



JOHNS HOPKINS

WHITING SCHOOL  
of ENGINEERING

# Cell and Tissue Engineering

Patient Protection

# Patent protection (1)

**Utility Patent** – “new and useful process, machine, manufacture or composition of matter”

**20yrs**



**Design Patent** – “new, original and ornamental design embodied in or applied to an article of manufacture”

**14yrs**

**Plant Patent** – “new and distinct, invented or discovered asexually reproduced plant”

**20yrs**

# Patent protection (2)

**Utility Patent** – “new and useful process, machine, manufacture or composition of matter”

**20yrs**

**Design Patent** – “new, original and ornamental design embodied in or applied to an article of manufacture”

**14yrs**

**Plant Patent** – “new and distinct, invented or discovered asexually reproduced plant”

**20yrs**



# Patent protection (3)

**Utility Patent** – “new and useful process, machine, manufacture or composition of matter”

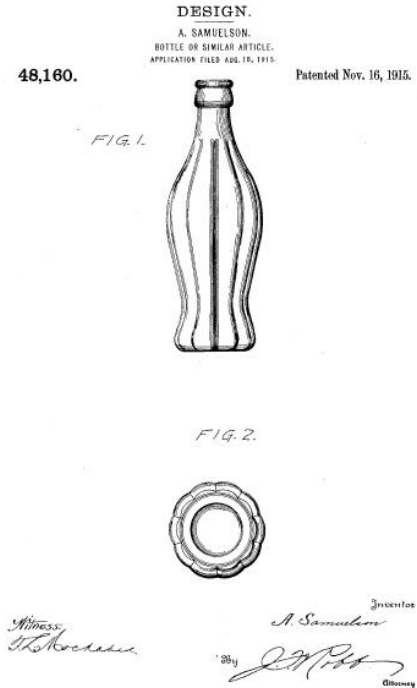
**20yrs**

**Design Patent** – “new, original and ornamental design embodied in or applied to an article of manufacture”

**14yrs**

**Plant Patent** – “new and distinct, invented or discovered asexually reproduced plant”

**20yrs**



# Patent protection (4)

**Utility Patent** – “new and useful process, machine, manufacture or composition of matter”

**20yrs**

**Design Patent** – “new, original and ornamental design embodied in or applied to an article of manufacture”

**14yrs**

**Plant Patent** – “new and distinct, invented or discovered asexually reproduced plant”

**20yrs**



# Patent protection - criteria

- Novelty
- Usefulness
- Non-obvious
- *Timing!*



# US commercial development

- Public Health Service – PHS
- Food and Drug Administration – FDA
- 6 Centers

CDRH  
Center for Devices and Radiological Health

CDER  
Center for Drug Evaluation and Research

CBER  
Center for Biologics Evaluation and Research

Food Safety and Cosmetics  
Veterinary Medicine  
Toxicological Research

Tissue  
Engineered  
Medical  
Products

**(TEMPS)**

# US commercial development (cont.)

**Public Health Service – PHS**

**Food and Drug Administration – FDA**

**Office of Combination  
Products**

Office of Orphan Products  
Office of Regulatory Affairs

*Safe Medical Device Act of 1990*

*Medical Device User Fee and Modernization Act of 2002*

PUBLIC LAW 101-629—NOV. 28, 1990

104

Public Law 101-629  
101st Congress

An Act

To amend the Federal Food, Drug, and Cosmetic Act to make improvements in the regulation of medical devices, and for other purposes.



# Regulatory process for combination product

## Request for Designation (RFD)

Primary Mode of Action (PMOA)

### Device

**Investigational  
Device Exemption  
(IDE)**

**Institutional  
Review Board  
(IRB)  
Phased Clinical  
Trials**

**Pre-Market  
Approval  
(PMA)**

**Predicate Device,  
Substantial  
Equivalence**

**Premarket  
Notification 510(k)**

**Clearance**

**Humanitarian  
Use Device  
(HUD)  
<4,000 patients**

**Humanitarian  
Device  
Exemption  
(HDE)**

### Biologic

**Investigational  
New Drug (IND)**

**Institutional  
Review Board (IRB)  
Phased Clinical Trials**

**Biologics License  
Approval (BLA)**

# What comes after the market?

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# HCT/Ps human cellular-and tissue-based products

- Current Good Tissue Practice for Human Cell, Tissues, and Cellular-and Tissue-Based Products (cGTP Rule)
- **Task Force on Human Tissue Safety**

## **Kick-down Criteria for 361 Products**

1. Minimal Manipulation of the source tissue (through processing)
2. Homologous use
3. Freedom from combination with another article  
(excluding sterilization, preservation or storage agents)
4. Absence of systemic effects or dependence on the metabolic activity of living cells  
(excluding autologous use, use in first degree relatives, or reproductive use)

# What does this all mean?

**FDA**  
evaluates  
benefits/risks  
for the population



**Provider**  
evaluates  
benefits/risks  
for a patient



**Patient**  
evaluates  
benefits/risks  
in terms of  
personal values





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