



Stop Animal Exploitation NOW!

Chong (Charles) Kim, Director,  
Office of Petitions  
United States Patent and Trademarking Office  
Via Email: ChongR.Kim@uspto.gov

4/17/23

Director Kim,

I am writing to you today in reference to U.S. Provisional Application No. 63/233,039 filed on Aug. 13, 2021 — Compositions and Methods For Reducing Immune Intolerance and Treating Autoimmune Disorders (Filed by Lapix Therapeutics inc. Boston, MA). This patent was published in March of 2023, so it is less than six months post-publication.

According to the USPTO website: “35 U.S.C. 122(e) provides a mechanism for third parties to submit patents, published patent applications, or other printed publications of potential relevance to the examination of a patent application with a concise description of the asserted relevance of each document submitted.”

As you know all declarations in a patent application are required to be accurate. In fact “A finding of “fraud,” “inequitable conduct,” or violation of duty of disclosure with respect to any claim in an application or patent, renders all the claims thereof unpatentable or invalid.” (<https://www.uspto.gov/web/offices/pac/mpep/s2016.html>).

On page 22 Example 2, (0244) the Lapix Therapeutics patent application states: “All animal studies were conducted under IACUC number B2020-91 and in compliance with Tufts University/Tufts Medical Center & Human Nutrition Research Center on Aging.”

The same statement is also made on page 22 Example 3 (0252); page 23 Example 4 (0263) and page 31 Example 8 (0306). see: <https://image-ppubs.uspto.gov/dirsearch-public/print/downloadPdf/20230089267>

All four of these statements are patently untrue, and therefore fraudulent. This protocol was apparently NOT done “in compliance” with much of anything. In fact, Tufts University has filed a NONCOMPLIANCE report with the Federal Office of Laboratory Animal Welfare regarding this project (protocol #B2020-91). The Principal Investigator (PI) associated with the project has been permanently banned from being a PI on an future animal-based study at Tufts. The report dated 10/26/22 starts out:

***“Tufts University, in accordance with Assurance number D16-00459 (A3775-01) and PHS Policy IV.F. 3., provides this report of serious and continuing noncompliance with PHS Policy and suspension of animal activities by the IACUC.***

***“On August 30, 2022 the following non-compliances were reported to the IACUC under \_\_\_\_\_ IACUC Protocol #B2020-91: injections in mice via an unapproved route/location, failure to provide required analgesia, inadequate supportive care and monitoring, and failure to euthanize mice upon reaching the approved humane endpoints.***

***The PI was asked to respond to the claims of noncompliance in a letter to the IACUC. In it he refuted most of the allegations and took no responsibility for his actions. At the October 5, 2022 IACUC meeting, Committee members discussed the allegations, the PI’s response, and reviewed information provided by the Comparative Medicine Service (CMS) which supported the claims. . . . The IACUC voted to consider these incidents Significant and approved the following corrective actions:***

- 1. \_\_\_\_\_ was immediately terminated as Principal Investigator for protocol #B2020-91. His privilege to act as PI on any future IACUC protocols at Tufts have been permanently revoked.***
- 2. \_\_\_\_\_ was suspended from all animal user privileges on any IACUC protocol at Tufts for a period of one year, at which time he may apply to the IACUC to lift this suspension.***

Please note that the statements in this patent application specifically say that these parts of the study were conducted “in compliance.” Nothing could be further from the truth. Tufts University overtly states that these incidents are “***serious and continuing noncompliance.***” Also, it is clearly the same project because the protocol numbers match.

Additionally, this is not solely an animal welfare issue. Institutional Animal Care and Use Committees approve and supervise protocols & Principal Investigators to insure that a project is performed consistently and in alignment with basic scientific standards. Clearly, these things cannot be said of this project.

Tufts University Research Administration goes so far as to suspend the protocol and PERMANENTLY BAN this PI from ever being a PI on an animal study at Tufts in the future. There is no more serious of an action that Tufts could have taken.

The Tufts University correspondence is attached.

Therefore, since this patent filing is in fact both fraudulent, and connected to “serious and continuing noncompliance” with PHS policy and federal regulations, it must be revoked.

I look forward to your prompt response within five business days.

Sincerely,

Michael A. Budkie, A.H.T.,  
Executive Director, SAEN



Office of the Vice Provost for Research  
Institutional Animal Care and Use Committee

October 26, 2022

Dr. Axel Wolff  
Office of Laboratory Animal Welfare (OLAW)  
National Institutes of Health  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, MD 20892

Dear Dr. Wolff:

Tufts University, in accordance with Assurance number D16-00459 (A3775-01) and PHS Policy IV.F.3., provides this report of *serious and continuing noncompliance* with the PHS Policy and *suspension of animal activities* by the IACUC. This letter provides a summary of the issues and resolution to OLAW as reported to the IACUC.

On August 30, 2022 the following non-compliances were reported to the IACUC under (b) (6)

(b) (6) IACUC protocol #B2020-91: injections in mice via an unapproved route/location, failure to provide their required analgesia, inadequate supportive care and monitoring, and failure to euthanize mice upon reaching the approved humane endpoints.

The PI was asked to respond to the claims of noncompliance in a letter to the IACUC. In it he refuted most of the allegations and took no responsibility for his actions. At the October 5, 2022 IACUC meeting, Committee members discussed the allegations, the PI's response, and reviewed information provided by the Comparative Medicine Service (CMS) which supported the claims. The documentation from CMS included a previous training outline, photographs of ulcer measurements, and e-mails between the researchers and CMS staff. The Committee also reviewed the PI's noncompliance history, which included minor non-compliances and another serious incident reported to OLAW earlier this year on May 16, 2022. The IACUC voted to consider these incidents Significant and approved the following corrective actions:

1. (b) (6) was immediately terminated as Principal Investigator of protocol #B2020-91. His privilege to act as PI on any future IACUC protocols at Tufts have been permanently revoked.
2. (b) (6) was suspended from all animal user privileges on any IACUC protocol at Tufts for a period of one year, at which time he may apply to the IACUC to lift this suspension.
3. The Senior Director of CMS was approved as temporary PI for protocol #B2020-91 and CMS assumed responsibility for the care, monitoring, and breeding of mice until a new PI is identified.
4. A new PI must complete all personnel requirements and submit a Change in PI form to the IACUC by Oct. 27, 2022. If a new PI has not been instated by this date, the protocol will be terminated at the next IACUC meeting.
5. All protocol personnel must complete 3 hands-on trainings with CMS (Orientation training, Rodents 101, and Rodents 102) to verify competency. Current animal users must complete these trainings by Nov. 9, 2022. All new animal users must complete this training before they can receive IACUC clearance to work with animals.
6. Additional IACUC oversight will be required in the form of monthly progress reports and IACUC inspections for the final year the protocol is active.

This letter provides a summary and resolution to OLAW. There is no NIH funding for this research.

Sincerely,

(b) (6)

Philip Hinds, PhD  
Senior Director of Research Compliance  
Institutional Official, Tufts University School of Medicine