

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

OCULAR THERAPEUTIX, INC.,	)	
	)	
Declaratory Judgment Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
MATI THERAPEUTICS, INC.,	)	
	)	
Declaratory Judgment Defendant	)	

**COMPLAINT FOR DECLARATORY JUDGMENT OF NON-INFRINGEMENT**

Ocular Therapeutix, Inc., complains against Mati Therapeutics, Inc., and alleges as follows.

**INTRODUCTION**

1. Ocular Therapeutix, Inc., is an innovative biopharmaceutical company focused on the development and commercialization of therapies for various diseases and conditions of the eye. Ocular has been developing the DEXTENZA<sup>®</sup> drug-eluting intracanalicular insert for treating post-surgical ocular pain and other ophthalmic conditions and has completed extensive Phase 2 and Phase 3 studies to test the safety and efficacy of these inserts. On November 30, 2018, Ocular received FDA approval to market DEXTENZA for intracanalicular use in the treatment of ocular pain following ophthalmic surgery. Ocular expects to begin marketing DEXTENZA during the first half of 2019.

2. Mati Therapeutics owns U.S. Patent No. 7,922,702 (“the ‘702 Patent, attached as Exhibit A). Mati did not invent the technology claimed in the ‘702 Patent. Instead, years after

the invention, Mati acquired from a third party the rights the '702 Patent. Mati has no products on the market. Nonetheless, aware of the impending FDA approval of the DEXTENZA insert, Mati sent Ocular a letter dated October 18, 2018, accusing the DEXTENZA insert of infringing the '702 Patent. By letter dated October 25, 2018, Ocular denied infringement. Additional written and oral communications between the parties followed in which Mati repeated its allegations.

3. This declaratory judgment is necessary to remove the cloud of Mati's threats so that Ocular can make this important, FDA-approved medical advancement (*i.e.*, the DEXTENZA insert) available to eye surgery patients.

#### **THE PARTIES**

4. Founded in 2006, Ocular Therapeutix, Inc., is a Delaware corporation based at 15 Crosby Drive, Bedford, Massachusetts, 01730.

5. Mati Therapeutics, Inc., was incorporated in Delaware on October 15, 2012, and, on information and belief, continues to be a Delaware corporation. Mati has its corporate headquarters at 4317 Dunning Lane, Austin, Texas, 78746.

#### **JURISDICTION AND VENUE**

6. This action is for a declaratory judgment that Ocular does not infringe Mati's '702 Patent. As such, this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338, and 2201 because this action arises under the patent laws and seeks relief under the Federal Declaratory Judgment Act.

7. Mati is subject to personal jurisdiction in Delaware because it is incorporated in Delaware and is thus resides here. Mati has also appointed a registered agent, CT Corporation, to accept service of process here.

8. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c) and 1400(b) because Mati is incorporated and resides in this District.

### **FACTUAL BACKGROUND**

#### **A. The Controversy**

9. Mati purports to own U.S. Patent No. 7,922,702 to Lazar (“the ‘702 Patent”), which is entitled “Treatment Medium Delivery Device and Methods for Delivery of Such Treatment Mediums to the Eye Using Such a Delivery Device.” The ‘702 Patent issued on April 12, 2011, based on an application filed July 1, 2005.

10. As prefaced above, on October 18, 2018, Mati sent a letter to Ocular alleging that Ocular’s DEXTENZA drug-eluting canalicular inserts infringe the ‘702 Patent. By letter dated October 25, 2018, Ocular denied infringement. In further communications between the companies, both in writing and in person, Mati continued to allege that the ‘702 Patent applies to DEXTENZA and demanded that Ocular pay exorbitant royalties to Mati.

11. On Friday, November 30, 2018, Ocular received FDA approval to market DEXTENZA for use in treating post-surgical ocular pain. Ocular, a public company, announced this important news in a press release on Monday, December 3, 2018.

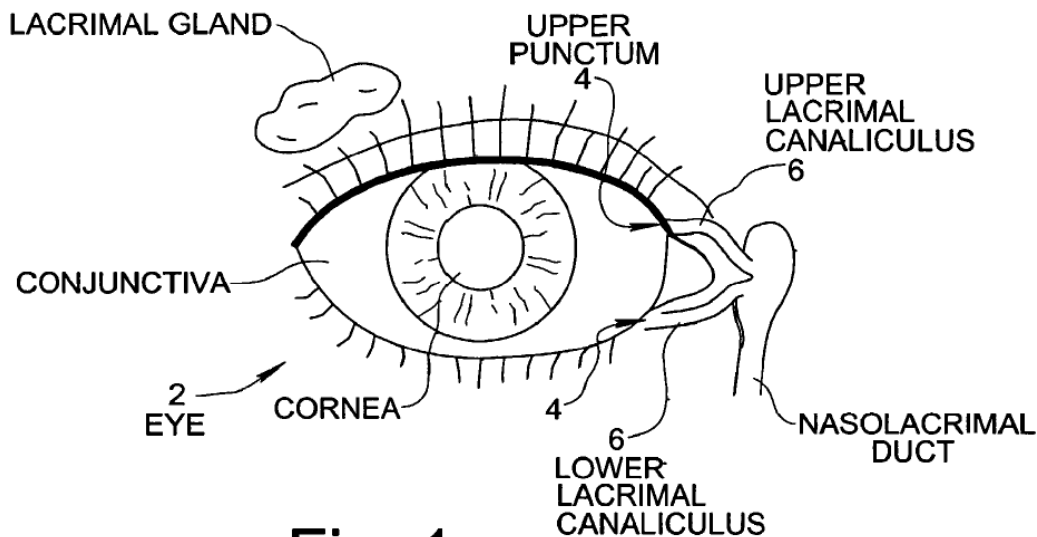
12. Predictably, Mati sent a letter the following day after this press release (on Tuesday, December 4) reiterating its position that Ocular could be liable for patent infringement. Specifically, Mati stated that “Ocular’s post-approval conduct, namely any making, using, selling, offering to sell, or importing of Dextenza, willfully infringes Mati’s patents.” Mati demanded that Ocular enter into expensive licenses or other costly payment arrangements to avoid infringement.

13. Now that Ocular has received FDA approval, it will begin to ramp up production and marketing so that it can begin to supply doctors with this important medical advance for their eye surgery patients. Accordingly, this action is necessary to settle the controversy so that Ocular may deliver DEXTENZA to the market without the cloud of patent infringement.

**B. The '702 Patent**

14. The '702 Patent is directed to drug delivery devices, particularly devices known as "punctal plugs" or "canalicular inserts," that are inserted through the punctum and into the canaliculus of an eye to block tear drainage or to deliver therapeutic agents to the eye. Such devices have been known and used in the ophthalmology field for decades to treat various disorders and conditions of the eye, such as dry eye syndrome and glaucoma.

15. Figure 1 from the '702 Patent, shown below, illustrates the relevant anatomy of a human eye, particularly the nasolacrimal system:

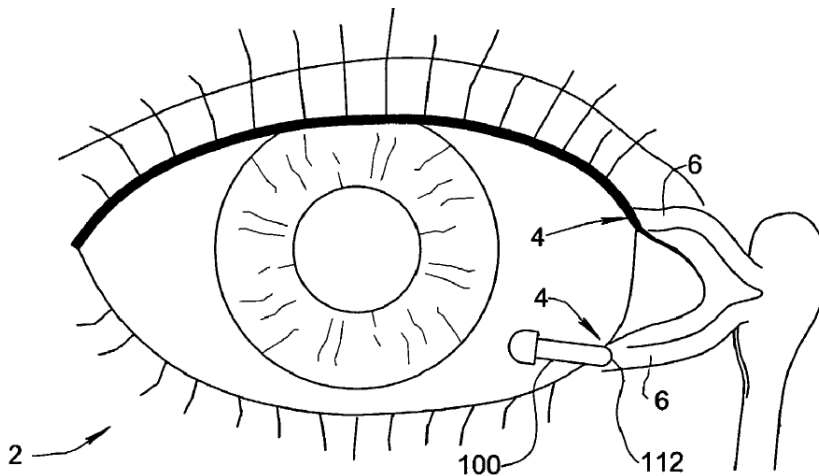


**Fig. 1**

16. The punctum is a sphincter-like opening that leads to the canaliculus, which is a lumen or passageway that leads from the eye to the nasolacrimal sac. Each eye has an upper and

lower punctum and associated upper and lower canaliculus. Tears drain from the surface of the eye, through the punctum, down the canaliculae, and out through the nasal system.

17. A long-known treatment for dry eyes is to block the canaliculus so that tears stay on the surface of the eye rather than drain away. Many companies over the years have introduced to market various devices, sometimes known as “punctal plugs” or “canalicular inserts,” to accomplish this task. Figure 5 of the ‘702 Patent shows an embodiment of the type of punctal plugs claimed in the ‘702 Patent. The plug is the mushroom shaped structure identified as component 100. The plug is inserted through the punctum (in this figure, the lower punctum) and into the beginning of the associated canaliculus.



**Fig. 5**

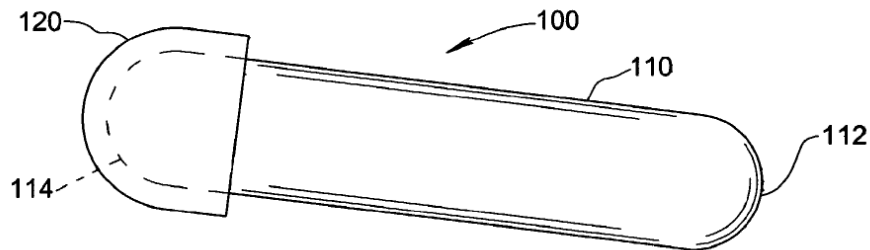
18. Exemplary Claim 15 of the ‘702 Patent claims the following device:

15. A device comprising:

- a first portion configured for insertion into a punctum of a mammalian eye and retention by a single lacrimal canaliculus of the eye;
- a second portion retained on or in the first portion, the second portion including an at least partially encapsulating jacket or a coating; and
- a treatment medium carried by the second portion, wherein the second portion releases the treatment medium to the eye.

19. As seen above, Claim 15 requires a device that has both a “first portion” and a “second portion.” In addition to Claim 15, the two other independent claims of the ‘702 Patent also recite devices having a “first portion” and a “second portion.” *See* Claims 1 and 28.

20. In Figure 2A, shown below, the ‘702 Patent illustrates one such embodiment of a device having first and second portions:



**Fig. 2A**

21. In the above figure, the claimed “first portion” is identified as the tube numbered 110, while the claimed “second portion” is identified as the cap numbered 120. *See* Ex. A, ‘702 Patent at 7:39-47 (describing Figure 2A). All other embodiments described in the patent also consist of at least two different structures or materials fitted or bonded together.

22. According to the claims and the specification, the claimed “second portion” is the structure that carries and then releases the “treatment medium.” A “treatment medium,” according to the patent, could be, for example, an antibiotic, analgesic, or medication used for treating dry eye. ‘702 Patent at 9:2-8.

23. During prosecution of the application that resulted in the ‘702 Patent, the inventors further defined “second portion” and distinguished the claimed devices from prior art consisting of unitary, one-piece structures. For example, the inventors argued that the particular prior art reference cited against the pending claims, the Freeman reference, “does not disclose, teach, or suggest a second portion that includes ‘an at least partially encapsulating jacket or

coating,” as recited in the claims. Ex. B, File History Excerpts, 06/30/2010 Response at pg. 8. The inventors then argued that “Freeman does not disclose, teach, or suggest such a feature [*i.e.*, “wherein the first portion includes structure adapted to support the second portion”], because the punctum plug of Freeman is a single integral piece.” *Id* (emphasis added). As such, the inventors disclaimed devices consisting of a single integral piece.

24. Ocular’s FDA-approved DEXTENZA insert does not infringe Claim 15 or any other claim of the ‘702 Patent. For example, Ocular’s DEXTENZA insert does not include a “second portion,” as recited in Claim 15 and the other two independent claims (and hence, by extension, in all of the dependent claims as well). Instead, the insert comprises a single structure consisting of a hydrogel insert with the anti-inflammatory medication dexamethasone dispersed throughout, rather than in a separate structure or coating. The insert is depicted below.



25. As one can see from this illustration, the insert has no second portion that is “retained on or in” the hydrogel insert, let alone a second portion that carries and releases the “treatment medium.” Nor does it have a second portion that includes an “encapsulating jacket or a coating,” as Claim 15 and the other claims require. Furthermore, to the extent that dexamethasone may be considered as the “treatment medium,” all of it is contained within the

one and only structure—namely, the hydrogel insert—rather than in a second structure or material.

26. Because all of the claims of the ‘702 Patent require a “second portion” that carries the treatment medium, the DEXTENZA insert cannot possibly infringe any other claim of the ‘702 Patent.

27. In addition, independent Claims 1 and 28 (and their dependent claims) are not infringed for a separate reason. Claim 1 requires that “the second portion is shaped to rest upon, or be located exteriorly of, the punctum when the first portion is retained by the lacrimal canaliculus.” Claim 28 requires that the “second portion of the delivery device is adjacent to an external surface of the eye.” In other words, both claims require that a portion of the device, such as a flange or cap, remains outside the punctum. Putting aside whether the accused DEXTENZA insert includes a first and a second portion, there is no portion that remains outside the punctum when the device is inserted. Rather, it is inserted fully through the punctum and into the canaliculus.<sup>1</sup>

### COUNT I

#### **Declaratory Judgment of Non-Infringement of the ‘702 Patent**

28. Ocular re-alleges and incorporates by reference the preceding paragraphs as if fully set forth herein.

29. A concrete and immediate controversy has arisen between the parties regarding infringement of the ‘702 Patent and Ocular’s obligation, if any, to pay Mati for rights in the patent. Mati has suggested that it will seek to enforce the patent in litigation against Ocular.

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<sup>1</sup> The above-summarized non-infringement arguments are just two example and other non-infringement arguments and defenses may be developed as this case evolves. Ocular reserves the right to raise other arguments as well during this matter.



30. For at least the reasons alleged above, Ocular has not infringed, induced others to infringe, or contributed to the infringement by others of the '702 Patent.

31. Ocular seeks and is entitled to a declaratory judgment that the DEXTENZA inserts do not infringe any claim of the '702 Patent under 35 U.S.C. § 271 (or any sub-section thereof).

### **REQUEST FOR RELIEF**

WHEREFORE, Ocular Therapeutix respectfully requests the Court to enter judgment in its favor and against Mati Therapeutics as follows:

1. that neither Ocular nor its accused DEXTENZA inserts infringe or have infringed under 35 U.S.C. § 271 (or any subsection thereof) any claim of the '702 Patent;
2. that Ocular should be awarded its reasonable attorneys' fees and costs incurred in connection with this action; and
3. for such other and further relief as the Court deems just and proper.

DATED: December 14, 2018

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