 12, the choice of which eye bank to use was always left to the discretion of the surgeon utilizing the tissue.

134. Thus, KRS 311.1939 violates Section 2 of the Kentucky Constitution.

....

136. Section 3 of the Kentucky Constitution provides that all men are created equal.

....

138. KRS 311.1939 irrationally discriminates against CorneaGen and Aurion based upon tax status.

139. In addition, KRS 311.1939(2) irrationally treats for-profit entities that process corneal tissue and cells differently than for-profit entities that process other human tissue.

140. There are no legitimate, rational reasons for treating CorneaGen and Aurion differently than all other similarly situated entities in Kentucky.

141. In addition, KRS 311.1939(4) has been applied discriminatorily against CorneaGen and Aurion in Kentucky.

142. Thus, KRS 311.1939 violates Section 3 of the Kentucky Constitution.

Verified Complaint at 2-6, 8-10, 14-20 (footnote omitted).

On August 16, 2022, plaintiffs filed a motion for summary judgment. They argued that KRS 311.1939 solely and particularly applied to CorneaGen, Inc. (CorneaGen) and Aurion Biotech, Inc. (Aurion), and for this reason, KRS 311.1939 constituted special legislation violative of Sections 59 and 60 of the Kentucky Constitution. Plaintiffs also maintained that KRS 311.1939 treats for-profit entities and nonprofit entities differently and that no legitimate government interests existed to justify the disparate treatment. As a result, plaintiffs believed

that KRS 311.1939 violated the equal protection guarantee of Section 3 of the Kentucky Constitution. Plaintiffs further asserted that KRS 311.1939 arbitrarily criminalized a for-profit entity's procurement and distribution of eye tissue in violation of Section 2 of the Kentucky Constitution.

The Attorney General filed a response. He argued that KRS 311.1939 was not special legislation as it only referred to for-profit entities rather than specifically named for-profit entities. The Attorney General reasoned that the fact that the law only applied to two entities in Kentucky upon passage in 2021 was not a feature of the law, but rather a feature of market conditions in Kentucky at that time. Additionally, the Attorney General maintained that the classification between for-profit and nonprofit eye banks in KRS 311.1939 was based upon legitimate governmental interests and did not violate the equal protection clause or the constitutional prohibition against arbitrary power.

The Eye Bank of Kentucky filed an *amicus curiae* brief. In its brief, the Eye Bank stated that it was a nonprofit organization that coordinates "ocular tissue donations, tissue recovery, and ocular distribution, and has worked in unison with the Kentucky Organ Donor Affiliates." Eye Bank Brief at 1. The Eye Bank argued that KRS 311.1939 was constitutional and did not violate Sections 2, 3, 59, or 60 of the Kentucky Constitution.

By Opinion and Order entered December 28, 2022, the circuit court granted plaintiffs’ motion for summary judgment and held that KRS 311.1939 was unconstitutional as violative of Sections 2, 3, 59, and 60 of the Kentucky Constitution. This appeal follows.<sup>2</sup>

To begin, summary judgment is proper where there exists no material issue of fact and movant is entitled to judgment as a matter of law. *See Steelvest, Inc. v. Scansteel Service Center, Inc.*, 807 S.W.2d 476, 480 (Ky. 1991). All facts and inferences therefrom are viewed in a light most favorable to the nonmoving party. *Id.* And, if there are no factual issues, summary judgment looks only to questions of law and we review a trial court’s decision to grant summary judgment *de novo*. *Brown v. Griffin*, 505 S.W.3d 777, 781 (Ky. App. 2016).

The Attorney General contends that the circuit court erred by rendering summary judgment and declaring KRS 311.1939 unconstitutional. The Attorney General initially points out that KRS 311.1939 enjoys a “strong presumption” of constitutionality. Attorney General Brief at 9. Under Sections 59 and 60 of the Kentucky Constitution, the Attorney General maintains that a statute is only considered special legislation if its language specifically refers by name to a

---

<sup>2</sup> Despite CorneaGen, Inc., Aurion Biotech, Inc, and Edward Holland’s assertion to the contrary, Daniel Cameron, as Attorney General of Kentucky, could properly file the instant appeal from the Opinion and Order of the Franklin Circuit Court declaring Kentucky Revised Statutes (KRS) 311.1939 unconstitutional. KRS 418.075; KRS 15.020.

particular individual, object, or locale. As KRS 311.1939 does not specifically reference a person or entity, the Attorney General asserts that it does not violate the prohibition against special legislation found in Sections 59 and 60 of the Kentucky Constitution.

The statute at issue, KRS 311.1939,<sup>3</sup> reads:

- (1) Except as otherwise provided in subsection (4) of this section, a person shall not, for valuable consideration, knowingly purchase, sell, transfer, or offer to purchase, sell, or transfer a part for transplantation or therapy if removal of a part from an individual has occurred, is intended to occur, or after the individual's death.
- (2) A for-profit entity shall not engage, directly or indirectly, in the procurement, transfer, or distribution of any human eye, cornea, eye tissue, corneal tissue, or portions of eyes.
- (3) A person who knowingly violates any of the provisions in this section shall be imprisoned in the penitentiary for not less than one (1) nor more than five (5) years or be fined not more than fifty thousand dollars (\$50,000), or both.
- (4) A nonprofit entity may charge a reasonable amount for the removal, processing, preservation, quality control, storage, transportation, implantation, or disposal of a part.

Under the plain and unambiguous language of KRS 311.1939, a for-profit entity is barred from engaging “in the procurement, transfer, or distribution

---

<sup>3</sup> The version of KRS 311.1939 amended effective June 29, 2021, is at issue herein. The prior version of KRS 311.1939 was amended effective July 15, 2010.

of any human eye, cornea, eye tissue, corneal tissue, or portions of eyes.” Under the previous version of KRS 311.1939, no differentiation existed between for-profit and nonprofit entities, and for-profit entities, like nonprofit entities, could engage in the “removal, processing, preservation, quality control, storage, transportation, implantation, and disposal of a part [of an individual].” KRS 311.1939(2) (amended effective July 15, 2010).<sup>4</sup>

The constitutional prohibition against special and local legislation is found in Sections 59 and 60 of the Kentucky Constitution. Section 59 prohibits special legislation in “cases where a general law can be made applicable[.]” And, Section 60 provides that “[t]he General Assembly shall not indirectly enact any special or local act by the repeal in part of a general act, or by exempting from the operation of a general act any city, town, district or county[.]” The Kentucky Supreme Court has recently held that a statute offends the constitutional prohibition against special legislation if “the statute applies to a particular individual, object, or locale.” *Calloway County Sheriff’s Department v. Woodall*, 607 S.W.3d 557, 573 (Ky. 2020).

In its summary judgment declaring KRS 311.1939 unconstitutional as special legislation, the Franklin Circuit Court reasoned:

---

<sup>4</sup> Under the prior version of KRS 311.1939(2), we note that only “a reasonable amount” could be charged by a for-profit or nonprofit eye bank for its services. KRS 311.1939(2) (amended effective July 15, 2010).

Under the *Calloway County* test for Section 59, local or special legislation, according to the well-known meaning of the words, applies exclusively to particular places or particular persons. *Calloway County Sheriff's Department v. Woodall*, 607 S.W.3d 557, 572 (2020). The appropriate test is whether the statute applies to a particular individual, object, or locale. *Id.* at 573. Here, the statute applies to a particular individual (CorneaGen), and to a particular object (corneal tissue transplants and donation).

In *University of Cumberlands v. Pennybacker*, the General Assembly passed a bill providing scholarship opportunities to Kentucky pharmacy students attending an accredited four (4) year institution of higher education with a main campus located in an Appalachian Regional Commission county in the Commonwealth and become certified pharmacists in the Commonwealth. [*University of Cumberlands v. Pennybacker*,] 308 S.W.3d 668, 672 (Ky. 2010). After reading the statute in its entirety, it is clear that the requirements to receive the scholarship could only be met by students attending the University of Cumberlands. *Id.* at 684. The Court held that the Bill violated Section 59 of the Kentucky Constitution because “the sole institution which would fit that description is [University of Cumberlands].” *Id.* at 683. The General Assembly’s failure to treat equally all members of the pharmacy student class was “precisely the type of special privilege and favoritism that section 59 condemns.” *Id.* at 685. While the *Pennybacker* court applied the previous special legislation test under *Schoo* [*v. Rose* 270 S.W.2d 940 (Ky. 1954)], *Calloway County* held that the Court reached the correct result because the statute applied to a particular object. *Calloway County Sheriff's Department*, 607 S.W.3d at 573 n.19. While the University of the Cumberlands was not explicitly named in the legislation, the classification was drawn so narrowly that it was the only institution that was eligible under the bill. Likewise in this case, although CorneaGen is not explicitly named in the bill, the

classification is drawn in a manner that it is the only company that is prohibited from engaging in business under this legislation.

....

It is undisputed that CorneaGen is the only for-profit entity in Kentucky in the business of selling and distributing eye tissue. There can be no doubt CorneaGen is specifically targeted under this statute. Defendants argue that the statute does not meet the *Calloway County* test for special legislation because it applies, at least theoretically, statewide to all for-profit entities, not CorneaGen in particular. This argument ignores the undisputed fact that CorneaGen is the only such entity in existence.

Moreover, the *Calloway County* case specifically affirmed the longstanding rule that legislation does not need to explicitly name the target of its discrimination in order to run afoul of the constitutional prohibition against special legislation. In *Calloway County*, the Court reaffirmed *University of Cumberland v. Pennybacker*, 308 S.W.3d 668, 672 (Ky. 2010), which struck down a classification that was so narrowly drawn it only applied to one university. Likewise, in this case, CorneaGen is not specifically named, and yet it is undisputed that it is the only entity to which the legislation applies. The Court agrees with Plaintiffs that the statute violates Sections 59 and 60 of the Kentucky Constitution because the record demonstrates that SB 12 applies only to a particular company, i.e., CorneaGen and its spinoff Aurion. Although the language of the statute contains no specific references to CorneaGen or Aurion, it's clear, based on the circumstances around the passing of SB 12, that the legislative intent of the Bill was to keep CorneaGen from doing business in Kentucky[.]

Opinion and Order at 12-13, and 17.



Thus, relying upon *Calloway County*, 607 S.W.3d 557, the circuit court determined that KRS 311.1939 constituted special legislation as it was so narrowly drawn to only apply in practice to two particular entities (CorneaGen and Aurion) and to only a particular object (corneal tissue). Conversely, the Attorney General interprets *Calloway County*, 607 S.W.3d 557 more narrowly as invalidating legislation only where a particular person, locale, or object is specifically referenced by name in the legislation.

Upon review of *Calloway County*, 607 S.W.3d 557, we acknowledge that the test enunciated therein is susceptible to differing interpretations. However, we agree with the circuit court's analysis of *Calloway County*, 607 S.W.3d 557 and view the *Calloway County* Court's approval of the result reached in *Pennybacker*, 308 S.W.3d 668 as key to its holding. Accordingly, we reject the Attorney General's argument that a statute must specifically reference by name a person, place, or object to constitute impermissible special legislation. As KRS 311.1939 clearly applies to only two particular entities (CorneaGen and Aurion) and to a single particular object (corneal tissue), we conclude that KRS 311.1939 constitutes special legislation and violates Section 59 and 60 of the Kentucky Constitution.

We view the Attorney General's remaining contentions of error as moot or without merit.

In sum, we are of the opinion that the circuit court properly granted summary judgment to appellees.

For the foregoing reasons, the Opinion and Order of the Franklin Circuit Court is affirmed.

ALL CONCUR.

BRIEFS FOR APPELLANT:

Matthew F. Kuhn  
Solicitor General  
Frankfort, Kentucky

Alexander Y. Magera  
Assistant Solicitor General  
Frankfort, Kentucky

ORAL ARGUMENT FOR APPELLANT:

Sarah Christensen  
Assistant Attorney General  
Frankfort, Kentucky

AMICUS CURIAE BRIEF FOR THE EYE BANK OF KENTUCKY:

Mickey T. Webster  
Thomas E. Travis  
Lexington, Kentucky

BRIEF FOR APPELLEES, CORNEAGEN, INC., AURION BIOTECH, INC., AND EDWARD HOLLAND, M.D.:

David M. Dirr  
Mark D. Guilfoyle  
Covington, Kentucky

ORAL ARGUMENT FOR APPELLEES, CORNEAGEN, INC., AURION BIOTECH, INC., AND EDWARD HOLLAND, M.D.:

David M. Dirr  
Covington, Kentucky