

Patenting materials derived from the human body: Does the law give adequate regard to the rights of donors?

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Overview

- *Moore v Regents of the University of California* (1990).
- What do donors of biological material actually want? Can they achieve their goals without property rights?
- Case studies:
 - PXE International;
 - Henrietta Lacks – ‘HeLa cells’ dispute;
 - Private genetic research databases - 23andMe vs Nebula Genomics.
- Thoughts for the future.

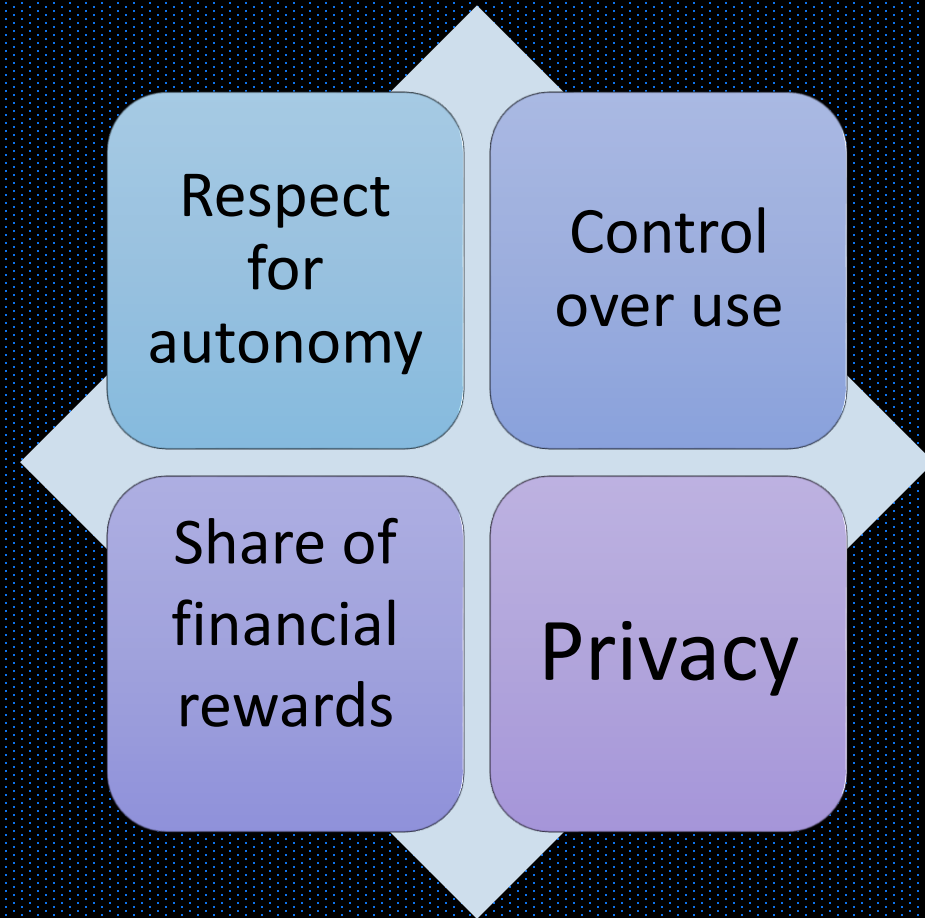
Moore v Regents of the University of California (1990)

- A patient who underwent treatment for leukemia at a UCLA medical center filed an action against his physician and others, alleging they used cells extracted from him in potentially lucrative medical research without his permission.
- Moore signed a written consent form, authorizing the procedure. It said the hospital could "dispose of any severed tissue or member by cremation," and his spleen was removed by surgeons. Spleen used to create a cell line which was patented and commercialised.

Moore v Regents of the University of California (1990)

- Supreme Court of California held that there was no conversion of property in relation to excised cells taken from the plaintiff during the course of medical treatment.
- But there was breach of fiduciary duty and lack of informed consent.
- Strong dissenting judgment (Justice Mosk).
- Policy concerns about causing disruption for biomedical research are a key reason for Supreme Court's rejection of conversion of property argument.

What do donors of biological material actually want?



PXE International

- Patient support group awarded a patent on the gene involved in the disorder pseudoxanthoma elasticum (PXE) in 2004.
- Sharon Terry, who has two children affected by PXE, listed as one of five co-inventors.
- Terry helped researchers at the University of Hawaii to isolate the gene by assisting in the laboratory and recruiting affected families.
- University of Hawaii granted the lead role in patent licensing to PXE International. PXE wants licences to be cheap and readily available. Any profits to be shared.
- Genetic freedom of contract?

Henrietta Lacks – dispute over ‘HeLa cells’

Henrietta Lacks and HeLa cells

- The HeLa cell line was established in 1951 from a biopsy of a cervical tumour taken from Henrietta Lacks, a working-class African-American woman treated at Johns Hopkins Hospital.
- The cells were taken without the knowledge or permission of her or her family, and they became the first human cells to grow well in a lab. Now widely used in research.
- Not patented at the time, but the cell line and downstream discoveries became extremely lucrative.

Interests of surviving family members

- **2013** HeLa genome published without knowledge of the family, which later endorses restricted access to HeLa genome data because of privacy concerns.
- 2017, media reports that a lawyer representing the eldest son and two grandsons of Henrietta Lacks requesting financial compensation. Arguments to be built around concept of guardianship rather than the property. Henrietta is continuing to be represented in life by her cells , guardianship order should be made to protect her interests.

Private genetic databases for genetic research: 23andMe

- Private company selling DNA analysis of saliva samples; personalised health and/or ancestry reports.
- World's largest consented, re-contactable database for genetic research.
- 2018, announcement that GSK to gain exclusive rights to mine 23andMe's customer data for drug targets. GSK also made USD \$300M investment in 23andMe.
- Customers can opt in or out to different research projects, but no clear mechanisms for sharing of profits.

Nebula Genomics

- Co-founded by George Church (MIT; Human Genome Project).
- Customers can get insights into their own health and contribute to medical breakthroughs.
- “... you own your genomic data, control who can use it, and are compensated for sharing access to your data”.
- Blockchain; those consenting to share their genetic data can earn Nebula’s cryptocurrency - “Nebula tokens”.
- Reach-through rights for downstream discoveries?

Thoughts for the future ...

- Moving towards recognition of donor's property rights?
England & Wales: *Yearworth* [2009]. Landmark case, but scope limited i.e. stored sperm for purposes of grounding negligence action when samples destroyed.
- Are property rights necessary and sufficient for successful retrospective lawsuits for unauthorised research and commercialisation? Maybe?
- Needed for fair prospective arrangements? Perhaps not!