**IN THE UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF ILLINOIS**
**EASTERN DIVISION**

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| AltaThera Pharmaceuticals LLC,<br><br>Plaintiff,<br><br>vs.<br><br>Hyloris Pharmaceuticals SA, Academic Pharmaceuticals Inc., John C. Somberg, M.D.,<br><br>Defendants. | Civil Action No.<br><br>**DEMAND FOR JURY TRIAL** |

# COMPLAINT

Plaintiff AltaThera Pharmaceuticals LLC ("AltaThera") brings this action for compensatory and punitive damages and permanent injunctive relief against Defendants Hyloris Pharmaceuticals SA ("Hyloris"), Academic Pharmaceuticals Inc. ("API"), and John C. Somberg, M.D. ("Dr. Somberg") (collectively, the "Defendants"), for their misappropriation of AltaThera's highly valuable trade secrets and confidential information, breaches of contract, and other tortious misconduct, in violation of both federal law under the Defend Trade Secrets Act and state law.

AltaThera also seeks a declaration that it is the owner of U.S. Patent Application No. 16/449,796 ("the '796 application"), and any patents that issue from that application (including U.S. Patent No. 11,364,213, or "the '213 patent"), as well as any patents and patent applications that claim priority to that application (including U.S. Patent Application No. 17/380,413 ("the '413 application")). AltaThera also brings this action pursuant to 35 U.S.C. § 256 to correct the inventorship of the '213 patent, to add Brandon Kashfian as a co-inventor of the subject matter claimed in that patent. AltaThera alleges as follows:

## NATURE OF THE ACTION

1. AltaThera is a hospital-focused pharmaceutical company dedicated to addressing unmet medical needs, including by developing innovative ways to repurpose existing drugs and administer treatments that are efficient, safe, and effective and provide excellent outcomes for patients.

2. AltaThera is the exclusive distributor in the United States of the drug product sotalol hydrochloride injection for intravenous use ("Sotalol IV") (NDA 022306) approved by the Food and Drug Administration ("FDA") in 2009. Sotalol IV is an antiarrhythmic agent indicated for "the maintenance of normal sinus rhythm" in certain circumstances.[1] Antiarrhythmic agents such as Sotalol IV are medications that are used to treat and prevent heart rhythms that are too fast and/or irregular, *i.e.*, arrhythmias. Sotalol IV was originally approved as a substitute for oral sotalol for patients unable to take sotalol orally.

3. Consistent with AltaThera's strategic focus, the company developed an innovative method for administering Sotalol IV in a way that would allow patients who would otherwise need to spend three days in the hospital to spend only one day there. Using the method, sotalol is administered via IV for approximately one hour. After that, the patient may be switched to oral sotalol, and may be safely discharged from the hospital within one day.

4. AltaThera's work in developing and obtaining FDA approval for its new one-day dosing method for Sotalol IV required the investment of millions of dollars over several years and the development of significant, highly valuable trade secrets and confidential information

[1] Sotalol IV is a Vaughan Williams class III antiarrhythmic agent. According to its label, Sotalol IV "has both beta-adrenoreceptor blocking (Vaughan Williams Class II) and cardiac action potential duration prolongation (Vaughan Williams Class III) antiarrhythmic properties."

across a range of areas, including technological innovations, business growth strategies, physician relationship building efforts, market research, commercialization planning, and regulatory strategies.

5. Like many pharmaceutical companies, AltaThera's ability to invest the resources necessary to develop, launch, and market its innovative therapy depended on appropriate protections for the company's intellectual property, so that others could not launch and market a competing antiarrhythmic agent built on AltaThera's investments in a way that would deprive the company of an appropriate return on those investments.

6. AltaThera accordingly maintained its innovative one-day dosing method for Sotalol IV and related business and commercial strategies as confidential while it worked to prepare confidential patent applications to protect its technological innovation, materials to be confidentially submitted to the FDA in order to obtain FDA approval for this new method of use, research on the market potential for this new method, and a plan for selling Sotalol IV for use with this new method to the doctors and hospitals who could provide the drug to patients.

7. AltaThera shared its confidential information and trade secrets with Dr. Somberg—a longtime consultant purportedly acting in AltaThera's interests through Dr. Somberg's consulting company, API—and Hyloris—a publicly-traded Belgian company from which AltaThera had licensed Sotalol IV.

8. Dr. Somberg, API [redacted] entered into contracts agreeing that they would not disclose AltaThera's confidential information or use it for their own business purposes. Pursuant to these contractual guarantees, AltaThera routinely provided its highly confidential and valuable information to [redacted] in the normal course of the parties' business relationships.

9. Unbeknownst to AltaThera, [redacted] Dr. Somberg, API, and Hyloris were secretly working together to take AltaThera's novel ideas, confidential drafts and materials, market research, and know-how, and using them to bring a competing antiarrhythmic drug to market: "intravenous dofetilide" or "Dofetilide IV."

10. By the time AltaThera learned that Defendants were using its confidential information and intellectual property to pursue a competing product, Defendants were already two years into their efforts to obtain patent protection and FDA approval for a Dofetilide IV one-day dosing method. They expect to bring the product to market in 2023.

11. On information and belief, Dr. Somberg, API, and Hyloris never would have pursued Dofetilide IV at all—or, in the alternative, would not have been in a position to pursue Dofetilide IV at the times and in the ways they have—if not for their improper use of AltaThera's confidential and proprietary ideas, information, know-how, and other materials. Through AltaThera's confidential information and intellectual property, Defendants learned about the scientific and commercial potential of an antiarrhythmic drug which can be administered intravenously during a short hospital stay, resulting in savings of time and money for hospitals and patients.

12. For example, Defendants learned about AltaThera's processes which make it possible to administer antiarrhythmic drugs intravenously safely over a short time period during a one-day hospital stay.

13. Defendants also learned how this shorter hospital stay makes an antiarrhythmic drug a more attractive option for hospitals and patients, and the resulting market potential. Hyloris has admitted as much, publicly stating that, "*based on* [a] *survey performed by* ...

*AltaThera* … a significant portion of the existing dofetilide use in hospitals for loading of patients could be converted to IV." (emphasis added).

14. Further, following a confidential meeting AltaThera had with the FDA [redacted], Defendants learned about a cheaper, faster pathway to FDA approval and AltaThera's confidential roadmap for quickly obtaining approval using that pathway for a new method of administering an antiarrhythmic drug. Defendants also learned that the FDA would be receptive to the use of this new regulatory pathway for the approval of new formulations, methods of use, or indications for an IV antiarrhythmic agent.

15. With the benefit of AltaThera's intellectual property and confidential information, Defendants secretly began to develop Dofetilide IV. For example, Dr. Somberg copied verbatim significant portions of a highly confidential patent application he helped prepare for AltaThera into a patent application for Dofetilide IV in his own name, and in doing so failed to identify the inventive contributions of AltaThera's founder, Brandon Kashfian. On information and belief, Dr. Somberg similarly copied portions of AltaThera's confidential regulatory materials prepared in connection with AltaThera's efforts to secure FDA approval of the one-day method for administering Sotalol IV. As for Hyloris, Hyloris has publicly admitted that "[b]ased on the similarities between sotalol and dofetilide, Hyloris has adopted *a very similar development strategy* [to AltaThera's strategy for Sotalol IV] for Dofetilide IV"—a development strategy Hyloris was able to learn only through access to AltaThera's confidential information and trade secrets—and "will therefore develop Dofetilide IV and propose a new loading dose strategy *based on the same scientific rationale* [as that of the Sotalol IV one-day method] … reducing hospitalization duration."

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