

STATE OF SOUTH CAROLINA)	
COUNTY OF RICHLAND)	IN THE COURT OF COMMON PLEAS
)	FIFTH JUDICIAL CIRCUIT
Opternative, Inc.,)	
)	Civil Action No. 2016-CP-40-_____
Plaintiff,)	
)	
vs.)	
)	<u>COMPLAINT</u>
South Carolina Board of Medical)	
Examiners,)	
)	
and)	
)	
South Carolina Department of Labor,)	
Licensing, and Regulation,)	
)	
Defendants.)	

INTRODUCTION

1. This civil-rights lawsuit seeks to vindicate the rights of consumers, doctors, and entrepreneurs to use innovative technology to enhance access to care for people in need of corrective lenses. Plaintiff Opternative, Inc., has developed an online technology (the “Technology”) that enables licensed ophthalmologists to conduct refractive examinations,¹ establish a diagnosis, and determine the correct prescription for many patients (an “Exam”). This Technology has been used across the country—including in South Carolina—but a recent law effectively prohibits South Carolina-licensed ophthalmologists from using the Technology to issue any prescriptions at all. The purpose of this new law is not to protect the public health or safety but instead to protect the profits of established businesses. Because the South Carolina Constitution forbids regulation for no purpose beyond economic protectionism, Defendants must

¹ Refractive examinations determine the refractive error of a person’s eye and therefore the proper corrective-lens prescription for that person.

be enjoined from enforcing the new law that has banned Opternative (and businesses like it) from continuing their work in South Carolina.

JURISDICTION AND VENUE

2. Plaintiff brings this action under Article I, Section 3 of the South Carolina Constitution, and the Uniform Declaratory Judgments Act, S.C. Code Ann. §§ 15-53-20, 15-53-30, and 15-53-120.

3. Plaintiff seeks declaratory and injunctive relief against enforcement of provisions of South Carolina’s Eye Care Consumer Protection Law (“ECCPL”), South Carolina Code sections 40-24-10(9), 40-24-20(C) and (D), which violate Plaintiff’s constitutional rights to equal protection and due process of law.

4. This Court has jurisdiction and venue lies pursuant to South Carolina Code section 15-77-50.

THE PARTIES

5. Plaintiff Opternative, Inc. (“Opternative”) is a Delaware corporation with its headquarters in Illinois.

6. Defendant South Carolina Board of Medical Examiners (“the BME”) is the state agency responsible for licensing physicians and for enforcing much of South Carolina’s eye care regulatory regime—including the ECCPL.

7. Defendant South Carolina Department of Labor, Licensing, and Regulation is the department of the South Carolina government which is responsible for administering the BME and in which the BME is incorporated. *See* S.C. Code Ann. § 1-30-65.

STATEMENT OF FACTS

South Carolina’s Eye-Care Regulatory Regime

8. Title 40 of the South Carolina Code authorizes the state to regulate certain professionals for the “health, safety, and welfare of the public.” S.C. Code Ann. § 40-1-10.

9. Among these are physicians and other miscellaneous healthcare professionals, who fall under the specific authority of the South Carolina Board of Medical Examiners. S.C. Code Ann. § 40-47-10.

10. Ophthalmologists are medical doctors specializing in eye and vision care, who by study and training are qualified chiefly to diagnose and treat ocular diseases, perform eye exams and surgeries, and prescribe lenses to correct vision problems.

11. As physicians, ophthalmologists are licensed and regulated by the BME. *Id.* The BME has broad powers to restrict the practice of ophthalmology, including the setting of minimum standards of professional care and the promulgation of rules of professional conduct. *Id.* The BME is also empowered to take disciplinary action—including suspension and even revocation of a physician’s license to practice ophthalmology—against those it deems guilty of professional misconduct. S.C. Code Ann. § 40-47-110.

12. Continuing to practice ophthalmology with a suspended or revoked license is a misdemeanor. S.C. Code Ann. § 40-27-200.

13. Unlike ophthalmologists, optometrists are not medical doctors. Rather, optometrists are more limited medical professionals who by study and training are qualified chiefly to detect and treat certain ocular diseases, perform eye exams and vision tests, and prescribe and dispense corrective lenses.

14. While optometrists provide professional medical care and fall under South Carolina’s Title 40 regulatory powers, they are not governed by the BME. Instead, optometrists

are licensed and regulated exclusively by the South Carolina Board of Examiners in Optometry. S.C. Code Ann. § 40-37-10.

15. South Carolina’s regulatory regime provides that the only way to obtain a prescription for corrective lenses in the state is through a licensed ophthalmologist or optometrist. S.C. Code Ann. § 37-25-20. Prescriptions must be based on “medical findings made and refractive error discovered during [an] eye examination.” S.C. Code Ann. § 40-24-20.

Opternative’s Innovative Eye Care Services

16. Opternative is a healthcare technology company founded in 2012 by optometrist Steven Lee and entrepreneur Aaron Dallek out of their sincere belief that appropriate eye care and corrective-lens prescriptions should be accessible and affordable to everyone.

17. As a practicing optometrist who had completed over 20,000 refractive exams, experience taught Steven that refractive eye exams—conducted by brick-and-mortar providers, typically through use of a phoropter²—were needlessly time-consuming, inconvenient, and expensive for patients.

18. Traditional refractive eye exams rely on patient self-reporting: An individual sits in a chair and reports to the administering optometrist or ophthalmologist what they perceive as they are shown a series of images using a phoropter.

19. Traditional refractive eye exams are *subjective*, in that they rely on an individual’s self-reporting of what they see, as distinct from *objective* exams that rely on physically measuring an individual’s eyes.

20. An Exam conducted using Opternative’s Technology relies on exactly the same self-reporting principle as a traditional exam.

² A phoropter is a mechanical device that switches multiple lenses in front of a patient’s eyes.

21. Opternative’s Technology is accessed through the Opternative website.
22. At the outset, an individual uses the Technology to answer a detailed list of questions, including (but not limited to) questions about their existing eyeglass prescription (if any) and their relevant medical history.
23. The Technology then presents a set of written and audio instructions that guides the individual through a self-administered vision assessment.
24. Opternative’s Technology is interactive in nature: An individual observes a series of individually calibrated ophthalmological images on a computer screen and uses a smartphone to self-report what they perceive.
25. As with a traditional in-person examination, the Technology relies on individuals’ honestly reporting what they perceive. Throughout the process, individuals are reminded that the correct answer is an honest answer, and the Technology employs a specialized algorithm to detect inconsistent responses.
26. A user’s interaction with the Technology—from answering the initial medical-history questions to self-reporting responses to the various images—generally takes 20–25 minutes.
27. The Technology automatically collects and generates data based on the patient’s interactive responses, which Opternative then shares with an ophthalmologist licensed to practice in the relevant state.
28. A licensed ophthalmologist reviews the data collected and generated by the Technology (which includes both the individual’s medical-history responses and their responses to the ophthalmological images) and decides either to write an appropriate prescription for corrective lenses or that no appropriate prescription can be written based on the data.

29. If a licensed ophthalmologist writes a prescription based on the data collected and generated by the Exam, the prescription is made available to the patient via Opternative's website. The patient can then use the prescription to purchase corrective lenses wherever they please.

30. While Opternative makes the Technology available on its website freely available to everyone, ophthalmologists working with Opternative will only conduct an Exam and write prescriptions for corrective lenses for individuals who meet certain criteria, which include age-, health-, and prescription-based considerations.

31. Opternative only charges a fee for an Exam—that is, for a doctor to review an individual's results; there is no fee for simply trying the Technology itself.

32. The Exam is designed to determine a patient's refractive error (and therefore the appropriate corrective prescription). It is not designed to be a comprehensive eye exam.

33. The American Academy of Ophthalmology recommends that otherwise-healthy patients (patients who do not have symptoms of disease or other risk factors for eye disease) who are between 18 and 39 years old receive a comprehensive eye-health exam once every 5–10 years. *See American Academy of Ophthalmology, Comprehensive Adult Medical Eye Evaluation*, at P216 (2015), *available at* [www.aaojournal.org/article/S0161-6420\(15\)01269-5/pdf](http://www.aaojournal.org/article/S0161-6420(15)01269-5/pdf).

34. The American Academy of Ophthalmology recommends that otherwise-healthy patients who are between 40 and 54 years old receive a comprehensive eye exam once every 2–4 years. *Id.*

35. The American Academy of Ophthalmology recommends that otherwise-healthy patients who are between 55 and 64 years old receive a comprehensive eye health exam once every 1–3 years. *Id.*

36. In order to encourage compliance with these guidelines, Opternative asks a series of preliminary questions before examining any patient to ensure compliance with its strict eligibility requirements, which are displayed on its website at www.opternative.com:

Opternative **is not a replacement** for a comprehensive eye examination. Our licensed Ophthalmologists use Opternative’s on-line technology to evaluate a patient’s visual acuity and a portion of the ocular health profile, diagnose refractive error, and issue a prescription for corrective eyewear, where clinically appropriate. Our services are limited to patients between the ages of 18 and 50 who are in good health. All examinations are conducted and all prescriptions are issued based on the independent clinical judgment of an ophthalmologist. Because our services are not a replacement for an eye health examination, we encourage everyone to obtain a comprehensive eye health exam at least once every 2 years. We prohibit patients from taking an Opternative exam more than 4 consecutive years without certifying that they have received a comprehensive eye health exam first. If you need help finding an eye care professional near you, please contact us at info@opternative.com.

37. The instructions on Opternative’s website regarding the importance of comprehensive eye exams far exceed the minimum recommendations of the American Academy of Ophthalmology.

38. Eyeglass prescriptions in South Carolina expire after only one year. S.C. Code Ann. § 40-24-20(B).

39. An ophthalmologist in South Carolina is not required to conduct a comprehensive eye-health exam in order to write a prescription for corrective lenses.

40. For eligible patients, an Exam using the Technology is just as effective in the diagnosis of refractive error as traditional exams performed by ophthalmologists and optometrists using phoropters in brick-and-mortar offices.

41. In a side-by-side clinical trial, Exams that used Opternative's Technology proved just as accurate as a traditional refractive exam performed by an optometrist or ophthalmologist using a phoropter.

42. Upon information and belief, Defendants have no evidence that Exams using Opternative's Technology are any less accurate than a traditional in-person refractive exam.

43. Upon information and belief, Defendants have no reason to believe that Exams using Opternative's Technology are any less accurate than a traditional in-person refractive exam.

44. For eligible patients, an Exam using Opternative's Technology is quicker, more convenient, and more affordable than traditional exams performed by ophthalmologists and optometrists using phoropters in brick-and-mortar offices.

45. For eligible patients, an Exam using Opternative's Technology expands access to prescriptions for corrective lenses for those who can least afford to visit traditional brick-and-mortar offices.

46. Upon information and belief, Defendants possess no evidence that Exams using Opternative's Technology result in lower patient satisfaction than a traditional in-person refractive exam.

47. Upon information and belief, Defendants have no reason to believe that Exams using Opternative's Technology result in lower patient satisfaction than a traditional in-person refractive exam.

South Carolina's Unconstitutional Ban on Online Eye Care

48. Upon information and belief, many professional optometrists make the majority of their revenue from selling expensive frames in their brick-and-mortar offices rather than from professional fees earned from conducting traditional in-person eye examinations.

49. Upon information and belief, Opternative's service model disrupts this bundling of in-person eye examinations and frame sales, allowing patients the option of taking an eye exam and obtaining a prescription from the comfort of their own homes without ever having to see or consider buying expensive eyeglass frames in a brick-and-mortar office.

50. Upon information and belief, since almost immediately after Opternative's founding in 2012, the American Optometric Association ("the AOA") and related local optometric groups have conducted both a public media and private lobbying campaign to drive Opternative out of business.

51. Upon information and belief, almost immediately after Opternative began providing its services in South Carolina, the AOA and related South Carolina optometric groups conducted both a public media and private lobbying campaign to drive Opternative out of the state. These efforts culminated in the passage of the aforementioned Eye Care Consumer Protection Law on May 11, 2016.

52. The ECCPL provides that vision assessments "may not be based solely on objective refractive data or information generated by an automated testing device, including an auto refractor or other electronic refractive-only testing device, to provide a medical diagnosis or to establish a refractive error for a patient as part of an eye examination." S.C. Code Ann. § 40-24-10(9).

53. The ECCPL specifically targets “kiosks,” or “automated equipment or an automated application, which is designed to be used on a phone, computer, or Internet-based device that can be used in person or remotely to provide refractive data or information.” S.C. Code Ann. § 40-24-10(4).

54. The ECCPL effectively prohibits ophthalmologists from conducting Exams or writing prescriptions based on Opternative’s Technology by providing that “[a] prescription for spectacles or contact lenses may not be based solely on the refractive eye error of the human eye or be generated by a kiosk.” S.C. Code Ann. § 40-24-20(C).

55. Opternative’s Technology is not a purely automated system; instead, Opternative’s Technology uses an interactive and adaptive system to elicit responses from a patient. As part of this system, Opternative’s Technology automatically collects and generates refractive data and information, which is transmitted to a participating ophthalmologist, who uses his training and judgment to write a prescription based on this data if it is appropriate to do so.

56. It is illegal to write a corrective-lens prescription based on an Exam using Opternative’s Technology in South Carolina because the patient responses on which the ultimate prescription is based are being automatically recorded and compiled by a computer system designed for use on a phone, computer, or Internet-based device instead of (for example) being written down by a human being holding a clipboard.

57. Writing a prescription based on a system similar to Opternative’s—which asked the same questions and showed the patient the same images—would be generally legal in South Carolina as long as the patient’s responses were written down by a human being instead of being automatically recorded and compiled by a computer system.

58. The purpose of the ECCPL is to prohibit South Carolina-licensed ophthalmologists from working with Opternative (or anyone providing technology like Opternative's).

59. The effect of the ECCPL is to prohibit South Carolina-licensed ophthalmologists from working with Opternative (or anyone providing technology like Opternative's).

60. Defendants have no authority or ability to interpret the ECCPL in a way that would allow South Carolina-licensed ophthalmologists to work with Opternative (or anyone providing technology like Opternative's).

61. Therefore, asking Defendants to issue an interpretation or regulation that would permit South Carolina-licensed ophthalmologists to work with Opternative (or anyone providing technology like Opternative's) would be futile.

62. The ECCPL threatens Opternative—and specifically, state-licensed ophthalmologists who work with Opternative—with the full range of penalties covered in ¶¶ 11-12 above. *Id.* § 40-24-20(D).

63. The ECCPL's ban on prescribing corrective lenses based on information that is automatically collected or generated is unrelated to the quality or accuracy of a prescription.

64. The ECCPL prohibits prescribing corrective lenses based solely on information generated through any computerized process, whether that process is Opternative's more traditional subjective exam or a meticulously accurate objective scan of a patient's eye.

65. South Carolina law does not require that ophthalmologists or optometrists physically examine patients for risk factors or diseases before writing a prescription for corrective lenses.

66. South Carolina law does not require that ophthalmologists or optometrists take into account any particular medical facts not generated by an eye exam before writing a prescription for corrective lenses.

67. South Carolina law does not require that patients obtain a comprehensive eye-health exam once per year, once every five years, or even at all, in order to obtain a prescription for corrective lenses.

68. An ophthalmologist who writes a corrective-lens prescription without conducting a comprehensive eye-health exam has not necessarily violated any standard of care.

69. The ECCPL has no valid public health or safety purpose.

70. Upon information and belief, Defendants possess no evidence that the ECCPL serves any valid public health or safety purpose.

71. The sole purpose of the ECCPL is economic protectionism.

72. The ECCPL, in purpose and effect, reduces access to online eye care in South Carolina in order to prop up professional optometrists' outdated business model.

73. On May 16, 2016, Governor Nikki Haley vetoed the ECCPL for precisely these reasons, specifically condemning its protectionist and anti-competitive nature.

74. Governor Haley's veto statement reads, in full:

I am vetoing this bill because it uses health practice mandates to stifle competition for the benefit of a single industry, effectively banning eye care kiosks statewide.

During my administration, South Carolina has expanded access to health care, including mental health services, to rural and underserved regions of our state using telemedicine. Unfortunately, a small group of eyecare professionals is seeking to block new technologies that expand low-cost access to vision correction services, using two basic arguments.

First, advocates state that kiosks pose a public health risk, which is simply untrue. Individuals can, and should, continue to see their doctor for comprehensive medical exams, and these kiosks do not offer medical evaluations or advice. Second, optometrists argue that kiosks create an uneven playing field because licensed practitioners cannot take advantage of this technology and charge patients for its use in a medical practice. The answer to this problem is not to ban a new technology, but rather to expand its use. **Send a bill to my desk that allows for the expanded use of automated vision evaluations in all settings, and I will sign it.**

If [the ECCPL were] allowed to become law, South Carolina would become the eighth state to impose such a ban, putting us on the leading edge of protectionism, not innovation. This is the wrong message to send to the business community. **I urge you to continue promoting South Carolina's use of innovative technologies to expand access to medical care and sustain this veto.**

Veto Message of Governor Nikki Haley, March 16, 2016, *available at* <http://www.governor.sc.gov/ExecutiveOffice/Documents/R.178,%20S.1016%20-%20Eye%20Care.pdf>.

75. The assertions in Governor Haley's May 16 veto statement are true.

76. On May 18, 2016, the South Carolina General Assembly voted to override Governor Haley's veto of the ECCPL.

77. The ECCPL stands in stark contrast to how South Carolina regulates telemedicine overall. On June 3, 2016, the South Carolina Telemedicine Act legalized telemedicine generally throughout the state. S.C. Code Ann. § 40-47-37.

78. Under the South Carolina Telemedicine Act, a medical doctor may use online tools to provide medical care provided the doctor otherwise meets the relevant standard of care.

79. Under the ECCPL, however, an ophthalmologist may not use online tools like Opternative's Technology to write corrective-lens prescriptions, even if they otherwise meet the relevant standard of care.

INJURY TO PLAINTIFF

80. As a direct result of the passage of the ECCPL, the use of Opternative's Technology has been effectively prohibited in South Carolina.

81. Prior to the adoption of the ECCPL, Opternative could (and did) allow a South Carolina-licensed ophthalmologist to write corrective-lens prescriptions for South Carolina residents.

82. As a direct result of the passage of the ECCPL, South Carolina-licensed ophthalmologists are legally prohibited from working with Opternative to provide corrective-lens prescriptions for South Carolina residents.

83. As a direct result of the passage of the ECCPL, South Carolina-licensed ophthalmologists are no longer willing to work with Opternative to provide corrective-lens prescriptions for South Carolina residents.

84. As a direct result of the passage of the ECCPL, Opternative has ceased its business operations in South Carolina.

85. But for the ECCPL, Opternative would still be facilitating corrective-lens prescriptions for South Carolina residents.

86. But for the ECCPL, state-licensed ophthalmologists would be willing to work with Opternative to provide corrective-lens prescriptions for South Carolina residents.

COUNT I: DUE PROCESS VIOLATION

87. Opternative re-alleges and incorporates by reference each and every allegation set forth in ¶ 1 through ¶ 86 of this Complaint as if fully set forth herein.

88. Article I, Section 3 of the South Carolina Constitution protects Opternative's right to pursue an honest living free from arbitrary, irrational, and protectionist regulation and the

rights of doctors and patients to make responsible decisions about medical care by providing that “[t]he privileges and immunities of citizens of this State and of the United States under this Constitution shall not be abridged, nor shall any person be deprived of life, liberty, or property without due process of law.” S.C. Const. art I, § 3.

89. South Carolina’s eye-care regulatory regime—specifically, the ECCPL provisions described above and codified at South Carolina Code sections 40-24-10(9), and 40-24-20(C) and (D)—does not further any valid public health or safety purpose, and therefore violates Opternative’s right to pursue an honest living free from arbitrary, irrational, and protectionist regulation.

90. The ECCPL is a purely protectionist piece of legislation, and protectionism is not a legitimate basis under the South Carolina Constitution for depriving Opternative of its constitutional right to pursue an honest living by providing innovative eye-care solutions to patients who need them.

91. Unless Defendants are enjoined from enforcing the ECCPL, Opternative will suffer continuing and irreparable harm.

COUNT II: EQUAL PROTECTION VIOLATION

92. Opternative re-alleges and incorporates by reference each and every allegation set forth in ¶ 1 through ¶ 86 of this Complaint as if fully set forth herein.

93. Article I, Section 3 of the South Carolina Constitution further protects the rights of South Carolinians by providing “nor shall any person be denied the equal protection of the laws.” S.C. Const. art I, § 3.

94. The ECCPL has no valid public health or safety purpose but is a purely protectionist piece of legislation, and therefore serves no legitimate state end.

95. The ECCPL draws an arbitrary and irrational distinction between ophthalmologists who write corrective-lens prescriptions based on an in-person refractive examination and ophthalmologists who write corrective-lens prescriptions based on Opternative's Exam.

96. The ECCPL draws an arbitrary and irrational distinction between ophthalmologists, who are not allowed to use their medical judgment to use online tools like Opternative to provide medical services that otherwise meet the general standard of care, and other kinds of medical doctors, who are allowed to use their medical judgment to use online tools to provide medical services that otherwise meet the general standard of care.

97. Unless Defendants are enjoined from enforcing the ECCPL, Opternative will suffer continuing and irreparable harm.

PRAYER FOR RELIEF

WHEREFORE, Opternative respectfully requests that this Court:

A. Enter a declaratory judgment that the Eye Care Consumer Protection Law, S.C. Code Ann. §§ 40-24-10(9), and 40-24-20(C) and (D), violates Article I, Section 3 of the South Carolina Constitution;

B. Enter a declaratory judgment that Defendants cannot legally penalize South Carolina-licensed ophthalmologists solely on the basis that they have written corrective-lens prescriptions using Opternative's Technology;

C. Enter an order permanently enjoining Defendants from enforcing the ECCPL;

D. Award Opternative its reasonable costs and attorneys' fees in this action;

E. Award Opternative any other legal or equitable relief to which Opternative is justly entitled.

Respectfully submitted,

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