

SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the United States Department of Veterans Affairs (“VA”) (collectively, the “United States”); Yale University (“Yale”) and John Krystal, M.D. (“Krystal”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

- A. Yale is a corporation organized and existing under, and by virtue of, a charter granted by the general assembly of the Colony and State of Connecticut and located in New Haven, Connecticut.
- B. Krystal is a psychiatrist, licensed to practice medicine in the State of Connecticut. At all relevant times, Krystal was employed part time by the VA as a salaried clinical psychiatrist with research responsibilities at the VA Medical Center located in West Haven, Connecticut. At all relevant times, Krystal was also employed part time at Yale in various positions and with various research responsibilities, including as a Professor of Psychiatry, Neuroscience, and Psychology, and Chair of the Department of Psychiatry in the Yale School of Medicine.
- C. The United States contends that it has certain civil claims against Yale and Krystal arising from their failure to share royalties with the VA in connection with certain patents on which Krystal was listed as an inventor, as specifically alleged in Paragraphs C.1. through C.13. That conduct is referred to below as the Covered Conduct.

1. In February 2003, the VA and Yale entered into a Cooperative Technology Administration Agreement (“CTAA”). Pursuant to the CTAA, the parties agreed to promptly and in confidence disclose to each other all “Joint Inventions,” defined as

“any future invention or discovery, which is or may be patentable...in which at least one employee with compensation from the VA and at least one person who has an appointment with Yale is named as a co-inventor.” The CTAA also provided that the definition of “Joint Invention” included within its scope any invention made solely by a “Dual Appointment Personnel” (“DAP”) or jointly by a “DAP” and others. The CTAA defined “DAP” as “any person who is employed with compensation by the VA and also had a simultaneous appointment with Yale or is an employee of Yale....”

2. VA regulations require all VA employees, such as Krystal, to promptly disclose to the VA all inventions they have made. 38 C.F.R. § 1.650-663. VA employees are required to complete and submit an Invention Certification Form providing the VA with details about any invention or believed invention.
3. Beginning in March 2006, Krystal and four co-inventors applied for several patents related to the use of intranasal ketamine for treatment of depression and suicidal ideation. The applications were numbered 60/785,108, 11/688,603, 14/197,767, and 14/306,382 and acknowledged VA funding support in the form of a “Merit Review Grant from the Department of Veterans Affairs.”
4. On approximately July 22, 2014, the U.S. Patent and Trademark Office (PTO) issued United States Patent Number 8,785,500 (Application No. 11/688,603). The PTO subsequently issued U.S. Patent Numbers 9,592,207 and 9,539,220, both continuations of the original filing, on January 10, 2017 and March 14, 2017 respectively. Collectively these three patents are referred to herein as the “Krystal Patents.”

5. Krystal assigned his interests in the Krystal Patents to Yale.
6. In or about October 2009, Yale entered into a Joint Invention Agreement with The Mount Sinai School of Medicine (“Mt. Sinai”) regarding the Krystal Patents. In that agreement, Yale appointed Mt. Sinai as its agent to (a) locate an appropriate licensee and to negotiate reasonable license terms for the commercialization of the Krystal Patents and (b) manage the patent prosecution of the Krystal Patents.
7. In or about December 2013, Mt. Sinai entered into a License Agreement with Janssen Pharmaceuticals, Inc. (“Janssen”) which granted Janssen an exclusive license to the Krystal Patents.
8. In or about February 2015, Yale began receiving royalty payments from Mt. Sinai arising from the Krystal Patents.
9. In May 2017, a Yale employee sent a VA employee a copy of United States Patent Number 8,785,500.
10. In or about November 2017, a VA employee reminded Krystal of his obligations as a VA employee to disclose inventions to the VA. In or about December 2017, Krystal submitted an Invention Certification Form to the VA disclosing the Krystal Patents. On November 9, 2018, VA issued a Determination of Rights (“DOR”), under which it determined that it was entitled to an ownership interest in the Krystal Patents. Krystal subsequently appealed the DOR to the National Institute of Standards and Technology (NIST), which upheld the VA’s ownership determination in the DOR.
11. In September 2017 and then again in January and June 2019 Mt. Sinai, in its role as agent under the Joint Invention Agreement, and in coordination with Yale and

Krystal, removed or caused to be removed the acknowledgment of VA support from the Krystal Patents.

12. Between February 2015 and February 2023, Yale and Krystal collectively received royalty payments in excess of \$3 million arising out of the Krystal Patents, including approximately \$245,000 they received before Krystal submitted the Invention Certification Form to the VA on December 9, 2017. Yale and Krystal did not share with the VA any of the royalty payments arising out of the Krystal Patents.
13. The United States contends that, during the time-period from March 2006, when Krystal and the other co-inventors filed the first patent application, to December 8, 2017, when Krystal submitted the VA Invention Certification Form disclosing the Krystal Patents to the VA (the “False Claims Act Time-Period”), Yale and Krystal knowingly and improperly avoided their obligations to disclose the Krystal Patents to the VA and to pay the VA its share of the royalty payments arising out of the Krystal Patents, and are therefore liable to the United States under the False Claims Act.
14. The United States contends that from December 9, 2017, after Krystal disclosed the Krystal Patents to the VA, through February 3, 2023 (the “Common Law Time-Period”), Yale and Krystal breached the CTAA and were unjustly enriched by failing to pay the VA its share of the royalty payments received for the Krystal Patents, and are therefore liable to the United States under the common law theories of breach of contract and unjust enrichment.

D. This Settlement Agreement is neither an admission of liability by Yale or Krystal nor a concession by the United States that its claims are not well founded. Yale and Krystal deny the United States’ allegations in Paragraph C.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Yale and Krystal shall pay to the United States the sum of \$1,507,743.67 (“Settlement Amount”) (of which \$1,347,799.31 is restitution). Yale and Krystal shall pay the Settlement Amount no later than five (5) business days after the Effective Date of this Agreement, by electronic funds transfer pursuant to written instructions to be provided by The Office of the United States Attorney for the District of Connecticut.
2. Krystal fully and finally releases the VA from paying him any share of any royalty payments arising out of the Krystal Patents on or before February 3, 2023. Krystal fully and finally releases the United States (including the VA) from paying him any share of the Settlement Amount.
3. Subject to the exceptions in Paragraph 5 (concerning reserved claims) below and the waiver of royalty payments in Paragraph 2, and upon the United States’ receipt of the Settlement Amount, the United States releases Yale and Krystal, from any civil or administrative monetary claim the United States has for the Covered Conduct during the False Claims Act Time-Period, under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of breach of contract, unjust enrichment and fraud.
4. Subject to the exceptions in Paragraph 5 (concerning reserved claims) below, and the waiver of royalty payments in Paragraph 2, and upon the United States’ receipt of the Settlement Amount, the United States releases Yale and Krystal, from any civil or administrative monetary

claim the United States has for the Covered Conduct during the Common Law Time-Period, under the common law theories of breach of contract and unjust enrichment.

5. Notwithstanding the releases given in Paragraphs 3 and 4 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability or enforcement right, or any administrative remedy, including the suspension and debarment rights of any federal agency;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- g. Any liability for failure to deliver goods or services due;
- h. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; and
- i. Any liability of individuals, except for Krystal.

6. Yale and Krystal waive and shall not assert any defenses Yale and Krystal may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth

Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

7. Yale and Krystal fully and finally release the United States and its agencies, officers, agents, employees, and servants, from any claims in their official and individual capacities (including attorney's fees, costs, and expenses of every kind and however denominated) that Yale and Krystal have asserted, could have asserted, or may assert in the future against the United States and its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

8.

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Yale and Krystal, their present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;
- (3) Yale and Krystal's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);
- (4) the negotiation and performance of this Agreement; and

(5) the payment Yale and Krystal make to the United States pursuant to this Agreement,

are unallowable costs for government contracting purposes (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Yale and Krystal, and Yale and Krystal shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Yale and Krystal further agree that within 90 days of the Effective Date of this Agreement they shall identify and repay by adjustment to future claims for payment or otherwise any Unallowable Costs included in payments previously sought by Yale and Krystal or any of their subsidiaries or affiliates from the United States. Yale and Krystal agree that the United States, at a minimum, shall be entitled to recoup from Yale and Krystal any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted requests for payment. The United States, including the Department of Justice and/or the affected agencies, reserves its rights to audit, examine, or re-examine Yale and Krystal's books and records and to disagree with any calculations submitted by Yale and Krystal or any of their subsidiaries or affiliates regarding any Unallowable Costs included in payments previously sought by Yale and Krystal, or the effect of any such Unallowable Costs on the amount of such payments.

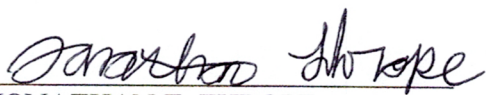
9. This Agreement is intended to be for the benefit of the Parties only.

10. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

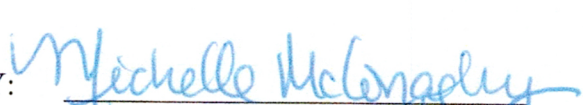
11. Each Party and signatory to this Agreement represents that it freely and voluntarily entered into this Agreement without any degree of duress or compulsion.
12. This Agreement is governed by the laws of the United States. The exclusive venue for any dispute relating to this Settlement Agreement is the United States District Court for the District of Connecticut. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.
13. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.
14. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.
15. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.
16. This Agreement is binding on Yale and Krystal's successors, transferees, heirs, and assigns.
17. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.
18. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles, scans of signatures, or electronic signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA


DATED: 9/20/23

BY: 
JONATHAN T. THROPE
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 9/18/23

BY: 
MICHELLE L. McCONAGHY
Assistant United States Attorney
Chief, Civil Division
District of Connecticut

DATED: 9/18/23

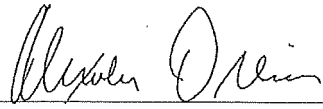
By: 
RICHARD M. MOLOT
Assistant United States Attorney
Chief, Affirmative Civil Enforcement Unit
District of Connecticut

DATED: _____

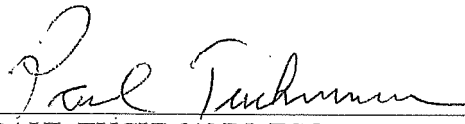
By: RICHARD HIPOLIT
Digitally signed by RICHARD HIPOLIT
Date: 2023.09.14 10:21:28 -04'00'
RICHARD HIPOLIT
Deputy General Counsel for
Veterans Programs, Performing the
Delegable Duties of the
General Counsel

YALE UNIVERSITY

DATED: 9/15/2023


BY: 
ALEXANDER E. DREIER
Senior Vice President for Institutional Affairs
and General Counsel Yale University

DATED: 9/15/23

BY: 
PAUL TUCHMANN, ESQ.
Wiggin and Dana LLP
Counsel for Yale University


JOHN KRYSTAL, M.D.

DATED: 09/13/23

BY: 

JOHN KRYSTAL, M.D.

DATED: 9/15/23

BY: 

SAPNA PALLA, ESQ.
Allen & Overy LLP
Counsel for John Krystal, M.D.