

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AQUESTIVE THERAPEUTICS, INC.
Petitioner

v.

IONO PHARMA, LLC
Patent Owner

Case No. IPR2025-00874
U.S. Patent No. 11,021,437

DECLARATION OF HASSAN ALMOAZEN, PH.D.

I, Hassan Almoazen, a resident of Memphis, Tennessee over 18 years of age, hereby declare as follows:

1. I have personal knowledge of all the matters about which I testify in this declaration.

2. I am listed as a sole inventor in U.S. Patent No. 11,021,437 (herein the “’437 Patent”), titled “PHARMACEUTICAL FORMULATIONS FOR SUBLINGUAL OR BUCCAL DELIVERY OF EPINEPHRINE OR A PRO-DRUG THEREOF.” I understand that the ’437 Patent is the patent at issue in this proceeding. I am familiar with the ’437 Patent, including its specification and claims.

3. I earned a Bachelor of Science in Pharmacy and Pharmaceutical Chemistry from Damascus University in 1991. I earned a Ph.D. in Pharmaceutical Sciences from Long Island University in 2002.

4. I am currently employed as an associate professor and Director of the Pharmaceutical Sciences Ph.D. Graduate Program and Dual Degree Pharm.D/Ph.D. Program at the University of Tennessee. I have been employed at the University of Tennessee since 2007. My research focuses on sublingual and pediatric drug delivery.

5. I am currently an Editor for special issue “The Pediatric Formulations: The Present and a Challenge for Future” for the International Journal “*children*”

6. I am also an Editor of special issue “Advanced Strategies for Sublingual and Buccal Drug Delivery” at the International Journal “*Pharmaceutics*”

7. In 2012, I began working on the technology that forms the basis of the '437 Patent, while I was a professor and the Director of the Pharmaceutical Sciences Ph.D. Graduate Program and Dual Pharm.D./Ph.D. Program at the University of Tennessee Health Science Center.

8. In October 2015, I founded Iono Pharma to commercialize various technologies related to my research in pediatric drug delivery. I am the sole owner and employee of Iono Pharma.

9. I was particularly interested in pediatric treatments using fast dissolving films and tablets. I observed that FDA-approved treatments for severe allergies were pharmaceutically limited and sought to fill that gap. I realized that, since Epinephrine shows therapeutic efficacy at low dose, it can be a candidate for incorporation into fast dissolving film delivery. I also realized that since epinephrine has very limited tissue absorption, it can be a candidate for prodrug design. I began researching epinephrine drugs and prodrugs that could be formulated into a fast dissolving film. As claimed in the '437 Patent, I discovered that certain epinephrine prodrugs with certain properties can be formulated into fast dissolving films.

10. I made significant personal sacrifices in the pursuit of my invention. I paid for the prosecution of the '437 Patent from my own personal pension fund. I

also invested portions of my pension fund into pursuing business relationships and licensing agreements with larger entities, including Aquestive Therapeutics, Inc (herein, “Aquestive”). *See, e.g.*, EX2014; EX2015; EX2016; EX2017.

11. Exhibit 2014 is a copy of an email sent to me from Abby Trotter on November 5, 2018, regarding my participation, on behalf of Iono Pharma, in the 2018 Life Science Tennessee Venture Forum.

12. Exhibit 2015 is a copy of an email sent to me from Gareth Sheridan, the CEO of Nutriband, on April 30, 2018, regarding an update on Iono Pharma’s pending projects.

13. Exhibit 2016 is a copy of an email sent to me from Amy Hopper on November 29, 2018, regarding Iono Pharma making it to the semifinal rounds of the Winrock International Delta I-Fund.

14. Exhibit 2017 is an email sent to me from Lili Jiang on October 20, 2020, regarding Iono Pharma’s participation in the China Focus Virtual Partnering Conference.

15. To date, I have invested five-figures from my pension fund into protecting and commercializing the technology claimed in the ’437 Patent.

16. In January 2016, I published a paper in the Pharmaceutical Development and Technology journal titled “Development of a fast dissolving film of epinephrine hydrochloride as a potential anaphylactic treatment for pediatrics.”

EX1022 (herein, the “Almoazen Paper”). That paper discusses “potential proof for using [fast dissolving films] as a replacement therapy of epinephrine injections for pediatrics.” *Id.* at 1.

17. I identified a significant shortcoming with developing a sublingual treatment using just the epinephrine hydrochloride (HCl) discussed in the Almoazen Paper: epinephrine HCl alone demonstrates poor permeability properties, and it cannot be absorbed into the human body. Since Epinephrine has therapeutic efficacy at low dose, it can be a candidate for delivery through buccal membrane or sublingual mucosa. I began investigating epinephrine prodrug compounds to overcome that limited absorption shortcoming. Those epinephrine prodrugs ultimately led to the claims of the '437 Patent.

18. On June 3, 2016, I received an unsolicited email from Ms. Ramona McCudden, a Human Resources representative at Aquestive, then called MonoSol RX, regarding interviewing me for a job opening. Exhibit 2001 is a copy of an email chain of a conversation with Ms. McCudden.

19. After I expressed interest in the position, Dr. Stephen Wargacki, then Aquestive’s Chief Science Officer, asked if I would travel to New Jersey and present on “Pathways and Barriers on Transmucosal Permeation.” EX2001 at 5. I asked to defer the interview process because I was in the process of moving and Ms. McCudden asked me to refer my former students for the job opening. *Id.* at 4.

20. On October 13, 2016, I asked to resume the interview process. *Id.* at 3-4. On October 15, 2016, in a separate email chain, I asked Aquestive if it was interested in “the development of the epinephrine fast dissolving film” and that I intended “to file a provisional patent before January 2017.” EX2002 at 4. Exhibit 2002 is a copy of that email chain.

21. On October 17, 2016, Ms. McCudden told me that I would need “to sign a confidentiality agreement” to discuss my forthcoming patent application with Dr. Wargacki. *Id.* at 3.

22. The next day, I emailed Dr. Wargacki stating that “I believe I have a solution to increase the absorption of epinephrine from the oral cavity and I believe this solution can be patented.” EX2011 at 1. I also told Dr. Wargacki that “I have disclosed this solution in a provisional patent which my lawyer will file next week.” *Id.* Exhibit 2011 is a copy of my email chain with Dr. Wargacki.

23. On October 20, 2016, I agreed to sign the confidentiality agreement. The next day, however, Dr. Wargacki told me that “we do NOT want you to disclose ANY confidential information to us during your visit” but that Aquestive would “revisit [my] provisional” if I was “working directly for [Aquestive].” EX2002 at 2. On October 22, 2016, I canceled my upcoming interview with Aquestive because I “hoped to share my research ideas with [Aquestive] and negotiate partnership and employment agreements” rather than “abandon my research ideas.” *Id.*

24. On October 22, 2016, Dr. Wargacki responded that “do [sic] to the position of this particular molecule in our pipeline, we do not want to comprise our position and IP by discussing potential art with you” and that he hoped I could “understand this from [sic] business perspective.” *Id.* at 1. Dr. Wargacki also requested that I “reconsider with the perspective that this is about employment to be part of a team that drives the companies [sic] vision to reality” and that my “[e]xisting and pending IP would be a subject for discussion upon advancement in the hiring process.” *Id.*

25. On October 22, 2016, I responded that “I am open to reconsider if the management at [Aquestive] is willing to talk about my provisional IP and discuss it as part of the hiring process.” *Id.* I told Dr. Wargacki that “I am not a typical employee that you normally see every day. I am an entrepreneur and have founded Iono Pharma LLC to advance the epinephrine project in addition to other projects I developed at UT and I am looking for a pharma company like MonoSol Rx to partner with me to advance my company.” *Id.* I did not hear back from Aquestive.

26. On June 9, 2018, I informed Dr. Wargacki that the PCT application, WO2018/089570, that eventually matured into the '437 Patent, had published. EX2003 at 1. I asked Dr. Wargacki to “[l]et me know if [Aquestive] has an interest.” *Id.* Dr. Wargacki did not respond to my email request. *Id.* Exhibit 2003 is a copy of that email chain.

27. On October 19, 2021, I learned that Aquestive was pursuing a patent application directed towards epinephrine prodrugs. Because the application's Information Disclosure Statement did not list the '437 Patent, I made a third-party submission of the '437 Patent against the application. EX2004 at 168-170.

28. On August 23, 2022, I received a phone call from Mr. Daniel A. Scola of Hoffman and Baron, LLP, on behalf of Aquestive. Mr. Scola told me that Aquestive wanted to purchase the '437 Patent and that, if I did not sell it, Aquestive would destroy it.

29. On August 25, 2022, Mr. Scola sent me an email stating his "strong preference ... to find a suitable arrangement for Aquestive to obtain rights to your patent, rather than challenge it and ultimately destroy it." EX2008 at 5-6. Mr. Scola further stated that "Aquestive is prepared to cover the cost of your obtaining the patent plus an increment of profit" in exchange for "all rights concerning" the '437 Patent. *Id.* Exhibit 2008 is a copy of that email chain.

30. On September 7, 2022, I declined Aquestive's offer to purchase the '437 Patent. *Id.* at 4. I told Mr. Scola that "Iono Pharma is not interested in selling the IP at this time. We can be interested in a licensing agreement." *Id.* Mr. Scola told me he would "convey [my] intentions to Aquestive and let [me] know when they have provided me with further guidance." *Id.* at 1. Mr. Scola did not respond further.

31. On December 6, 2023, Mr. Hermant Gupta of Epstein Becker Green on behalf of Iono Pharma sent a letter to Mr. Scola to “reopen the dialog” a partnership with Aquestive. EX2009 at 1. After Aquestive failed to respond, Mr. Gupta sent a second letter on March 29, 2024, and informed Aquestive that the “prior license offer communicated in Dr. Almoazen’s email to you on September 7, 2022, is no longer available as Iono Pharma, LLC and Dr. Almoazen are keeping options open with other interested parties.” *Id.* at 2-3. On April 9, 2024, Mr. Scola responded, stating that “Aquestive originally proposed a purchase of the ’437 Patent, as there may have been some future use, but, upon further inspection, the inherent infirmities in its content and prosecution are burdensome.” *Id.* at 4. Exhibit 2009 is a copy of those three letters.

32. I did not hear from Aquestive again until it filed its petition for *Inter Partes* Review on May 16, 2025.

33. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code. If called to testify as to the truth of the matters stated herein, I could and would testify competently.

Executed this 18th day of August, 2025.

Hassan Almoazen

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