

# Identity & Invention: The Culture of Personalized Medicine Patenting



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# Main Points



- Legal developments
- Legal theory
- Legal policy

**Identity, Invention, and  
the Culture of  
Personalized Medicine  
Patenting**  
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(57)

## ABSTRACT

The present invention provides methods of treating and preventing mortality associated with heart failure in an African American patient with hypertension and improving oxygen consumption, quality of life and exercise tolerance by administering a therapeutically effective amount of at least one hydralazine compound and at least one of isosorbide dinitrate and isosorbide mononitrate, and, optionally, one or more compounds, such as, for example, a digitalis, a diuretic compound, or a compound used to treat cardiovascular diseases. In the present invention, the hydralazine compound is preferably hydralazine or a pharmaceutically acceptable salt thereof. Preferred methods of the invention comprise administering hydralazine or a pharmaceutically acceptable salt thereof and isosorbide dinitrate.

# Requirements for patentability



- Patentable subject matter
- Industrial Application
- Novelty
- Inventive step (or nonobviousness)

# European Patent Office Decision (2009)



- **Stem cells derived from destruction of human embryo are not patentable**

- **Basis for decision**

**European Patent Convention restriction on patenting of human embryo for industrial purpose.**

- **Key distinctions**

**Human versus cell lines or tissue lines**

**Destruction of human embryo versus non-destruction**

**Industrial versus non-industrial purpose.**

# Article 27(2) TRIPS Agreement



Members **may exclude from patentability** inventions, the prevention within their territory of the commercial exploitation of which is **necessary to protect *ordre public* or morality**, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

# Comparisons with United States



- Under Bush administration, ban on federal funding for human embryonic stem cell research
- State funding filled in the gap
- No restriction on patenting in US

Patent policy to promote research and invention

Patent law view of industrial application (utility)



# Industrial Applicability in US



- **Lowell v. Lewis (US case from the year 1817):** patent can be denied if injurious to well-being, good morals or sound policy of society.
- **Brenner v Manson (US Supreme Court case from 1966):** movement away from “moral utility.” Invention must have application that is substantial and specific.
- **Juicy Whip v. Orange Bang (US case from year 1999):** rejection of “moral utility.” “Congress never intended that the patent laws should displace the police powers of the States, meaning by that term those powers by which the health, good order, peace and general welfare of the community are promoted.”

# Tale of Two Patent Laws



- **EPO**
- **Consideration of public order and morality**
- **Exclusion from patenting**

- **United States**
- **Patents as a purely technical matter**
- **Very little exclusion from patenting**
- **Patent office remains outside of politics**

# Recent developments in US patent law



- **Diamond v Chakravarty (1980):**
  - Biotechnology patenting begins
  - “Anything under the Sun made by man”
  - Courts defer to Congress
- **Laboratory Corp v Metabolite (2006):**
  - Medical diagnostic patent
  - Hint that patentable subject matter has limits
- **Bilski v. Kappos (2010):**
  - Business method patent
  - Abstract ideas are not patentable subject matter

# Biotechnology Developments in US



- **American Pathological Society v Myriad (Fed Circuit 2011)**
  - District Court invalidates patent on breast cancer gene and method to diagnose likelihood of cancer
  - Federal Circuit restores patent on breast cancer gene but affirms invalidation of method to diagnose patent
- **Prometheus v Mayo (2012)**
  - Supreme Court invalidates patent on method to diagnose and treat Crohn's Disease
  - Method is an abstract idea without concrete application and law of nature

# America Invents Act of 2011



- Codifies ban on patents relating to “human organisms”
- Allows opposition to granted patents
- Limits patents as applied to “prior users”

# Developments in EU



- **Brustle v Greenpeace (European Court of Justice (2011)):**
  - Patents relating to human stem cells can be excluded by nation states
  - Directive on technology prevents exploitation of embryos for industrial or commercial purposes
  - Medical diagnosis and therapy not an industrial or commercial purpose
  - Question of whether human stem cells are “embryos” left to nation states
  - Human embryo: “any human ovum after fertilization, any non-fertilized human ovum into which the cell nucleus from a mature human cell has been transplanted, and any non-fertilized human ovum whose division and further development have been stimulated by parthenogenesis”

# Legal theory



- **Personhood and Patenting**
  - Margaret Radin
- **Persons and Justifications**
  - Derek Parfit
- **Persons and Human Activity**
  - Hannah Arendt

# Legal policy



- **Patenting and consequences**
- **Ownership and Use**
- **Institutional Contexts for Intellectual Property**