

UNITED STATES PATENT AND TRADEMARK OFFICE

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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AQUESTIVE THERAPEUTICS, INC.

Petitioner

v.

IONO PHARMA, LLC

Patent Owner

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Case No. IPR2025-00874

U.S. Patent No. 11,021,437 B2

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**PETITIONER'S REQUEST FOR DIRECTOR REVIEW  
OF DISCRETIONARY DENIAL DECISION DENYING INSTITUTION OF  
*INTER PARTES* REVIEW**

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**EXHIBITS REFERENCED IN THIS BRIEF**

| <b>Exhibit</b> | <b>Description</b>                                                                                                                                                                                                                              |
|----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| EX1001         | <b>The ‘437 Patent</b> - U.S. Patent No. 11,021,437 B2, entitled “ <i>Pharmaceutical Formulation For Sublingual Or Buccal Delivery Of Epinephrine Or A Pro - Drug Thereof</i> ”, Almoazen inventor, <u>issued on June 1, 2021</u> .             |
| EX1002         | <b>Truelove 1</b> - U.S. Patent No. 3,809,714, entitled “ <i>Novel Ester Of [(Methylamino)Methyl] Benzyl Alcohol</i> ”, Hussain and Truelove inventors, <u>issued on May 7, 1974</u> .                                                          |
| EX1005         | <b>‘437 FH</b> - U.S. Patent No. 11,021,437 prosecution file history, serial no. 16/347,625.                                                                                                                                                    |
| EX1014         | <b>‘437 PCT Application</b> , WO2018/089570 A1 (PCT/US2017/060761), entitled “ <i>Pharmaceutical Formulation For Sublingual Or Buccal Delivery Of Epinephrine</i> ”, <b>Almoazen and Haynes</b> , co-inventors, <u>published May 17, 2018</u> . |
| EX1050         | <b>Rautio</b> - Declaration of Jarkko Rautio, Ph.D.                                                                                                                                                                                             |
| EX1051         | <b>Meanwell</b> - Declaration of Nicholas A. Meanwell, Ph.D.                                                                                                                                                                                    |

|        |                                                                  |
|--------|------------------------------------------------------------------|
| EX2008 | Email Correspondence between Daniel Scola and Hassan<br>Almoazen |
|--------|------------------------------------------------------------------|

## I. REQUEST FOR DIRECTOR REVIEW

Petitioner, Aquestive Therapeutics, Inc., requests Director Review of the Decision Denying Institution of *Inter Partes* Review (Paper 11, “Decision”), in accordance with the March 26, 2025 Memorandum on Interim Processes for PTAB Workload Management (“Process Memorandum”)<sup>1</sup> as updated on the Interim Director Discretionary Process Webpage.<sup>2</sup> Petitioner requests Director Review, because the Decision was based on, *inter alia*, an erroneous material fact – the date the patent issued, which resulted in discretionary denial and because the other considerations relied on in the Decision do not weigh in favor of discretionary denial, especially as there are no parallel proceedings. Petitioner respectfully requests the Director vacate the Decision and refer the Petition to the Board.

### A. The Erroneous Finding of Material Fact.

The Decision erroneously relies on 2018 as the issue date of challenged U.S. Patent No. 11,021,437 (“the ‘437 Patent”), a date seven (7) years prior to the filing of the Petition. Decision 2. However, the challenged patent issued on June 1, 2021, and the Petition was filed May 13, 2025, within four (4) years after the ‘437

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<sup>1</sup> <https://www.uspto.gov/sites/default/files/documents/InterimProcesses-PTABWorkloadMgmt-20250326.pdf>.

<sup>2</sup> <https://www.uspto.gov/patents/ptab/interim-director-discretionary-process>.

Patent's issue date - not the seven (7) years implicated by the Decision. U.S.

Patent No. 11,021,437 (“the ‘437 Patent”), EX1001; *see also* portion of first page of EX1001 copied below.

|                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |           |                     |        |              |           |   |        |       |           |   |        |         |              |    |        |                |              |    |        |                     |              |    |        |                |
|-----------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|---------------------|--------|--------------|-----------|---|--------|-------|-----------|---|--------|---------|--------------|----|--------|----------------|--------------|----|--------|---------------------|--------------|----|--------|----------------|
| (12) <b>United States Patent</b><br><b>Almoazen</b>                                                                   | (10) <b>Patent No.:</b> <b>US 11,021,437 B2</b><br>(45) <b>Date of Patent:</b> <b>Jun. 1, 2021</b>                                                                                                                                                                                                                                                                                                                                                                                                                    |           |                     |        |              |           |   |        |       |           |   |        |         |              |    |        |                |              |    |        |                     |              |    |        |                |
| (54) <b>PHARMACEUTICAL FORMULATION FOR<br/>SUBLINGUAL OR BUCCAL DELIVERY OF<br/>EPINEPHRINE OR A PRO-DRUG THEREOF</b> | <table> <tr> <td>4,136,145</td> <td>A</td> <td>1/1979</td> <td>Fuchs et al.</td> </tr> <tr> <td>4,145,441</td> <td>A</td> <td>3/1979</td> <td>Bodor</td> </tr> <tr> <td>4,320,144</td> <td>A</td> <td>3/1982</td> <td>Resnick</td> </tr> <tr> <td>2003/0180357</td> <td>A1</td> <td>9/2003</td> <td>Martino et al.</td> </tr> <tr> <td>2007/0202163</td> <td>A1</td> <td>8/2007</td> <td>Rawas-Qalaji et al.</td> </tr> <tr> <td>2019/0022023</td> <td>A1</td> <td>1/2019</td> <td>Schobel et al.</td> </tr> </table> | 4,136,145 | A                   | 1/1979 | Fuchs et al. | 4,145,441 | A | 3/1979 | Bodor | 4,320,144 | A | 3/1982 | Resnick | 2003/0180357 | A1 | 9/2003 | Martino et al. | 2007/0202163 | A1 | 8/2007 | Rawas-Qalaji et al. | 2019/0022023 | A1 | 1/2019 | Schobel et al. |
| 4,136,145                                                                                                             | A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 1/1979    | Fuchs et al.        |        |              |           |   |        |       |           |   |        |         |              |    |        |                |              |    |        |                     |              |    |        |                |
| 4,145,441                                                                                                             | A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 3/1979    | Bodor               |        |              |           |   |        |       |           |   |        |         |              |    |        |                |              |    |        |                     |              |    |        |                |
| 4,320,144                                                                                                             | A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 3/1982    | Resnick             |        |              |           |   |        |       |           |   |        |         |              |    |        |                |              |    |        |                     |              |    |        |                |
| 2003/0180357                                                                                                          | A1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 9/2003    | Martino et al.      |        |              |           |   |        |       |           |   |        |         |              |    |        |                |              |    |        |                     |              |    |        |                |
| 2007/0202163                                                                                                          | A1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 8/2007    | Rawas-Qalaji et al. |        |              |           |   |        |       |           |   |        |         |              |    |        |                |              |    |        |                     |              |    |        |                |
| 2019/0022023                                                                                                          | A1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 1/2019    | Schobel et al.      |        |              |           |   |        |       |           |   |        |         |              |    |        |                |              |    |        |                     |              |    |        |                |
| (71) Applicant: <b>Iono Pharma, LLC</b> , Bartlett, TN (US)                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |           |                     |        |              |           |   |        |       |           |   |        |         |              |    |        |                |              |    |        |                     |              |    |        |                |
| (72) Inventor: <b>Hassan Almoazen</b> , Bartlett, TN (US)                                                             | OTHER PUBLICATIONS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |           |                     |        |              |           |   |        |       |           |   |        |         |              |    |        |                |              |    |        |                     |              |    |        |                |
| (73) Assignee: <b>IONO Pharma, LLC</b> , Bartlett, TN (US)                                                            | Arya, A. et. al., “Fast dissolving oral films: An innovative drug delivery system and dosage form,” Int. J. ChemTech Res., vol. 2,                                                                                                                                                                                                                                                                                                                                                                                    |           |                     |        |              |           |   |        |       |           |   |        |         |              |    |        |                |              |    |        |                     |              |    |        |                |

The error is predicated on an erroneous finding that the issue date was 2018 and not 2021. Specifically, the Decision states: “Patent Owner informed Petitioner of the preparation of a provisional application in 2016, as well as the publication of the non-provisional PCT patent application that matured into the challenged patent in 2018”. Decision 2 (emphasis added). The Decision makes no other reference to the ‘437 Patent’s issue date. As is clear from the above, that was an error. The excerpt from the Patent Owner’s brief cited in the Decision for supporting an erroneous 2018 date was referring to when the PCT application was provided to Petitioner and not the actual issue date of the ‘437 Patent. *See* DD Req. 5. At that point in time there was only a PCT application with claims that could be and ultimately were significantly amended.

The 2021 issue date of the ‘437 Patent was less than four (4) years from the filing date of the Petition (May 16, 2025), two (2) years before the six (6) year touchstone for favoring a Patent Owner’s settled expectations. Using the incorrect 2018 issue date, which placed the filing of the Petition seven (7) years out from the alleged issuance of the ‘437 Patent, was a material mistake that tainted the Decision’s consideration of the facts asserted by Patent Owner. Reliance on this material mistake must be addressed. Importantly, the filing of a petition within four (years) after a patent’s issuance with its final patent claims, does not, in and of itself, support settled expectations.

B. Patent Owner’s Notices of Applications Do Not Favor Discretionary Denial.

The Decision further places weight on Patent Owner’s notices to Petitioner that (i) Patent Owner was preparing to file a provisional application, and (ii) a PCT application was published. These unsolicited notices do not counsel in favor of discretionary denial. The trigger date for Patent Owner’s settled expectations can only reasonably be the date the final claims issue because this is when their validity and patentability are available to be challenged. In fact, the Process Memorandum clearly indicates that settled expectation is decided based on “the length of time the claims have been in force.” Process Memorandum 3 (emphasis added). Clearly, neither a provisional application nor a published PCT application

can be considered as having claims “in force” so as to favor Patent Owner’s request for discretionary denial.

Arguably, at most the notices go to Petitioner’s knowledge that an application was pending and could eventually be subject to examination by the US Patent Office. Notably, the scope of the PCT application claims was so broad that the International Search Report (“ISR”), included with the PCT application provided to Petitioner, presented prior art “X” references, indicating “the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone.” ‘437 PCT Application, EX1014, p.32. Any party having reviewed the ISR would have understood that the PCT application claims would require significant amendment if there was any hope that a patent would ultimately issue. *See, e.g.,* Pet., p.21-22 (claims amended to add “a half-life  $t_{1/2}$  range from 1-6 minutes”). Thus, consideration of the PCT application and its relevance, if any, would have been premature until such amendments were made and a patent issued with those amended claims. However, filing the Petition less than four (4) years after issuance, as is the case herein, does not favor discretionary denial.

C. Rule 56 IDS Citations Should Not Be a Factor in Favoring Discretionary Denial.

The Decision relies on Petitioner's citation of the '437 Patent in IDS's Petitioner submitted to the USPTO in connection with its own patent applications. However, this should not be a consideration in determining denial, because once any patent applicant is informed of a potential prior art reference the applicant is basically required to file notice of same in an IDS to fulfill its Rule 56 duty of disclosure obligations. To do otherwise potentially jeopardizes Petitioner's own subsequently issued patents, because it is necessary for an applicant to protect against an adversary arguing, rightly and wrongly, that a reference was material and was not cited in an IDS. At most, the citation goes to Petitioner's knowledge of the '437 Patent within the four (4) years prior to filing the Petition.

D. Petitioner's Offer to Purchase the Patent Does Not Favor Discretionary Denial.

The Decision also relies on the attempt by Petitioner to purchase the '437 Patent. Purchasing the patent would have avoided any necessity to file a costly IPR Petition with a necessarily concomitant increase in the Board's workload. DD Opp, Paper 8, 31; EX2008, p.4; *see Rates Tec., Inc. v. Speakeasy, Inc.*, 685 F.3d 163, 172 (2d Cir. 2012) ("courts have recognized a strong judicial policy favoring the settlement of litigation, including patent litigation"). However, statements by

Petitioner to Patent Owner that ‘437 Patent possessed obvious infirmities, coupled with Petitioner’s threats to destroy it provided Patent Owner with more than adequate notice that the ‘437 Patent would likely be challenged. Thus, rather than providing comfort to the Patent Owner that no challenges should be expected, such communications put the Patent Owner on notice that a challenge should be expected and thus does not weigh in favor of discretionary denial.

E. Material Factual Errors Made During Prosecution Were Fundamental to the Improper Issuance of the ‘437 Patent.

**To begin**, a quick summary of the patented ‘437 Patent invention is warranted. The ‘437 Patent is directed to prodrug compounds of epinephrine. The prodrug compounds provide increased permeability in penetrating the sublingual and buccal membranes as compared to the permeability of epinephrine itself through the membranes. The prodrugs are formed by adding diester groups to the epinephrine to form the epinephrine prodrug compounds, which must then penetrate the membranes. As described in the ‘437 Patent:

Once the prodrug penetrates biological membranes (sublingual and buccal), the biological enzyme carboxyesterase will degrade the ester bond and release epinephrine for therapeutic activity. A prodrug is a biologically inactive compound that can be metabolized in the body to produce a drug. One characteristic of the selected prodrug compounds is **fast hydrolysis in plasma**.

‘437 Patent, EX1001, 2:65-3:4 (emphasis added). The ‘437 Patent quantifies the speed of hydrolysis of the prodrug in plasma as the compound’s half-life and claims a “half-life  $t_{1/2}$  range from 1-6 minutes” for these epinephrine prodrug compounds. This is the time for one half of the diester prodrug of epinephrine compound to have its diesters cleaved by enzymatic hydrolysis of the prodrug in human plasma so as to release epinephrine into the plasma. Pet., pp. 17-18; Rautio, ¶¶106-114; Meanwell, ¶¶100-108.

**The errors.** The Office committed factual errors during the prosecution of the ‘437 Patent. It is clear that without these factual errors the ‘437 Patent would not have been issued. The Examiner’s errors were not due to interpretation, but due to her ignoring the clear, express disclosures of the ‘437 Patent.

The ‘437 Patent is completely devoid of data relating to the amended language, *i.e.* a “half-life  $t_{1/2}$  range from 1-6 minutes”. The patent’s sole reference to a half-life value is to the Truelove 1 (prior art) epinephrine prodrug as having a half-life of 30 minutes. DD Opp 6-7; Rautio, EX1050, ¶¶67, 414; Meanwell. EX1051, ¶100.

**First**, the Examiner confused disclosures relating to “epinephrine” with disclosures relating to the claimed “prodrugs of epinephrine”. She also improperly

relied on disclosures relating to the release of epinephrine from a film in “simulated saliva”, confusing them with disclosures relating to the claimed “enzymatic hydrolysis” of prodrugs in human plasma. In doing so, *e.g.*, she improperly relied on the epinephrine-containing film formulation data found in Table 5 and Figure 9, respectively, of the ‘437 Patent and erroneously used this data as if it actually applied to the claimed diester prodrugs of epinephrine. However, Table 5 and Figure 9 only disclose “epinephrine” film formulations containing “epinephrine” and do not disclose the claimed formulations containing “the epinephrine prodrug”. Importantly, she also confused the release of epinephrine from an epinephrine film in “simulated saliva” as shown in Figure 9 with the claimed “enzymatic hydrolysis” in human plasma of the claimed prodrug of epinephrine. These improper material substitutions are laid out in the ‘437 Patent’s Statement of the Reasons for Allowance.

### Statement of Reasons for Allowance

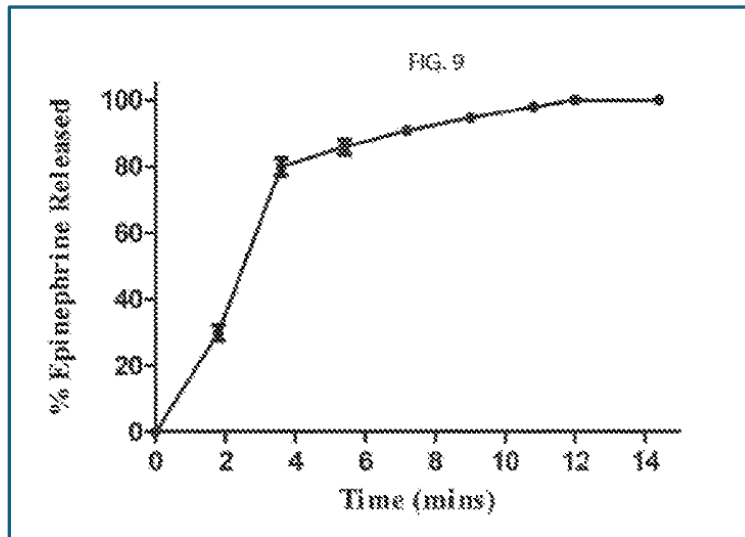
**. . . . Applicants have demonstrated novel compound structures in their disclosure as originally filed.[<sup>3</sup>] Applicants' disclosure includes embodiments built around the claimed Formula and discloses the species embodiments and their Log P values. Applicants' disclose that epinephrine formulations have disintegrations times ranging from 10 to 30 seconds (see specification, p. 14, Table 5) and further disclose exemplified embodiment of epinephrine release from hydrolysis where the half-life is within 4 minutes (see Drawings, Fig. 9).**

'437 FH, Exhibit 1005, pdf. p. 14 (emphasis added).

Focusing on Figure 9: Figure 9 does not relate to the claimed prodrugs of epinephrine, nor their associated half-lives. Figure 9 merely discloses the timeline for the release of epinephrine in simulated saliva from a film containing epinephrine (not the claimed epinephrine prodrug).

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<sup>3</sup> The '437 Patent states that the Figure 7 diester prodrugs of epinephrine (three of which are claimed and challenged) were taken from the prior art, namely Truelove 1 (Exhibit 1002). '437 Patent, EX1001, 2:5-39; Rautio, EX1050, ¶¶ 54-59.



‘437 Patent, EX1001, Figure 9. As described in the ‘437 Patent:

FIG. 9 shows a release profile of the epinephrine [not epinephrine prodrug] from the optimized fast dissolving film in 500 ml Simulated Saliva [not human plasma] at 37° C.

‘437 Patent, EX1001, 4:13-15 (emphasis added); *see also* DD Opp. 6-7, 11-12; Pet., pp.23-24; Rautio, EX1050, ¶90. Thus, the Statement of the Reasons for Allowance, citing Figure 9’s disclosure as support for the claimed half-life  $t_{1/2}$  of four (4) minutes, was baseless. The “half-life” the Examiner deduced from Figure 9 is for the disintegration of a film containing epinephrine (not a prodrug) via “simulated saliva” and not for the claimed “enzymatic hydrolysis” of the diester prodrug of epinephrine in human plasma.

The Office's error was material because the claim limitation of a "half-life  $t_{1/2}$  range from 1-6 minutes" was essential to the allowance of the '437 Patent.

**Applicant has amended claims and persuasively argued the unexpected result of the claimed epinephrine prodrug genus having a rapid half-life ranging from 1 to 6 minutes. Applicant points out that prior art prodrugs have 30 minute half-life. The instantly claimed genus is thus suitable for sublingual or buccal administration having a much shorter half-life.** Subsequent to persuasive arguments the rejection is withdrawn.

'437 FH, Exhibit 1005, pdf. p. 14 (emphasis added).

By misstating what Table 5 and Figure 9 disclosed, the Examiner erroneously cited them as support for the issuance of the '437 Patent, notwithstanding the prior art. Thus, the Examiner committed material errors in allowing the '437 Patent to issue by (i) substituting disclosures relating to "epinephrine" for disclosures relating to the claimed "epinephrine prodrug" and (ii) substituting the release of epinephrine from an epinephrine film in simulated saliva for the "enzymatic hydrolysis" of the claimed epinephrine prodrug in human plasma.

**Second**, the Examiner accepted without analysis, Patent Owner's arguments that the prior art, as exemplified by Truelove 1 (EX1002), only disclosed diester

prodrugs of epinephrine with half-lives greater than thirty (30) minutes in human plasma (see above) – this is also not correct because Truelove 1, Table 3 itself unequivocally disclosed half-lives of diester prodrugs of epinephrine falling within the claimed 1-6 minutes. *See* DD Opp. 5-12, 38-49; *see also*, Pet., pp.35-39; Rautio, EX1050, ¶¶81, 87, 116-179; Meanwell, ¶¶44-91. This mistake was also material to the issuance error of the ‘437 Patent.

Addressing these material Office errors is certainly a salutary use of the post grant process.

## **II. CONCLUSION**

As discussed above, the Decision relied on the incorrect 2018 date for the issuance of the ‘437 Patent, a date which erroneously put the length of time the claims were in force seven (7) years out from the filing of the Petition, and not the actual 2021 date of its issuance, which was less than four (4) years out from the filing of the Petition. If the correct 2021 issue date is applied, the Petition was filed in less than four (4) years from the date the ‘437 Patent claims were in force.

The Decision begins by crediting the fact that the parties are not engaged in a parallel proceeding involving the challenged patent as counseling against discretionary denial. Decision 2; DD Opp. 8. Petitioner agrees.

Additionally, the Decision's reliance on Petitioner's awareness of the filing of Patent Owner's provisional application or the publication of Patent Owner's '437 PCT Application is contrary to the Process Memorandum direction to consider the time the claims are in force and fails to support any claim of settled expectations. Additionally, mere notice of a provisional application, yet to be filed or disclosed, or publication of a PCT application, do not favor discretionary denial. This is especially true in view of the ISR cited "X" references for the '437 PCT Application.

Further, the limited discussions regarding possibly acquiring rights to the challenged patent occurred after the patent issued in 2021. These discussions expressly put Patent Owner on notice that its patent would be invalidated if the parties could not arrive at a reasonable business resolution. However, Patent Owner's demands were unreasonable, and the parties' discussions quickly concluded. These limited discussions do not support settled expectations, nor do they weigh in favor of discretionary denial.

The listing of the '437 Patent in IDS filings by the Petitioner was at the very least arguably associated with the requirements of Rule 56 and as such could provide no comfort or expectation to Patent Owner that the '437 Patent would not be the subject of an *inter parties* review.

Finally, institution would permit the Board to correct the material errors associated with the prosecution of the ‘437 Patent that directly led to the ‘437 Patent’s imprudent issuance in the first place. Correcting these material errors, as they relate to the prior art and otherwise, via an *inter partes* review proceeding is an appropriate use of Board resources.

Thus, without waiving any arguments in its Brief Opposing Discretionary Denial, Petitioner respectfully requests that the Director determine that discretionary denial of institution is not appropriate in this proceeding, vacate the Decision and refer the Petition to the Board for merits review.

Dated: October 27, 2025.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

Pursuant to 37 C.F.R. § 42.6(e), the undersigned certifies that on October 27, 2025, a complete copy of the foregoing document was served on counsel of record for the Patent Owner by filing this document through P-TACTS and by sending this document via electronic mail to the following addresses:

|                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
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Dated: October 27, 2025

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