

Bioprinting – Intellectual Property

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Prof. Angela Panoskaltzis–Mortari's BME 5361,
3D Bioprinting

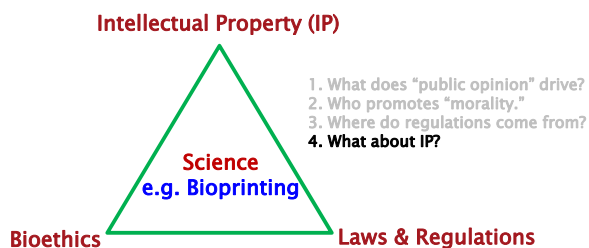
Overview

- ▶ Legal landscape.
 - Henrietta Lacks and the HeLa Cell Line.
 - Moore v. Regents of University of California.
 - Bayh-Dole Act 1980.
 - The Myriad Decision.
- ▶ Intellectual property protection.
 - Patents, Copyright, Trade Secrets, Trademarks/Domain names.
- ▶ Bioprinting perspective.
- ▶ International scene.
 - UK/EU, Wales



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The Ensemble



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Adopted from Buechner, B. "Embryonic Stem Cell Research in Law, Ethics and Science: When Law and Ethics Rule, Research Has to Pay?". *Cytotherapy* 15, no. 4 (Apr 2013): 527-527.

Legal Landscape

- ▶ Case law
 - Henrietta Lacks and the HeLa Cell Line
 - Moore v. Regents of University of California
 - Bayh-Dole Act 1980
 - The Myriad Decision



Harbaugh, J. T. "Do You Own Your 3d Printed Body?" *American Journal of Law & Medicine* 41 (2015): 22.

Continentaleurope. Statue of Justice at the Castellania in Valletta, Malta, Creative Commons

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Henrietta Lacks and the HeLa Cell Line

- ▶ In 1951 a patient named Henrietta Lacks went to Johns Hopkins Medical School for a biopsy of a lesion on her cervix.
- ▶ Dr. George Gey received a portion of the tissue, and his successful proliferation of the cells in vitro gave rise to the popular HeLa cell line.
- ▶ Dr. Gey freely distributed the cell line without patenting.
- ▶ The scientific community viewed the cell line as an extension of Lacks.
 - If the HeLa cells could exist apart from Lacks, their validity as a human analog and as a living organism would be questioned.
- ▶ In the 1980 thinking changed, and cell lines were patented.
 - Lockean labor view of property - "people own the fruits of their labor."
 - Redefinition of "living" as the ability to "retain . . . biochemical integrity and . . . replicate."

Harbaugh, J. T. "Do You Own Your 3d Printed Body?". *American Journal of Law & Medicine* 41 (2015): 22.

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Moore v. Regents of University of California

- ▶ Supreme Court of California considered an argument for an absolute property right in tissues and organs that have been abandoned by a patient.
- ▶ Plaintiff John Moore was treated for hairy-cell leukemia, and underwent a splenectomy.
 - The University attending physician and the researcher filed a patent that entitled them to a share of the university's royalties and profits from the "potentially lucrative" cell line developed from the spleen.
- ▶ Moore's claims was a claim for conversion, under the theory that Moore had ownership and possessory rights to the cell line and he did not extend authorization for the use of his spleen.
 - The court disagreed, Moore could not have a possessory interest in the spleen after its removal. Conversion theory could not be extended to this case.
 - The public has a strong interest in encouraging socially important medical research.

Harbaugh, J. T. "Do You Own Your 3d Printed Body?". *American Journal of Law & Medicine* 41 (2015): 22.

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Bayh-Dole Act 1980

- ▶ The federal government would no longer retain title to inventions supported by government funding.
 - Cut down on bureaucracy and encourage private industry to utilize government financed inventions through the commitment of the risk capital necessary to develop such invention to the point of commercial application.
 - Gene research was influenced the most; approximately 33,000 patents related to DNA were granted by 2006.

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Harbaugh, J. T. "Do You Own Your 3d Printed Body?". *American Journal of Law & Medicine* 41 (2015): 22.

The Myriad Decision

- ▶ Myriad Genetics, Inc. ("Myriad") made a medical breakthrough in discovering the location of the BRCA1 and BRCA2 gene sequences.
 - Myriad used this knowledge to develop tests for the detection of BRCA1 and BRCA2 mutations that would signal an increased risk for breast and ovarian cancer.
 - They proceeded to obtain broad patents that claimed the DNA sequences for BRCA1 and BRCA2, the cDNA sequences that code for BRCA1 and BRCA2, and subsets of these sequences.
- ▶ The Supreme Court held that the mere isolation of a naturally occurring DNA segment is not patent-eligible under 35 U.S.C. § 101, but a distinguishable cDNA segment is patent-eligible.
 - The latter did pass the test of having "markedly different characteristics from any found in nature," whereas the former did not.
 - In creating the cDNA, the court determined Myriad had created or altered genetic information, which was patentable.

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Harbaugh, J. T. "Do You Own Your 3d Printed Body?". *American Journal of Law & Medicine* 41 (2015): 22.

Intellectual Property Protection

- ▶ **Patents**
 - Strongest protection.
 - Most expensive and difficult to obtain.
- ▶ **Copyrights**
 - Easiest and least expensive to obtain.
- ▶ **Trade Secrets**
 - Must be kept secret.
 - No protection against independent development.
- ▶ **Trademarks/Domain Names**
 - Protection grows based on fame.



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Salmela, A. *Getting from Idea to IP: Formulating a Global IP Strategy*. Innovation Fellows Presentation, University of Minnesota, Patterson Thuyente Pederson, P.A., 2017.

Why obtain IP protection?

- ▶ Protect technology/brand/investment.
- ▶ Obtain financing.
- ▶ Provide an asset to increase the value of a company.
- ▶ Establish barriers to entry.
- ▶ Leverage against lawsuits.
- ▶ Establish licensing revenue.

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Gartner, Inc. "World's leading Research and Advisory Company"
Stamford, Conn., January 29, 2014.
<https://www.gartner.com/newsroom/id/2658315>

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IP Comparison Chart...

	PATENT	TRADE SECRET	TRADEMARK	COPYRIGHT
Subject Matter	Devices, apparatus, machines, systems, kits	All things listed under PATENTS, but legal secret instead of patenting	Company names and logos, product names	Books, articles, brochures, photos, architectural and artistic designs, software code
Right to Exclude	Making, using, selling, importing	Unfairly acquiring	Using similar mark on similar product	Copying (all or part)
Scope of Protection	Potentially broad, defined by the claims	Typically narrow, limited to the secret	Proportional to the commercial strength of the mark	Typically narrow, limited to the work, fair-use exceptions
Duration of Protection	20 years from the application	Perpetual (until not secret)	Perpetual (until not used or abandoned)	Varies (usually 30+ years)
Cost	Expensive	Inexpensive	Moderately expensive	Inexpensive
Legal Requirements	New, useful & non-obvious	Commercial value & secret	Source indicating & creative	Original work & fixation (on tangible medium)

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Patents

- ▶ A patent gives you the **right to exclude others from making, using, selling, importing or patenting your invention** (as defined by claims) for 20 years from the filing date.
 - You can sue a competitor for infringement.
 - You can assign or license in exchange for payment.
- ▶ Just about anything made by a person is patentable.
 - *Abstract ideas* and *laws of nature*, not made by someone, are **not patentable**.

Salmela, A. *Getting from Idea to IP, Formulating a Global IP Strategy*; Innovation Fellows Presentation, University of Minnesota, Patterson Thunte Pederson, P.A., 2017.

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What Can be Patented?

- ▶ Any **"new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof"**.
- ▶ The **patent applicant need not have actually built or produced a marketable product**, however.



Van Norman, G. A., and R. Eisenkot. "Technology Transfer: From the Research bench to Commercialization: Part 1: Intellectual Property Rights—Basics of Patents And copyrights: Part 1: Intellectual Property Rights—Basics of Patents And copyrights." *JACC: Basic to Translational Science* 2, no. 1 (2017): 85-97.

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Usefulness...

- ▶ Must **perform as stated with intended purpose**.
- ▶ Cannot be issued for an **idea, suggestion, law of nature, or physical phenomena**.
- ▶ The patent is a full description and instruction to the public regarding the purpose of the technology and how to build it.

Van Norman, G. A., and R. Eisenkot. "Technology Transfer: From the Research bench to Commercialization: Part 1: Intellectual Property Rights—Basics of Patents And copyrights: Part 1: Intellectual Property Rights—Basics of Patents And copyrights." *JACC: Basic to Translational Science* 2, no. 1 (2017): 85-97.

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Novelty...

- ▶ Cannot have been previously invented, have a patent application already filed, or be known to others or otherwise available to the public anywhere in the world.
- ▶ Includes types of disclosures such as “an oral presentation at a scientific meeting, a demonstration at a trade show, a lecture or speech, a statement made on a radio talk show, YouTube™ video, or a website or other online material.”

Van Norman, G. A., and R. Eisenkot. "Technology Transfer: From the Research bench to Commercialization: Part 1: Intellectual Property Rights—Basics of Patents And copyrights: Part 1: Intellectual Property Rights—Basics of Patents And copyrights." *JACC: Basic to Translational Science* 2, no. 1 (2017): 85-97.

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- ▶ If a *grant application* is disclosable (Freedom of Information Act), there may be sufficient information to violate the novelty.
- ▶ There is a *12 month grace period* in the United States (disclosure to patent).
- ▶ May not be patentable if not sufficiently different from existing methods or materials to make it *nonobvious* to someone skilled in the area and viewing the available literature.

Van Norman, G. A., and R. Eisenkot. "Technology Transfer: From the Research bench to Commercialization: Part 1: Intellectual Property Rights—Basics of Patents And copyrights: Part 1: Intellectual Property Rights—Basics of Patents And copyrights." *JACC: Basic to Translational Science* 2, no. 1 (2017): 85-97.

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What a Patent Does *Not* Do?

- ▶ **Provide a government-enforced monopoly on the invention.**
 - Claims must be self-enforced.
- ▶ **Protect you from being sued for infringement.**
 - May still infringe other's patent.
- ▶ **Guarantee**
 - May be found invalid or not infringed. Courts interpret what a patent means and juries determine whether there is infringement.

Salmela, A. *Getting from Idea to IP. Formulating a Global IP Strategy.* Innovation Fellows Presentation, University of Minnesota, Patterson Thuentje Pederson, P.A., 2017.

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Bioprinting and the Patent Landscape...

- ▶ Remember that patent eligible material excludes "laws of nature, physical phenomenon and abstract ideas."
- ▶ Essentially anything made by people is patentable – except human organism (Plant and animal organisms are ok).
- ▶ Technically, bioprinting processes and bioprinted products are man-made, and patentable. "Process" is preferred if "Product" is forbidden.
- ▶ If a bioprinted organism or its living tissue is a *complete redesign* of another naturally occurring organism or its living tissue, then that bioprinted material can be patentable. *What if structurally similar?*

Tran, JA. Patenting Bioprinting, *Harvard Journal of Law & Technology*, September 23, 2015. jolt.law.harvard.edu/digest/patenting-bioprinting.
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- ▶ Consider expressing bioprinted human living tissue as *implants* or *medical devices*.
- ▶ Clone printing of a naturally existing organism is not likely patentable, but clone printing of a manmade organism (i.e., a genetically engineered animal) would likely be patentable.

Tran, JA. Patenting Bioprinting, *Harvard Journal of Law & Technology*, September 23, 2015. jolt.law.harvard.edu/digest/patenting-bioprinting.
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Types of Patent Applications...

- ▶ **Provisional**
 - 1 year from date of filing.
 - Not examined or published.
 - "patent pending" status.
 - Can set priority date for non-provisional application filed within one year.
- ▶ **Non-Provisional**
 - 20 year term
 - Published 18 mos. from earliest priority date.
 - Legally enforceable rights defined by the claims.

Salmela, A. *Getting from Idea to IP, Formulating a Global IP Strategy*, Innovation Fellows Presentation, University of Minnesota, Patterson Thuyente Pederson, P.A., 2017.
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Leahy-Smith America Invents Act (AIA)...

- ▶ September 16, 2011 – effective March 16, 2013.
- ▶ First major legislative overhaul of the U.S. patent system in 60 years.
- ▶ Switching from a “first-to-invent” system to a “*first-inventor-to-file*” (harmonizing with the rest of the world).
- ▶ Grants patents to inventors *who first file* their applications with the U.S. Patent and Trademark Office, rather than *who actually conceived of the invention first*.
- ▶ Encourages inventors to file their patent applications quickly – almost *at the proof-of-concept* or *invention-formation* stage.
- ▶ Inventors can *no longer base their patent rights on proof of originality* of an invention.

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Buntz, B. *What Medtech Entrepreneurs Need to Know about Patent Reform*. Interview with David Dykeman. Medical Device and Diagnostic industry Qmed January 17, 2012.

Consequences...

- ▶ Companies should make sure their patent applications are on file *before* they talk to any third parties or potential investors.
- ▶ Rush to file may lead to weaker patents.
- ▶ May need to file additional *provisional applications* to ensure all aspects of the technology are covered.
- ▶ *Harmonization* simplifies the patent process in other countries.

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Buntz, B. *What Medtech Entrepreneurs Need to Know about Patent Reform*. Interview with David Dykeman. Medical Device and Diagnostic industry Qmed January 17, 2012.

- ▶ File several *provisional patent applications* to secure priority claims while buying time to more fully develop their technology and applications.
- ▶ Cover the *current technology* as well as *future technology innovations* and *alternative embodiments* to prevent opportunities for competitors to design around their patents.

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Buntz, B. *What Medtech Entrepreneurs Need to Know about Patent Reform*. Interview with David Dykeman. Medical Device and Diagnostic industry Qmed January 17, 2012.

Copyright

- ▶ Copyright holders have *exclusive rights to reproduce the work, create derivative works, distribute copies of the work, perform the work publicly, display the work publicly, or perform a sound recording by means of digital audio.*
- ▶ *Does not protect ideas, procedures, processes systems, methods of operation, concepts principles, or discoveries,* “regardless of the medium in which they are described, explained, illustrated or embodied in such work”

Van Norman, G. A., and R. Eisenkot. "Technology Transfer: From the Research bench to Commercialization: Part 1: Intellectual Property Rights—Basics of Patents And copyrights: Part 1: Intellectual Property Rights—Basics of Patents And copyrights." *JACC: Basic to Translational Science* 2, no. 1 (2017): 85-97.

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- ▶ The *mere creation* of a material copy of an original work that falls under the copyright protection act is all that is required to acquire copyright protection.
- ▶ *Registration within 5 years* of a work’s creation can be used as *prima facie evidence of ownership* in a court of law.
- ▶ Furthermore, if a creator chooses at any time to pursue an action against another for *copyright infringement*, they will be required to first register the work with the Copyright Office.

Van Norman, G. A., and R. Eisenkot. "Technology Transfer: From the Research bench to Commercialization: Part 1: Intellectual Property Rights—Basics of Patents And copyrights: Part 1: Intellectual Property Rights—Basics of Patents And copyrights." *JACC: Basic to Translational Science* 2, no. 1 (2017): 85-97.

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Registering...

- ▶ Required*:
 - Completed application form.
 - Nonrefundable filing fee \$35 to \$55.
 - Nonreturnable copy or copies of the work being registered.
- ▶ Software** :
 - Must deposit first and last 25 pages of source code.
 - Code that is considered a trade secret can be redacted.



*Van Norman, G. A., and R. Eisenkot. "Technology Transfer: From the Research bench to Commercialization: Part 1: Intellectual Property Rights—Basics of Patents And copyrights: Part 1: Intellectual Property Rights—Basics of Patents And copyrights." *JACC: Basic to Translational Science* 2, no. 1 (2017): 85-97.

**Olson, M.Y., and C.S. Krummen. *Protection and Enforcement of Software as a Medical Device*. Presentation to IFP August 16, 2017, Minneapolis, MN.

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Trade Secrets

- ▶ Owner of a business chooses not to disclose information, innovations or processes that it develops.
- ▶ Once disclosed for any reason, they are no longer trade secrets.
- ▶ Trade secret law does not apply to information, innovations, or other materials that are readily deducible or obvious.
- ▶ Only recourse of a breach is against the one who disclosed (“morally offensive breach”).



Van Norman, G. A., and R. Eisenkot. "Technology Transfer: From the Research bench to Commercialization: Part 1: Intellectual Property Rights—Basics of Patents And copyrights: Part 1: Intellectual Property Rights—Basics of Patents And copyrights." *JACC: Basic to Translational Science* 2, no. 1 (2017): 85-97.

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Trademarks

- ▶ Governed by federal & state law.
- ▶ A trademark is a word, symbol, phrase, color, packaging used to identify a particular manufacturer or seller's products and distinguish them from the products of another (e.g. Nike swoosh).



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<https://cyber.harvard.edu/metaschool/fisher/domain/tm.htm#toc>

- ▶ A mark must be distinctive -- that is, it must be capable of identifying the source of a particular good. The courts group marks into four categories, based on the relationship between the mark and the underlying product:
 - Arbitrary or fanciful e.g. Nike swoosh, McDonald arches,
 - Suggestive – e.g. Coppertone,
 - Descriptive – requires time to obtain secondary meaning – e.g. “Holiday Inn”),
 - **Generic – no trademark protection – e.g. “Apple” by an apple seller – unfair competitive advantage.**

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<https://cyber.harvard.edu/metaschool/fisher/domain/tm.htm#toc>

Bioprinting Perspective

- ▶ Patents: bioprinters, bioprinting materials, and fabrication and postproduction maturation processes.
- ▶ Copyrights would protect the CAD-CAM files for scanning, manufacturing, and bioprinter control.
- ▶ The U.S. Code permits patents on "any new and useful process, machine, manufacture or composition of matter."
 - Products of nature are not patent-permissible; however, variations of naturally occurring organisms may be patented.

Prof. Steven S. Salterman Varkey, Mathew, and Anthony Atala. "Organ Bioprinting: A Closer Look at Ethics and Policies." *Wake Forest Journal of Law & Policy* 5, no. 2 (2015): 275-98.

Biofabrication.....

- ▶ Raw *digital blueprints* from an organ scan will unlikely receive the benefit of patent protection.*
- ▶ Less clear is the patentability of a *scanned organ that retains its form but has been transformed* into a mesh structure with structural improvements in order to function as a scaffold.*
- ▶ Bioprinted constructs *integrating imaging data, cells and other materials may be patentable.*
 - Additional consideration must be given if proprietary cell lines and materials are used.

Prof. Steven S. Salterman *Harbaugh, J. T. "Do You Own Your 3d Printed Body?." *American Journal of Law & Medicine* 41 (2015): 22.

- ▶ Bioprinted *in-vitro* devices for drug testing and other applications may be patentable.
- ▶ Newly developed software will require copyright rather than patent protection.**
 - Copyright protects the means of expression of an idea and can be useful to protect software, code, digital drawings, sculptures, and 3D models.

Prof. Steven S. Salterman **Esmond, R. W. et al. "The Additive Manufacturing Revolution and the Corresponding Legal Landscape This Paper Discusses the Ways to Protect Innovations in Additive Manufacturing in This Fast Changing World." *Virtual and Physical Prototyping* 10, no. 1 (2015): 9-12.

Public or Private Goods?

- ▶ **Rivalry and exclusivity** of patient, physician, university, and biotechnology company.
 - **Rivalry** is the degree that the use or consumption of a good reduces its availability for a subsequent user.
 - **Exclusivity** is the ability to prevent others from enjoying the good.
- ▶ The three main components of **bioprinted organs**—the **blueprints**, the **biomaterials**, and the **cells**—can generally be characterized as being nonrivalrous and noncompetitive
 - However, arguments for broader property rights and increased regulation could be supported even if bioprinted organs are conclusively determined to be public or private goods by nature.

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Harbaugh, J. T. "Do You Own Your 3d Printed Body?". *American Journal of Law & Medicine* 41 (2015): 22.

Potential Patenting Areas...

Areas of potential IP	Examples of possible IP contents
Hydrogel/extracellular matrices (ECM) materials	-New formulation of ECM/hydrogel precursor materials with tissue-like functional properties with inert immunological responses. -Novel methods on how to derivatize/these such materials.
Isolation and growth/differentiation of cells in the context of bioprinting	-Novel methods on how to derive cells, either primary or pluripotent, that can be used as sources for bioprinting. -Methods to prepare the cells for printing, with or without the combination of scaffold materials.
Bioreactor/method to grow printed organ precursors	-Methods of integration and coupling of printed organ precursors with the external bioactors. -Development of modular bioreactor/bioreactor components that subserve different culture conditions. -Novel methods that enable automated organ growth after printing.
Methods of dispensing/printing techniques	-Single-cell precision loading and dispensing of various types of cells. -Method to improve speed of printing, for example, deployment of multiple dispensing arrays. -Novel methods to dispense liquid materials with higher viscosities, in form of droplets, which may broaden the choices of printable materials.
Methods of novel 3D fabrication techniques	-Hybrid approaches to constructively enhance the current 3D printing principles.

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Yoo, S. S. "3d-Printed Biological Organs: Medical Potential and Patenting Opportunity." *Expert Opinion on Therapeutic Patents* 25, no. 5 (May 2015): 507-11.

International

"Stem-cell researchers in Europe are reeling after the court of Justice of the European Communities issued an opinion questioning the ethics of their work and threatening to ban them from patenting stem-cell lines."



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Abbott, Alison. "Europe Rules against Stem-Cell Patents: Work with Human Embryonic Stem Cells Is 'Contrary to Ethics';(European Law)." *Nature* 471, no. 7338 (2011): 280.

UK/EU

- ▶ **Human Tissue Act 2004:**
 - Only a licensed person is allowed to remove a living person's transplantable material.
 - Such removal would need to be non-commercial.
 - A full informed consent process should minimize the risk of harm and possible violation of ethical considerations.
 - Express consent from the donor is required to remove, store, and use his or her tissues.
- ▶ **Legislation** relevant to 3D printing:
 - ATMP Regulation
 - EC Tissues and Cells Directive
 - Pharmaceutical Regulation
 - Medical Device Regulation

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Li, P., and A. Faulkner. "3d Bioprinting Regulations: A UK/EU Perspective." *European Journal of Risk Regulation* 8, no. 2 (Jun 2017): 441-47.

Wales

- ▶ **The Human Transplantation (Wales) Act 2013**
 - The Act aims to increase deceased donor organ and tissue donation in Wales by introducing a '**soft opt-out**' system to replace the previous requirement of express 'appropriate' consent under the Human Tissue Act 2004.
 - Adults dying in Wales (with certain exceptions) will be '**deemed to consent to donation**', unless evidence of their objection is produced, and a duty is imposed on Ministers to promote transplantation and inform the public through awareness campaigns about how to choose the deemed status or opt out

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Douglas, James F., and Antonia J. Cronin. "The Human Transplantation (Wales) Act 2013: An Act of Encouragement, Not Enforcement." *Modern Law Review* 78, no. 2 (2015): 324-48.

Summary

- ▶ Legal landscape.
 - Henrietta Lacks and the HeLa Cell Line.
 - **Moore v. Regents of University of California.**
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