

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.
UNDER 37 C.F.R. §1.130

DECLARATION OF HASSAN ALMOAZEN

I, Hassan Almoazen, declare as follows:

1. 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.”

2. Alaadin Alayoubi, Lindsay Haynes, Hemlata Patil, Baher Daihom, Richard Helms, and I are identified as co-authors of “Development of a fast dissolving film of epinephrine hydrochloride as a potential anaphylactic treatment for pediatrics” published on January 6, 2016, in Pharmaceutical Development and Technology (herein the “Almoazen Paper” (EX1022)).

3. I understand that Petitioner cites the following disclosures from the Almoazen Paper against certain claim limitations of the ’437 Patent:

- A. “*Objective*: To develop a fast dissolving film strip containing epinephrine HCl for the potential treatment of pediatric anaphylaxis” as disclosed in the abstract.
- B. “Fast dissolving films (FDF) could be a promising alternative for the delivery of epinephrine. These are very thin strips that disintegrate or dissolve very rapidly in the oral cavity, releasing

the medication to be absorbed through the oro-mucosal route” as disclosed in the introduction.

C. “The formulations compositions of the FDFs are mentioned in Table 1” as disclosed in the methods section.

Table 1. List of the compositions of the four FDFs formulations.

Ingredient (% w/w)	Use	F1	F2	F3	F4
Epinephrine HCl	Drug	5.9	5.9	5.9	5.9
Sodium metabisulfite	Antioxidant	5.9	5.9	5.9	5.9
Lycoat [®] RS720 (hydroxypropyl starch)	Film-forming polymer	20	25	27	30
Glycerin	Plasticizer	3	3	3	3
Tween 80	Surfactant	2	2	2	2
Citric acid monohydrate	Buffer; increases absorption in oral cavity	0.5	0.5	0.5	0.5
Sodium citrate monobasic	Buffer	0.5	0.5	0.5	0.5
Xylitol	Sweetener	10	10	10	10
Tutti Frutti	Flavor	6	6	6	6
Water		46.2	41.2	39.2	36.2

D. “Other excipients and epinephrine HCl were added to the solution on the next day at room temperature” as disclosed in the methods section.

E. “Volunteers were asked to place the film on the interior surface of their buccal cavity until film is fully disintegrated” as disclosed in the *Human taste panel* section.

F. “A dose range of 5 mg to 30 mg of a drug can only be incorporated into the film” as disclosed in the results and discussion section.

4. I am submitting herewith as Exhibit 2018 a copy of the Almoazen Paper that has these portions highlighted in orange.

5. Of the five other authors listed on the Almoazen Paper, four of the authors—Alaadin Alayoubi, Lindsay Haynes, Hemlata Patil, and Baher Daihom—were post doctorate, graduate or undergraduate students working under my direction and supervision. I alone came up with the concepts that the Petitioner cites from the Almoazen Paper in the Petition, without input from any one of my post doctorate, graduate or undergraduate students.

6. The remaining author, Richard Helms, was a pharmacy clinical faculty collaborator from the University of Tennessee Health and Science Center, Le Bonheur Children's Hospital. He also did not come up with the concepts that the Petitioner cites from the Almoazen Paper in the Petition. Mr. Helms' only contribution was assisting with putting pen-to-paper the results of the experiments and the associated technical explanations in a manner that is more suitable for publication. Mr. Helms did not work in my laboratory, nor did he contribute to coming up with the concepts that the Petitioner cites from the Almoazen Paper prior to the experiments having been carried out.

7. 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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