Jose L. Linares
Mark M. Makhail
MCCARTER & ENGLISH, LLP
4 Gateway Center
Newark, NJ 07102
(973) 622-4444
jlinares@mccarter.com
mmakhail@mccarter.com

Christopher M. Mikson
Perham Gorji (*pro hac vice* forthcoming)
DLA PIPER LLP (US)
500 Eighth Street, NW
Washington, DC 20004
(202) 799-4000
christopher.mikson@us.dlapiper.com
perham.gorji@us.dlapiper.com

Michael Sitzman (*pro hac vice* forthcoming)
MCDERMOTT WILL & SCHULTE LLP
415 Mission Street, Suite 5600
San Francisco, CA 94105
(628) 218-3800
msitzman@mwe.com

Timothy P. Best (*pro hac vice* forthcoming)
MCDERMOTT WILL & SCHULTE LLP
2049 Century Park East, Suite 3200
Los Angeles, CA 90067-3206
(310) 551-9321
tbest@mwe.com

Attorneys for Taiho Pharmaceutical Co., Ltd. and Taiho Oncology, Inc.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TAIHO PHARMACEUTICAL CO., LTD., a Japanese Limited Liability Company, and TAIHO ONCOLOGY, INC., a Delaware corporation,

Plaintiffs,

v.

JOHN SQUIRES, in his official capacity as the Director of the United States Patent and Trademark Office; THE UNITED STATES PATENT AND TRADEMARK OFFICE; MARTIN A. MAKARY, in his official capacity as Commissioner of the Food and Drug Administration; THE UNITED STATES FOOD AND DRUG ADMINISTRATION; ROBERT F. KENNEDY, JR., in his official capacity as the Secretary of Health and Human Services; THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendants.

Civil Action No.: _____

COMPLAINT

Plaintiffs Taiho Pharmaceutical Co., Ltd. and Taiho Oncology, Inc. (collectively "Taiho") bring this Complaint against Defendants Acting Director Coke Morgan Stewart, the United States Patent and Trademark Office ("PTO"), Commissioner Martin A. Makary, the United States Food and Drug Administration ("FDA"), Secretary Robert F. Kennedy, Jr., and the United States Department of Health and Human Services ("HHS") (collectively, the "Defendants") and in support thereof Taiho alleges the following:

NATURE OF THE CASE

1. Taiho seeks relief under the Administrative Procedure Act, 5 U.S.C. §§ 551–706, to set aside the denial of its two identical applications for patent-term extension (collectively, the "PTE applications") under 35 U.S.C. § 156 with respect to U.S. Patent Nos. 9,108,973 and 10,434,103 (respectively the "'973 and '103 patents" and collectively the "Patents").

2. In denying the PTE applications, the PTO does not claim that Taiho's circumstances lacked any of the substantive requirements for obtaining PTE. Instead, the PTO denied Taiho's PTE applications on the sole basis that it deemed the application to be filed out of time. This conclusion, however, was based on its legally erroneous and arbitrary and capricious decision to afford Taiho less time to file than Congress prescribed in 35 U.S.C. § 156(d)(1).

3. Under 35 U.S.C. § 156(d)(1), a patent owner may file an application "within a sixty-day period beginning on the date the product received permission . . . for commercial marketing or use."

4. Taiho received a defective approval letter from FDA on September 30, 2022. Exhibit A. Taiho promptly notified FDA of its error by letter dated October 3, 2022. Exhibit B. It only received a corrected approval—from which it obtained effective permission to market and use its products—by letter dated October 5, 2022. Exhibit C. Taiho was not permitted to sell and did not sell

the approved product until after October 5, 2022. Taiho filed its PTE applications on November 29, 2022—55 days after the corrected approval letter.

5. Contrary to Congress's command, however, the PTO determined that (1) Taiho effectively had only 59 days, instead of 60 days, to submit its PTE applications and (2) the period to file the PTE applications began when Taiho received the defective letter on September 30 instead of when Taiho received the corrected approval letter on October 5, 2022. To make matters worse, the PTO disregarded the supplement to the PTE applications submitted by Taiho which corrected the paragraphs in the PTE applications referencing the date of first permitted commercial marketing to state the October 5, 2022 date of the corrected FDA action letter.

6. Defendants' denial of Taiho's PTE applications carries devastating consequences. Taiho invested years of research and millions of dollars in developing a life-saving cancer drug called LYTGOBI. To help recoup that investment and allow for the funding of additional research into new uses of LYTGOBI or new therapeutics, Taiho sought patent protection and—based on the time taken by FDA for regulatory review—a statutory award of PTE. Defendants did not deny Taiho's PTE applications based on any public health rationale or because they thought it would help patients. Instead, they denied Taiho's PTE applications because—based on an erroneous interpretation of law and arbitrary and capricious conduct—they deemed the PTE applications one day late.

7. Defendants' decision is not only legally erroneous as well as arbitrary and capricious, but also profoundly unfair and undermines the remedial purpose of the PTE process. Defendants' decision threatens to inflict enormous harm on Taiho. The PTE applications for the '973 patent (1,330 days) and the '103 patent (188 days) would have extended the patent term to October 5, 2036. Taiho estimates that the denial of the PTE applications and the consequent early loss of exclusivity will result in a loss of over $1 billion over the life cycle of LYTGOBI.

8. Defendants' decision also has devastating public health consequences. By erecting an arbitrary barrier to obtaining PTE in this case, the PTO's position undermines the Hatch-Waxman Act's incentives for innovation which were designed to encourage the expensive, time-consuming, and unpredictable research necessary to develop a new drug and bring it to market. The unexpectedly early loss of exclusivity will lessen Taiho's ability to conduct further clinical research into promising new indications for LYTGOBI.

9. Taiho has formally and informally requested that Defendants reconsider their respective positions. Those requests have all been denied.

10. Having exhausted its other options for a remedy, Taiho respectfully requests that this Court set aside the defendants' erroneous denial of Taiho's PTE applications.

PARTIES

11. Plaintiff Taiho Pharmaceutical Co., Ltd. is a wholly owned subsidiary of Otsuka Holdings, is a Japanese liability company with its principal place of business in Tokyo, Japan, and is the owner of the '973 and '103 patents. Taiho is an innovative pharmaceutical company focused on research and development of cancer treatments.

12. Plaintiff Taiho Oncology, Inc. is incorporated in the State of Delaware, has a principal place of business in Princeton, New Jersey, is the holder of NDA 214801 for LYTGOBI (futibatinib) (the "NDA") and has authorized Taiho Pharmaceutical Co., Ltd. to rely on its regulatory activities conducted before FDA in connection with the NDA for purposes of the PTE applications and the Patents that are the subject of this matter. Exhibit D.

13. Defendant John Squires is the Director of the PTO. Taiho is suing him in his official capacity as Director.

14. Defendant PTO is a federal agency within the United States Department of Commerce.

Its headquarters are in Alexandria, Virginia.

15. Defendant Martin A. Makary is the Commissioner of FDA. Taiho is suing him in his official capacity as Commissioner.

16. Defendant FDA is a federal agency within HHS. FDA's headquarters are located in Silver Spring, Maryland.

17. Defendant Robert F. Kennedy, Jr. is the Secretary of HHS. Taiho is suing him in his official capacity as Secretary.

18. HHS is a cabinet-level federal agency with its headquarters in the District of Columbia.

JURISDICTION AND VENUE

19. The Court has subject-matter jurisdiction over this action under 28 U.S.C. § 1331 because Taiho raises all its claims under the federal Administrative Procedure Act, 5 U.S.C. §§ 551–706. The Court has subject-matter jurisdiction pursuant to 28 U.S.C. § 1338(a) because this case arises under 35 U.S.C. § 156, a statute relating to patents, and 28 U.S.C. § 1338(a) because this is an action seeking to compel federal officers to perform their duties.

20. There exists an actual and justiciable controversy between Taiho and Defendants requiring resolution by this Court, including injunctive relief to prohibit Defendants from violating laws and regulations. This Court has jurisdiction pursuant to 28 U.S.C. §§ 2201-2202.

21. Venue is proper here under 28 U.S.C. §§ 1391(b) & (e).

22. Trenton is the proper vicinage for this case under Local Rule 40.1 of the Local Civil Rules of the District Court for the District of New Jersey because it is the vicinage of Plaintiff Taiho Oncology, Inc.'s principal place of business.

23. These connections to New Jersey also satisfy the requirements of personal jurisdiction under New Jersey law and the federal Constitution.

24. The defendants' denial of Taiho's requests for reconsideration constitutes a final agency action for purposes of 5 U.S.C. § 704.

BACKGROUND

The Patents and FDA Approval

25. The Patents are directed to LYTGOBI, an innovative cancer medicine used to treat adults with cholangiocarcinoma, a cancer that develops in the bile ducts that has a specific gene mutation. LYTGOBI is indicated for patients in whom the cancer is locally advanced or metastatic after treatment with other therapeutics and has spread to such an extent that it cannot be removed surgically and thus offers treatment to patients in dire conditions. Patients are administered LYTGOBI in tablet form and it blocks a specific enzyme involved in the cancer's growth and thus prevents further spread.

26. Since its approval in 2022, LYTGOBI has been administered to thousands of patients who otherwise would have no further treatment options for their bile duct cancer that was previously treated, is unresectable, is locally advanced or metastatic, and carries a specific gene mutation.

27. Taiho filed its patent applications that resulted in the '973 and '103 patents on January 17, 2013 and March 31, 2016, and the PTO issued the Patents on July 29, 2015 and September 18, 2019, respectively. As a result, Taiho's twenty-year patent terms expire on February 13, 2033 (including 27 days of patent term adjustment under 35 U.S.C. §154(b)) and March 31, 2036, respectively.

28. Although Taiho obtained issuance of the Patents by the PTO, Taiho could not begin marketing LYTGOBI on that basis. Apart from the patent process, drugs like LYTGOBI must be investigated in several preclinical studies and in human clinical trials under an Investigational New Drug application ("IND"). Those results are then incorporated in a New Drug Application ("NDA")

filed with FDA. Only after a difficult and expensive approval process that can take many years—consuming much of the patent term—may the NDA applicant receive permission from FDA to market and sell the product commercially.

29. Taiho began its clinical development of LYTGOBI on March 12, 2014, the effective date of its IND. Taiho conducted human clinical trials in 103 patients between March 12, 2014 and January 31, 2022 with LYTGOBI. On January 31, 2022, Taiho filed for accelerated approval with FDA, a special process designed to expedite the approval of drugs treating serious conditions that existing medicine cannot adequately treat. As FDA recognized, LYTGOBI was one of these critical new medicines.

30. FDA issued an approval letter on Taiho's NDA on September 30, 2022. Exhibit A. Unfortunately, that letter was defective as it contained at least two material errors.

31. First, the September 30 letter provided text for the Prescribing Information that erroneously listed the approval date as "YYYY" rather than 2022. Exhibit A. Second, the September 30 letter provided carton and container labeling that inaccurately specified the storage conditions as "Store below 30°C (86°F). Do not refrigerate or freeze." Exhibit A. On the contrary, LYTGOBI tablets have not been shown to be safe and effective if stored above 25°C or below 20°C. As later confirmed by FDA, LYTGOBI tablets must be stored from 20°C to 25°C (68°F to 77°F) with only "excursions" (meaning brief periods) permitted between 15°C and 30°C (59°F to 86°F). Exhibit C.

32. Because of these errors in FDA's September 30 letter, Taiho did not have permission to market or use the product commercially as of that date. FDA's September 30 letter explicitly stated that the labeling must be "identical to the enclosed" labeling. meaning the labeling provided with that letter. Exhibit A. Thus, had Taiho marketed at that time it would have been compelled to use an erroneous label—endangering patients and exposing Taiho to liability for engaging in prohibited acts

under the Federal Food, Drug, and Cosmetic Act for false labeling and misbranding drugs. 21 U.S.C. §§ 352(a), 331(a). Thus, Taiho did not sell LYTGOBI at this time.

33. On October 3, 2022, Taiho sent FDA a letter identifying the errors and offering corrections. Exhibit B.

34. On October 5, 2022, FDA sent Taiho a "Corrected Approval" letter acknowledging "the correction of the error." Exhibit C. Thus, Taiho obtained permission for commercial marketing of LYTGOBI lawfully starting on October 5, 2022. Thereafter, Taiho began selling LYTGOBI with the corrected label and carton information.

Patent Term Extension Statutory Framework

35. Congress has long recognized that the gap in time between when a drug is developed and when it can be commercially marketed and sold reduces the effective patent term for the inventor, reduces the ability of the inventor to recoup its investment, and thus reduces the incentive to create new vital medicines. To address this issue, Congress passed Title II of the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch–Waxman Act"). Among other things, the Hatchman–Waxman Act permits the extension of the patent term for certain drug and medical-device patents based on the length of FDA's "regulatory review period" and allows for a maximum extension of five years. 35 U.S.C. §§ 156(c), (g)(6)(A).

36. A patent holder must apply for PTE under the Hatch–Waxman Act "within a sixty-day period beginning on the date the product received permission . . . for commercial marketing or use." 35 U.S.C. § 156(d)(1).

37. The PTO and FDA review the PTE applications. The PTO and HHS share the responsibility of reviewing PTE applications, although HHS has delegated certain aspects of its

authority to FDA. *See* 35 U.S.C. § 156(d)(1)(C), (e). This relationship is set forth in Memorandum of Understanding 225-86-8251 (the "MOU") as well as by statute. *See id.*; Exhibit E.

38. As relevant here, the PTO issues the final decision whether to approve or deny a PTE applications. 35 U.S.C. § 156(e). Yet it is FDA that determines, among other things, "whether the patent term extension application was submitted within 60 days after the product was approved." Exhibit E, Part II. FDA provides this information to the PTO only after "receipt of a written request from PTO." *Id.* Thus the determination whether a PTE application is timely is made by FDA and the PTO acting in concert.

Defendants' Arbitrary, Capricious and Unlawful Conduct in Rejecting Taiho's PTE Applications

39. Taiho submitted its PTE applications on November 29, 2022—55 days after the corrected approval letter and 60 days after it received FDA's first, defective approval letter. Exhibits F-G.

40. The PTO then sent FDA a letter on September 20, 2023 regarding Taiho's PTE applications. The PTO told FDA that it considered Taiho's application "not timely filed" for two reasons. Exhibit H. *First*, the PTO concluded erroneously that the trigger date under the statute was the date of the defective September 30, 2022 letter—not the corrected October 5, 2022 approval letter. Exhibit H. *Second*, the PTO erroneously calculated the 60-day time by treating September 30, 2022, as day one, giving Taiho only 59 days to submit its PTE applications. Exhibit H. As a result of these two arbitrary, capricious and unlawful decisions, individually and collectively, the PTO concluded that Taiho's PTE applications were untimely.

41. On January 24, 2024, FDA advised the PTO that the patented drug was "approved on September 30, 2022, which makes submission of the patent term extension application on November 29, 2022, not timely." Exhibit I.

42. On February 8, 2024, Taiho submitted a supplement correcting its PTE applications to accurately reflect the date on which it first received permission for commercial marketing and use – October 5, 2022, not September 30, 2022. Exhibits J-K.

43. On the same day, Taiho requested that FDA update its advisory letter to the PTO, using October 5, 2022, as the date of first permission for commercial marketing. Exhibit L.

44. Before FDA could respond, the PTO issued a "Notice of Final Determination – Ineligible" denying Taiho's PTE applications on March 18, 2024. Exhibits M-N.

45. Once again, the PTO determined that Taiho had not filed its application within 60-days of receiving permission for commercial marketing. Exhibits M-N. The PTO reached this erroneous conclusion on the basis that the date of the first, erroneous approval letter should be counted as day one, giving applicants only 59 days thereafter to submit their PTE applications. Exhibits M-N.

46. The PTO also erroneously concluded, once again, that the trigger date for filing the PTE applications was the date of the erroneous approval letter -- September 30, 2022. The PTO relied on Taiho's initial application, FDA's letter to the PTO, and FDA's corrected approval on October 5 which stated that "[t]he effective action date will remain September 30, 2022, the date of the original letter." Exhibits M-N. It then dismissed Taiho's correction, requesting the PTO to use October 5 as the date of first permitted marketing, as "wholly uncorroborated" and faulted Taiho for failing "to provide any evidence." Exhibits M-N.

47. The effective approval date is irrelevant, however, and the only "evidence" the PTO needed was the October 5 corrected approval letter, which was the first time FDA permitted Taiho to commercially market and use LYTGOBI lawfully

48. Taiho wrote to FDA on May 30, 2024 to request a response from FDA to the PTO as prescribed by the MOU. Exhibit O.

49. FDA declined on June 11, 2024 and instead informed Taiho that "USPTO had made a final determination" and "any request for reconsideration . . . should be submitted to PTO." Exhibit P. It also observed that there was no "request from USPTO to FDA to consider the arguments made" by Taiho in Taiho's amendment. *Id.*

50. Left with no other recourse, on October 3, 2024, Taiho filed a request for reconsideration with the PTO. Exhibit Q-R. Taiho again explained that it did not have permission to commercially market or use LYTGOBI as of September 30, 2022. *Id.* Thus, the date that Taiho first "received permission . . . for commercial marketing or use" was October 5, 2022 when FDA issued its corrected approval letter. 35 U.S.C. § 156(d)(1); Exhibits Q-R. Taiho also argued that "within the sixty-day period" beginning on the date of approval means 60 days after the date of approval. Exhibits Q-R. Taiho pointed out that this is how courts, agencies, and even FDA interpret identical and similar language. *Id.*

51. On March 27, 2025, the PTO denied Taiho's request for reconsideration, largely reiterating its previous decision. Exhibits S-T.

52. Once again, the PTO reaffirmed its prior decision to afford Taiho only 59 days after the date of first permitted commercial marketing or use, not 60. Exhibits S-T. As a result, Taiho lost PTE consisting of 1,325 days for the '973 Patent and 183 days for the '103 patent.

53. The PTO also concluded that the date of first permitted commercial marketing or use was based on the defective September 30 approval letter. *Id.* As before, the PTO relied on FDA's statement in the October 5 corrected approval letter that "the effective action date will remain September 30, 2022." *Id.* The PTO also relied on Taiho's statements in the initial November 29, 2022 application, rather than considering the corrected application, which represented October 5, 2022, as

the date of effective approval. The PTO did not contact FDA to request its input regarding Taiho's amended application. Exhibits S-T.

54. Defendants' repeated arbitrary, capricious and unlawful actions carry serious consequences for Taiho and for the future development of life-saving therapeutic products. Under the Defendants' erroneous interpretation of the applicable law and statute, the regulatory review period ends on the date FDA approves the product even if that approval was defective and would not legally permit the patent holder to market or use their product commercially. Because the length of the regulatory review period also determines the length of the patent extension, 35 U.S.C. § 156(c), the Defendants' decision also artificially truncates the extension period and thwarts Congress's clear intent.

55. An essential goal of the Hatch-Waxman Act is to protect drug developers who are also patent holders from being effectively penalized by lengthy FDA regulatory review periods during which their patent term continues to run but they are unable to market or use their product commercially. As this case demonstrates, that purpose of the statute would be thwarted if a patent holder's protections were reduced, or even eliminated, by FDA providing a defective approval letter under which the patent holder could not market its drug without exposing itself to liability, compromising product quality, and endangering patients.

56. Defendants' actions described herein were in concert and were arbitrary, capricious and unlawful. As a direct result of Defendants' conduct, the value of Taiho's patents has been greatly diminished. Defendants' unlawful conduct has caused irreparable harm to Taiho. Defendants have failed to comply with 35 U.S.C. § 156. In the absence of injunctive relief, Taiho will continue to suffer irreparable injury. Accordingly, Taiho seeks relief from this Court under the Administrative Procedure Act.

COUNT I

Decision not according to law under 5 U.S.C. § 706(2)(A) of the Administrative Procedure Act by all Defendants

57. Taiho repeats and realleges the foregoing paragraphs as if fully restated herein.

58. The defendants' denial of Taiho's PTE applications was contrary to law because the defendants erroneously applied 35 U.S.C. § 156(d)(1) as permitting Taiho only 59 days to submit its PTE applications from the date it received FDA's approval for commercial marketing and use.

59. Similarly, defendants erroneously interpreted 35 U.S.C. § 156(d)(1) as affording Taiho only 59 days to submit its PTE applications from the date it received FDA's permission for commercial marketing and use.

60. Had Defendants correctly applied the plain language of 35 U.S.C. § 156(d)(1), which permits Taiho to file its PTE applications within 60 days of FDA approval, Taiho's PTE applications would be considered timely.

61. Defendants offered no other reason for denying Taiho's PTE applications, so the PTE applications would have been approved but for Defendants erroneous legal interpretation.

62. Taiho will be irreparably harmed unless the PTO is required to withdraw its rejection of Taiho's PTE applications and accept them as timely made.

63. There is no mechanism by which Taiho can be made whole for the injury that has resulted from Defendants' conduct. Taiho is without an adequate remedy at law because of the unique nature of the harm.

64. The intent of Congress will be served by an Order directing PTO and FDA to determine that Taiho's PTE applications were timely filed and accept them as timely.

COUNT II

Arbitrary and capricious decision under 5 U.S.C. § 706(2)(A) of the Administrative Procedure Act by all Defendants

65. Taiho repeats and realleges the foregoing paragraphs as if fully restated herein.

66. Defendants' denial of Taiho's PTE applications and decision to afford Taiho only 59 days from approval to submit them was arbitrary, capricious and unlawful.

67. After long adhering to the common-sense interpretation that 60 days means 60 days, the defendants suddenly changed their mind about the deadline in 2008 and provided no persuasive explanation for its decision. Further, this calculation methodology is inconsistent with calculations of similar time periods effected by the PTO, FDA, and other government agencies. Exhibit U.

68. But for Defendants' arbitrary, capricious and unlawful decision, Taiho's PTE applications were timely filed according to the statute within 60 days. Because Defendants offered no other reason for denying Taiho's PTE applications, the PTE applications would have otherwise been approved.

69. Taiho will be irreparably harmed unless the defendants are required to withdraw the rejection of Taiho's PTE applications and accept them as timely made.

70. There is no mechanism by which Taiho can be made whole for the injury that has resulted from Defendants' conduct. Taiho is without an adequate remedy at law because of the unique nature of the harm.

71. The intent of Congress will be served by an Order directing defendants to determine that Taiho's PTE applications were timely filed and accept them as timely.

COUNT III

Decision not in accordance with law under 5 U.S.C. § 706(2)(A) of the Administrative Procedure Act by all Defendants

72. Taiho repeats and realleges the foregoing paragraphs as if fully restated herein.

73. Defendants' denial of Taiho's PTE applications and decision that FDA's defective approval letter constituted "permission . . . for commercial marketing or use" rather than the corrected

and effective approval letter was not in accordance with law because it misinterpreted 35 U.S.C. § 156(d)(1) by interpreting "permission" to be based upon a defective letter that by law and in practice did not permit Taiho to use or market LYTGOBI tablets.

74. If Defendants had interpreted 35 U.S.C. § 156(d)(1) correctly and treated the corrected FDA approval letter as the date Taiho first received "permission . . . for commercial marketing or use," they would have accepted Taiho's application as timely because Taiho filed its PTE applications within 60 days of the corrected letter. Given that Defendants offered no other reason for denying Taiho's PTE applications, the PTE applications would have been approved but for the erroneous legal interpretation.

75. Taiho will be irreparably harmed unless the PTO is required to withdraw its rejection of Taiho's PTE applications and accept them as timely made.

76. There is no mechanism by which Taiho can be made whole for the injury that has resulted from Defendants' conduct. Taiho is without an adequate remedy at law because of the unique nature of the harm.

77. The intent of Congress will be served by an Order directing defendants to determine that Taiho's PTE applications were timely filed and accept them as timely.

COUNT IV

Arbitrary and capricious decision under 5 U.S.C. § 706(2)(A) of the Administrative Procedure Act by all Defendants

78. Taiho repeats and realleges the foregoing paragraphs as if fully restated herein.

79. Defendants denied Taiho's PTE applications because they considered the FDA's defective approval letter as the relevant date of permission under 35 U.S.C. § 156(d)(1). That reasoning was arbitrary, capricious and unlawful.

80. Defendants' decision—effectively stating that Taiho could have used and marketed LYTGOBI tablets based on the defective September 30, 2022 approval letter—would expose Taiho to liability for misbranding under federal law and hurt patients.

81. Under 21 U.S.C. § 352, a drug "shall be deemed misbranded" "[i]f its labeling is false or misleading in any particular." If Taiho labeled its LYTGOBI tablets with storage information it knew to be incorrect—potentially rendering the tablets unsafe or ineffective—as required by the September 30 erroneous approval letter, it would have been subjected to liability for misbranding. More importantly, the misbranded drug could hurt patients in dire need of life-saving medication. Defendants' decision was thus arbitrary and capricious. Taiho did not sell product until after October 5, 2022.

82. If Defendants had treated the corrected FDA approval letter as the date Taiho first received "permission … for commercial marketing or use," they would have accepted Taiho's application as timely because Taiho filed its PTE applications within 60 days of the corrected letter. Because Defendants offered no other reason for denying Taiho's PTE applications, the PTE applications would have been approved.

83. Taiho will be irreparably harmed unless the PTO is required to withdraw its rejection of Taiho's PTE applications and accept them as timely made.

84. There is no mechanism by which Taiho can be made whole for the injury that has resulted from Defendants' conduct. Taiho is without an adequate remedy at law because of the unique nature of the harm.

85. The intent of Congress will be served by an Order directing defendants to determine Taiho's PTE applications were timely filed and accept them as timely.

COUNT V

Arbitrary and capricious decision under 5 U.S.C. § 706(2)(A) of the Administrative Procedure Act by all Defendants

86. Taiho repeats and realleges the foregoing paragraphs as if fully restated herein.

87. Defendants' failure to accept and treat as superseding Taiho's February 8, 2024 amended PTE applications were arbitrary and capricious.

88. The PTO erroneously and repeatedly relied on Taiho's initial PTE applications, from November 29, 2022, which mistakenly treated the FDA's defective approval letter as the operative date of permission. Taiho corrected that error, but the PTO would not accept that correction. The PTO has failed to provide any explanation as to why it was appropriate to rely on the November 29 application's representation rather than the February 8, 2024 amended application.

89. Similarly, FDA never issued a letter to PTO considering Taiho's letter sent to FDA on February 8, 2024 explaining FDA's miscalculation of the PTE applications deadline based on the erroneous September 30, 2022 letter. And the PTO never requested an updated letter from FDA that would have considered Taiho's amended PTE applications.

90. Defendants should have allowed Taiho to amend its application and treat the representations and arguments in that amended application as controlling.

91. If Defendants had accepted Taiho's amended application, they would have deemed Taiho's application as timely.

92. Taiho will be irreparably harmed unless the PTO is required to withdraw its rejection of Taiho's PTE applications and accept them as timely made.

93. There is no mechanism by which Taiho can be made whole for the injury that has resulted from Defendants' conduct. Taiho is without an adequate remedy at law because of the unique nature of the harm.

94. The intent of Congress will be served by an Order directing defendants to determine that Taiho's PTE applications were timely filed and accept them as timely.

PRAYER FOR RELIEF

Wherefore, Taiho respectfully requests the following relief:

A. A declaration pursuant to 28 U.S.C. § 2201 that PTO's denial of Taiho's PTE applications was in excess of statutory authority and otherwise unlawful under 35 U.S.C. § 156.

B. A declaration pursuant to 28 U.S.C. § 2201 that Defendants' conduct in denying Taiho's PTE applications was arbitrary, capricious and unlawful under the APA and the Patent Act.

C. An injunction and order that PTO vacate its March 18, 2024 and March 27, 2025 decisions denying Taiho's PTE applications and accept Taiho's PTE applications as timely filed.

D. An injunction and order that PTO and FDA determine that Taiho's PTE applications were timely filed, accept them as timely, and extend the term of U.S. Patent Nos. 9,108,973 and 10,434,103 to the full period required under 35 U.S.C. § 156, as determined by FDA.

E. An award Taiho costs and reasonable attorneys' fees as appropriate; and

F. Grant such further relief as this Court deems just and proper.

DATED: November 6, 2025

Respectfully submitted,

/s/ *Jose L. Linares*

Jose L. Linares
Mark M. Makhail
MCCARTER & ENGLISH, LLP
4 Gateway Center
Newark, NJ 07102
(973) 622-4444
jlinares@mccarter.com
mmakhail@mccarter.com

Attorneys for Taiho Pharmaceutical Co., Ltd. and Taiho Oncology, Inc.

OF COUNSEL:

Michael Sitzman (*pro hac vice* forthcoming)
MCDERMOTT WILL & SCHULTE LLP
415 Mission Street, Suite 5600
San Francisco, CA 94105
Tel: (628) 218-3800
msitzman@mwe.com

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2049 Century Park East, Suite 3200
Los Angeles, CA 90067-3206
Tel: (310) 551-9321
tbest@mwe.com

Christopher Mikson
Perham Gorji (*pro hac vice* forthcoming)
DLA PIPER LLP
500 Eighth Street, NW
Washington, DC 20004
Tel: (202) 799-4201
christopher.mikson@us.dlapiper.com
perham.gorji@us.dlapiper.com