

GENETICS

Patent dispute threatens US Alzheimer's research

Lawsuit could expose hundreds of scientists to property-rights litigation.

BY ERIKA CHECK HAYDEN

The website of the Alzheimer's Institute of America (AIA) doesn't reveal much about the organization, but portrays it as committed to supporting research and patients. Among people who study Alzheimer's disease, however, the AIA, based in St Louis, Missouri, is best known for filing lawsuits against companies and researchers — a practice that scientists say could hamper the progress of research into combating the dreaded disease.

An AIA lawsuit filed in February 2010 against the Jackson Laboratory in Bar Harbor, Maine — a source of laboratory mice funded by the US National Institutes of Health (NIH) — now threatens hundreds of government-sponsored Alzheimer's researchers with litigation. The lab is so concerned about the financial and scientific costs of defending itself that it has asked the NIH to assume the defence of the case.

"The lawsuits raised by the AIA are unfortunate, and constitute a large drain on valuable scientific resources at a time when scientific funds are increasingly tight," says Benjamin Wolozin, an Alzheimer's researcher at Boston University in Massachusetts.

The suit concerns an AIA patent on a human DNA sequence used in mouse models of Alzheimer's disease. The sequence encodes the 'Swedish mutation' (discovered in a Swedish family), which causes early-onset Alzheimer's. Michael Mullan, a biomedical researcher who is now head of the Roskamp Institute in Sarasota, Florida, patented the sequence in 1995, then sold it to the AIA.

The NIH requires scientists to share transgenic mouse strains developed using NIH money, and the agency funds Jackson to breed, house and distribute these mouse models, says David Einhorn, house counsel at the lab. The

AIA is alleging that Jackson infringed on its Swedish mutation patent, and others, when the lab distributed 22 strains of mice with the mutation to researchers; the organization is seeking unspecified damages.

The lawsuit also accuses six commercial companies of improperly profiting from the Swedish mutation, for instance by using mice bearing the mutation to test potential drugs. Furthermore, the AIA has filed four separate suits relating to the patent against academic institutions and companies in Oklahoma, Florida, Missouri and Pennsylvania (see 'Patent disputes').

But the litigation against Jackson could have the broadest impact on research. According to Einhorn, the AIA is demanding that Jackson hands over the names of all scientists who have worked with the relevant mouse models; this raises the possibility that those individual researchers might also be sued.

Last month, judge Elizabeth Laporte for the US District Court of Northern California recognized the potential impact of the suit on Alzheimer's research. She denied an AIA request to expand the suit by adding another patent-infringement claim, writing in her decision that the AIA has not disputed Jackson's claim that "prolonging the litigation in this case would harm Jackson and the public by extending the chilling effect of the litigation on mice research on Alzheimer's disease".

The AIA says that it allows academic research on mouse models covered by its patents, but does not permit work that profits from them. "Jackson Laboratory is not giving away the mice for academic research. On the contrary, these mice are being sold, and Jackson Laboratory is making quite a lot of money in the process. Furthermore, the mice Jackson sells are, in many instances, being used for commercial, not academic, purposes," the institute wrote in a statement.

Einhorn counters that the lab doesn't make enough from distributing mouse models to cover its operating costs, and it relies on philanthropy and public and private grants to support its work. He says that Jackson only allows academics, not companies, to use the models, and points out that asserting

ONGOING LAWSUITS

Patent disputes

The Alzheimer's Institute of America (AIA) in St Louis, Missouri, is involved in multiple lawsuits regarding alleged infringement of its patents.

- AIA vs University of Pennsylvania and Avid Radiopharmaceuticals. Filed November 2010 in Pennsylvania.
- AIA vs Jackson Laboratory, Elan, Eli Lilly, Anaspec, Immuno-biological Laboratories, Invitrogen and Phoenix Pharmaceuticals. February 2010; Northern California.
- AIA vs Oklahoma Medical Research Foundation and Comentis. December 2009; Oklahoma.
- AIA vs Pfizer. June 2009; Missouri.
- Mayo Clinic Jacksonville vs AIA. March 2005; Florida.

rights in such cases runs counter to common practice, which is established by NIH policy.

Defending against the lawsuit puts Jackson in a difficult spot. Proving that the AIA's allegations are groundless could take years and millions of dollars. It could also cast a pall over the Alzheimer's-research field, which has already been scarred by an extensive fight over the Swedish mutation patents during the 1990s (see *Nature* 404, 319–320; 2000). But settling out of court would require Jackson to hand over researchers' names, a demand that Einhorn calls "repugnant".

"We haven't been able to settle this case because we're trying to do the right thing by trying to support the NIH policy and protect researchers out there in the community," says Einhorn.

Kathy Hudson, NIH deputy director for science, outreach and policy, says that the agency is considering the lab's request for help, made last December. "We're trying to evaluate the legal risks and the risks to the research community," she says. ■



Transgenic mouse models used in research are at the heart of the litigation.