

Stem Cells and the European Patent System

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ESRC Stem Cell Initiative



S.I.B.L.E

Aims



- Overview of patentability of biotechnological inventions and moral exclusions in Europe
- Analysis of the leading EPO case on stem cells
- Evaluation of emerging systemic fault-lines
- Roadmap for the future

What is patentable in Europe?

Article 5(1)

The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, **cannot** constitute patentable inventions.

Article 5(2)

An element *isolated* from the human body or otherwise *produced by means of a technical process*, including the sequence or partial sequence of a gene, may constitute a patentable invention, *even if the structure of that element is identical to that of a natural element*.

EU Directive on Biotechnological Inventions 98/44/EC

Moral Exclusions



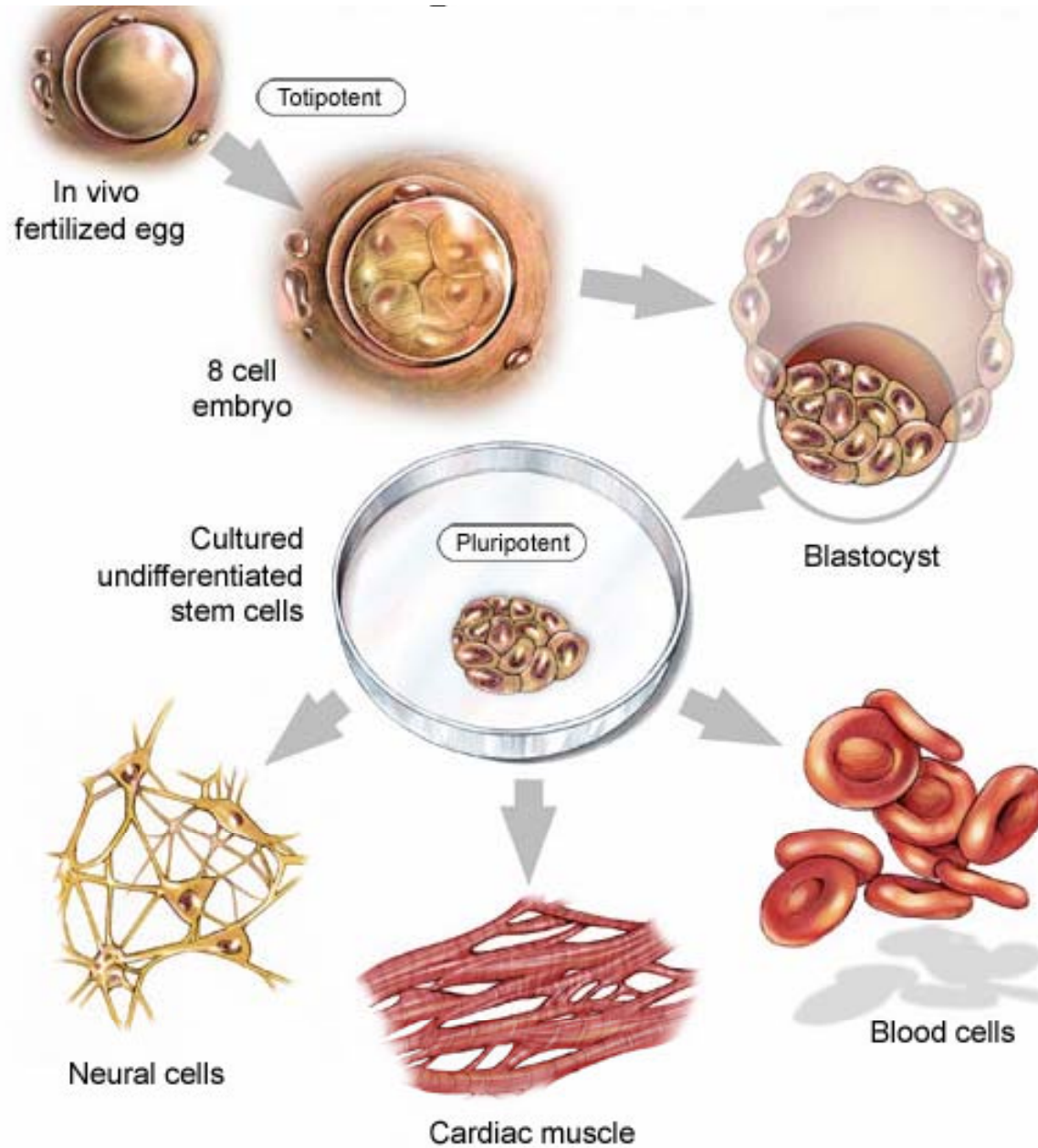
Article 6(1) /Article 53(a) EPC

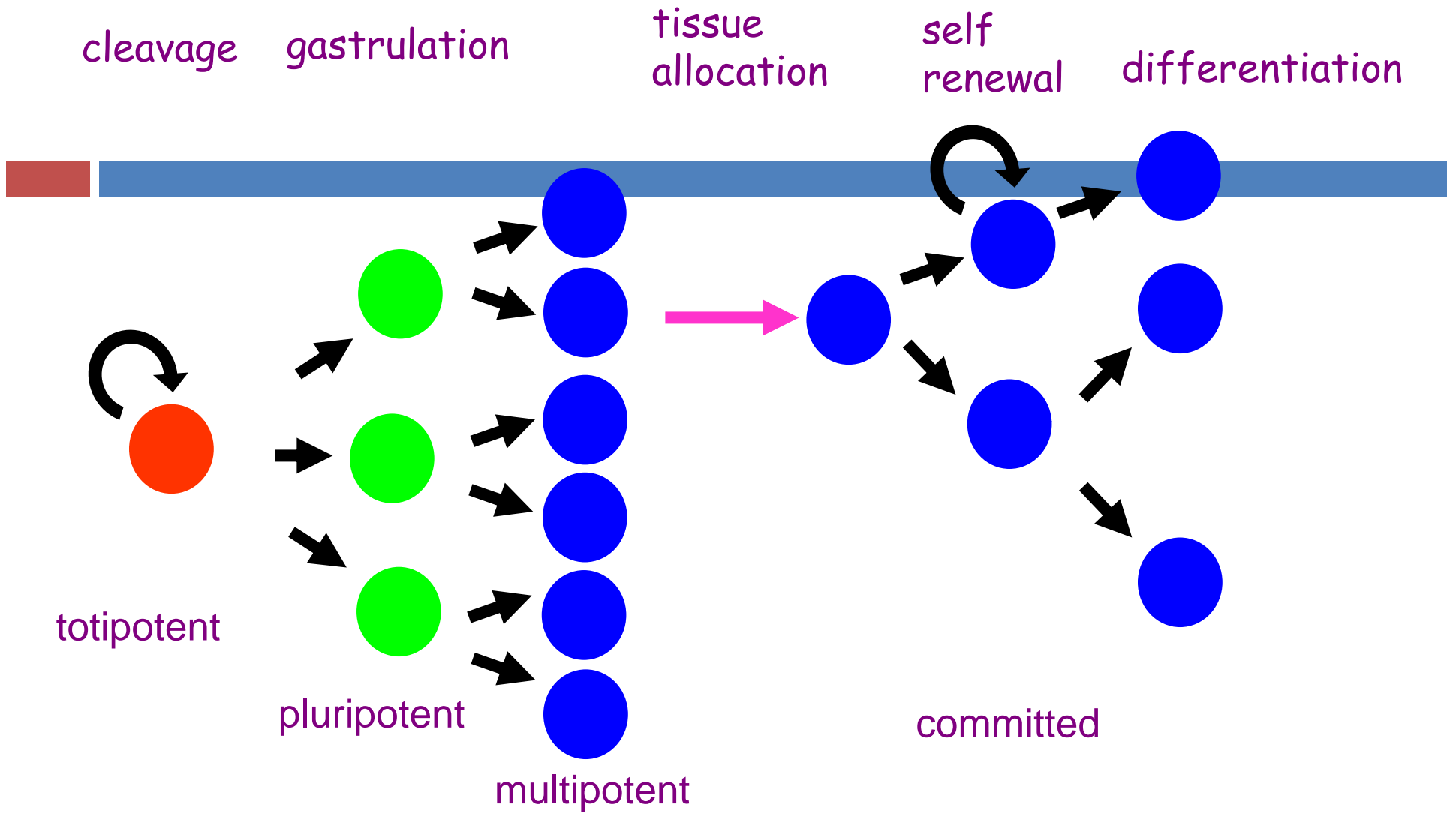
Inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality ...

Article 6(2)(c)/Rule (23)d(c) now 28(c) EPC

- Uses of human embryos for industrial or commercial purposes.

Es cells: in vitro can self-renew indefinitely, or differentiate to many fates





Scope of Exclusion

The Narrow Approach: UK



Not Patentable

- ❑ Human embryos
- ❑ Totipotent hES cells
- ❑ Processes for extracting stem cells from the human embryo

Patentable

- ❑ Pluripotent hESC cells

UKIPO Practice Statement (2003)

Sweden

Not Patentable

- Human embryos
- Processes involving repetitive use of the human embryo

Patentable

- Pluripotent hESC cells


WARF 'Method of Differentiation of Pluripotent hES cells into hematopoietic cells (SE 526490)


The Broad Approach: EPO Boards



Rule 23 d(c) has to be interpreted broadly to encompass not only direct uses of the embryo but also the human ES cells retrieved therefrom by destruction of the human embryo.

Edinburgh Case (OD, 21 July 2003)


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- ... For the purpose of the morality assessment it is not sufficient that the objectionable method is not claimed *per se*, as long as it is the only thinkable – and workable- option of obtaining the claimed subject-matter.

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- ... does rule 23d(c) [now 28(c)] EPC forbid the patenting of claims directed to products (here hESC cultures) which – as described in the application – at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, if the said method is not part of the claims?

Referral of Technical Board of Appeal (T 1374/04)

E.B.A. WARF ruling

- Legislative purpose was to prevent a misuse in the sense of commodification of human embryos ... with one of the essential objectives of the whole Directive to protect human dignity (para. 18).
- Scope of exclusion not confined to claims but includes “the technical teaching of the invention as a whole as to how the invention is to be performed..”
- Here the “only teaching of how to perform the invention to make hESC cultures is the use (involving their destruction) of human embryos.” (Para. 22)

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- Making the claimed product remains commercial or industrial exploitation of the invention even where there is an intention to use that product for further research (para. 25).
 - It is not the fact of the patenting itself that is considered to be against *ordre public* or *morality*, but it is the performing of the invention, which includes a step (the use involving its destruction of a human embryo) that has to be considered to contravene those concepts (para. 29).

Clear as mud?

- This decision is not concerned with the patentability in general of inventions relating to human stem cells or human stem cell cultures. It holds unpatentable inventions concerning products (here human stem cell cultures) which can only be obtained by the use involving their destruction of human embryos.

Emerging Tensions



- Integrity of legal system; systemic conflict between research laws and patent law.
- Encroachment of constitutional boundaries.
- Legitimacy and authority of EPO's rulings on morality

Research Ethics v. Patent Ethics



- In 2006, the German Federal Patent Court invalidated on moral grounds a national patent granted to Oliver Bruestle in 1999, notwithstanding the German Stem Cell Law allowing the import of hESC lines and the public funding of this research by the German Ministry for Science & Education. The corresponding EU patent had been granted by the EPO only months before.

Legitimacy of EPO's rulings on morality



- EPC Treaty vests authority on EPO boards to apply moral bars on patents but is silent on the legal and constitutional boundaries within which the exercise of this power is to be conducted.

Legal Parameters in the Directive



- ... substantive patent law cannot serve to replace or render superfluous national, European or international law (R 14)
- ...ethical or moral principles **supplement** the standard legal examination under patent law (R 39)
- ...whereas *ordre public* and morality **correspond** in particular to ethical or moral principles **recognised** in a Member State (R 39)

Constitutional Boundaries




- ... fundamental rights form an integral part of the general principles of law the observance of which the Court ensures, and that, for that purpose, the Court draws inspiration from the constitutional traditions common to the Member States and from the guidelines supplied by international treaties for the protection of human rights on which the Member States have collaborated or to which they are signatories. *The ECHR has special significance in that respect...*

(Netherlands Case: ECJ – C-377/98)

The Jurisprudence of the ECrtHR on the embryo's right to life

The Court recalls...that in *Vo v France* it held that, in the absence of any European consensus on the scientific and legal definition of the beginning of life, the issue of when the right to life begins comes within the margin of appreciation which the Court generally considers that States should enjoy in this sphere. Under English law ... an embryo does not have independent rights or interests and cannot claim –or have claimed on its behalf- a right to life under Article 2.

Evans v UK (6339/05) at para. 46.

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- “... it is common ground that this provision (Article 6) allows the administrative authorities and courts of the Member States a wide scope for manoeuvre in applying this exclusion.” (para. 37)
 - “... that scope for manoeuvre is necessary to take account of the particular difficulties to which the use of certain patents may give rise in the social and cultural context of each Member State (para. 38).

(Netherlands Case: ECJ – C-377/98)

SYSTEMIC FAULTLINES

Institutions

- Fragmented governance of IP - lack of integration of national, EU and EPO law.
- Overlapping roles of patent offices and courts

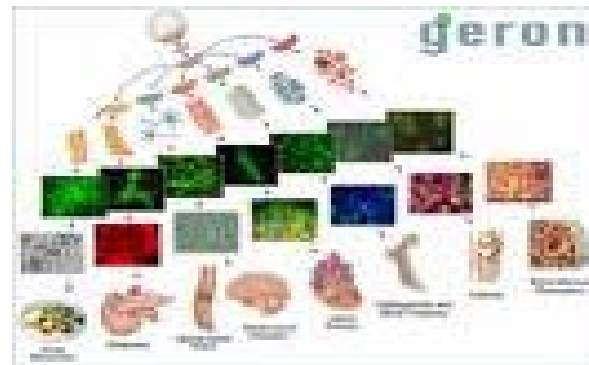
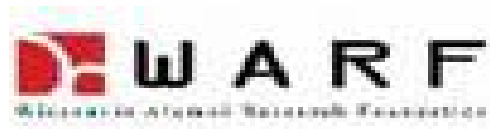
Rules

- Indeterminate rules on scope and validity of moral exclusions on patents.
- Divergent and inconsistent approaches by different patent offices/courts

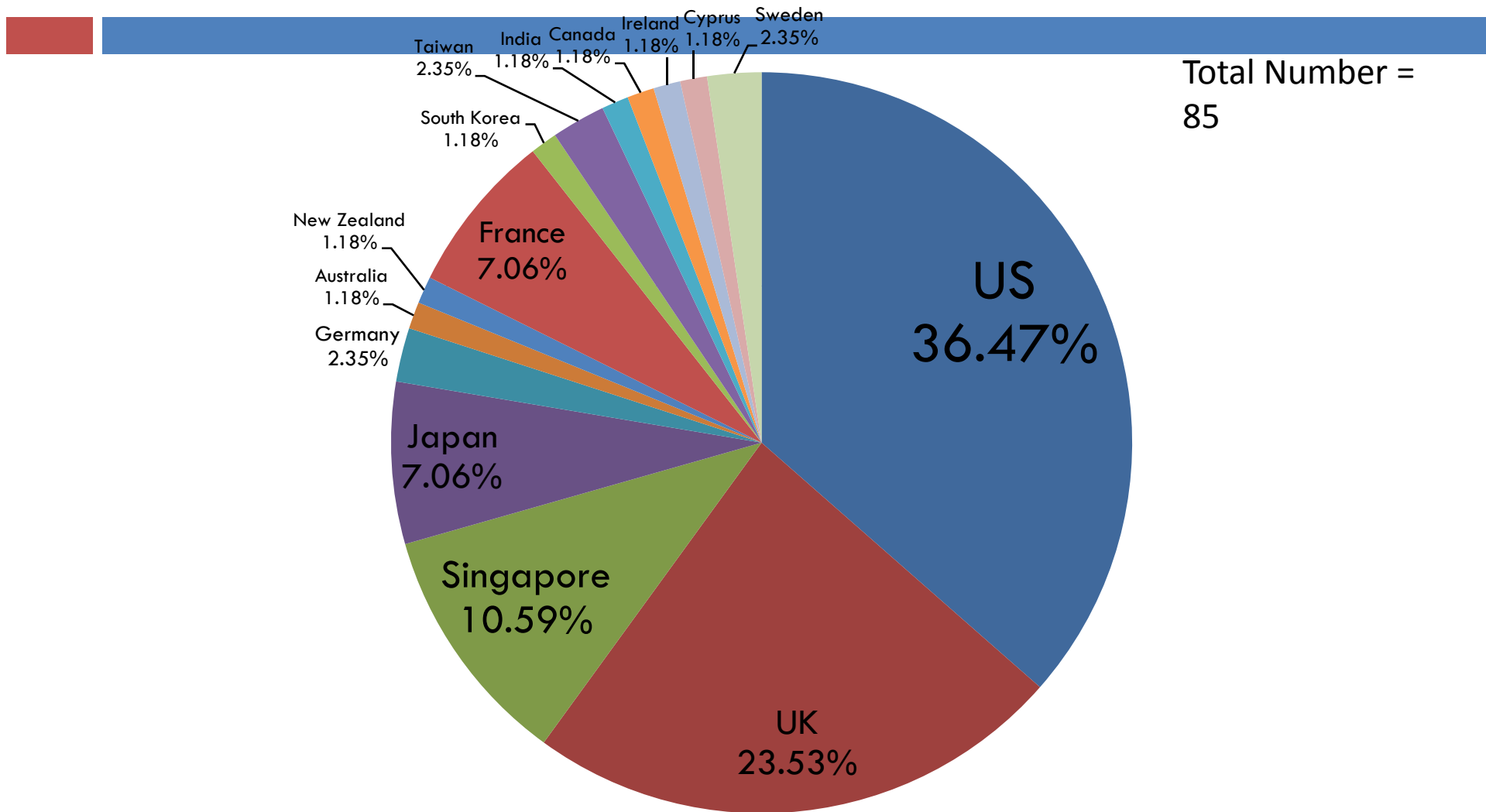


Uncertainty, Latency, High Social and Economic Costs, Gaming the system

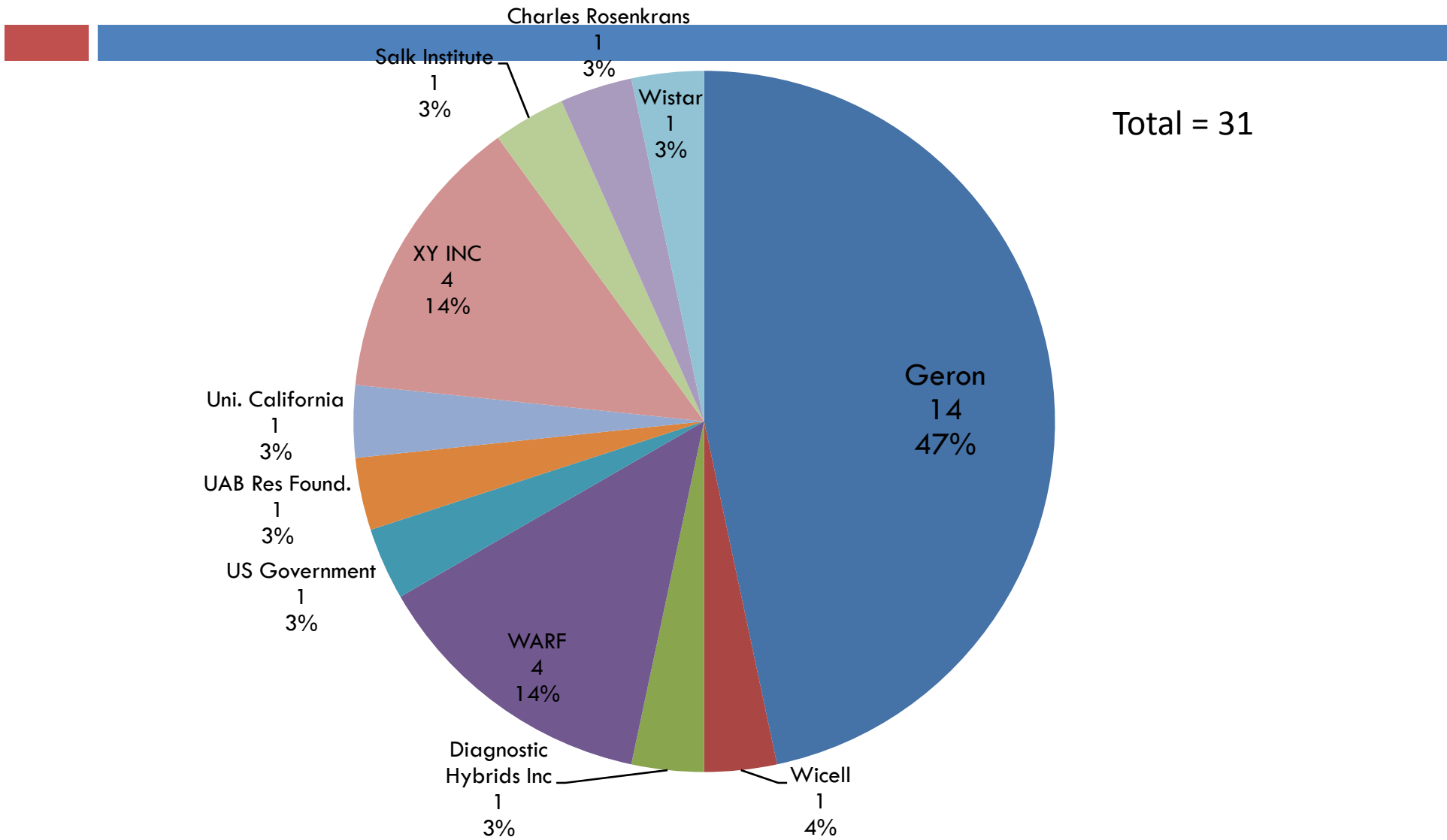
The European 'Moral' Maze



Distribution of UK Grants per Patentees Country of Residence as of January 2009



% of UK Patents per US based Institution



Out of the Moral Maze



- Preserve integrity of legal system
- Narrow construction of specific moral exclusions
- Respect constitutional boundaries and autonomy of Member States