
Event

Members of the PACEOMICS Team recently published two related papers^{1,2}, examining the impact of academic patenting and licensing practices, and subsequent enforcement by a 'non-practicing entity' (NPE) on translational Alzheimer's Disease research. NPEs, colloquially called 'patent trolls', are groups or individuals who enforce patents against purported infringers without themselves intending to use the patented invention.

Significance

Patents are a policy tool intended to incentivize innovation – thus in the realm of biomedicine, patents should support the advance of medical research and development (R&D). However, there is ongoing concern that patents on research tools, including genes and mutations, may have detrimental effects on the progress of science. Research tool inventions may be so fundamental, that if exclusively licensed and enforced they can block wide swathes of basic academic research, or obligate the purchase of costly licenses. Further, when the enforcer is an aggressive NPE, transaction and legal costs may be highly elevated in the absence of any significant contribution to the field, or delivery of a service or therapeutic.

Analysis

In this case study, a rare mutation for early-onset Alzheimer's disease was patented by a sole academic inventor and licensed to a non-practicing entity (NPE), the Alzheimer's Institute of America (AIA). This NPE launched suits against 18 defendants, including one university, one foundation, and three non-profit organizations incurring significant costs in court years, legal fees, and expert time. AIA's litigation eventually failed on the grounds of non-disclosure of co-inventors, state laws on ownership and assignment of university inventions, and enablement. However, it seems likely that the bulk of licensing revenue went to support the litigation, much more than research. There is little public record to support AIA's contribution to knowledge advancement, and much legal documentation that indicates that it imposed enormous costs on the research institutions and private companies it sued. The net result of the AIA's trolling activities was to hamper Alzheimer's research.

This case discusses the policy implications of the litigation, raising key questions about the value of patents in the research ecosystem and the role of NPEs in biotechnological innovation. Further, it illustrates tactics that may be deployed against NPEs including: avenues to invalidate patent claims; the use by the National Institutes of Health of *Authorization and Consent* to rescue one of the public sector defendants - The Jackson Laboratory; legislative reforms specifically targeting NPEs; reforms in the America Invents Act; and judicial action and rules for judicial proceedings. In its analysis, the case informs ongoing debates about how patents affect research, disposition of university inventions, and the distribution of benefits from publicly funded research.

Conclusion

This case study illustrates multiple mistakes in how patents were obtained, administered, and enforced, but in the end, the legal system also rectified many of these, albeit slowly, laboriously, and at great cost. The AIA clearly put research institutions in its litigation crosshairs and hampered Alzheimer's research in order to extract money without significantly contributing to the public good. The legal system ultimately neutered the AIA's ability to continue these practices. Nevertheless, this represents a cautionary tale in which broad exclusive patent rights applied to research tools can (and did) become real-world impediments to biomedical research.

1. **Bubela T**, Vishnubhakat S, Cook-Deegan R (2015) The Mouse that Trolled: The Long and Torturous History of a Gene Mutation Patent that became an Expensive Impediment to Alzheimer's Research. *Journal of Law and the Biosciences*. April 23, 2015: 1-50. [ePUB Ahead of Print](#).

2. **Bubela T**, Cook-Deegan R (2015) Defending Access to Research Tools: Keeping Score, Strengthening Policy, and Fighting Bad Actors. *Nature Biotechnology* 33(2): 143-147.