



Does Stem Cell Research in Europe Use Human Embryos for Industrial or Commercial Purposes?

A Comment of EBA G 02/06 Decision

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Grand Challenges and New Opportunities"**

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- **Regulatory Rules vs. Patents - Complex Relationship - A Reminder**
- **International and European Legal Framework**
- **Ethics - Stem Cell Research & Patents**
- **The WARF Decision of the Enlarged Board of Appeal**
- **Impact of WARF Decision on Exploitation of Research Results**
- **Time for Action - HUGO as Model?**

Regulatory Rules vs. Patents

Complex Relationship



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- **Regulatory rules depending on:**
 - **actual state of science and technology (e.g. feasibility, safety, etc.)**
 - **social/public acceptance**
 - **can be changed and adapted accordingly at will**

Regulatory Rules vs. Patents

Complex Relationship



- **Patents**
 - **Exclusive rights granted for 20 years & statutory research exemption**
 - **No license** to use the patented invention
 - **Once an invention state of the art – no patent protection available**
 - **Investment effected – where protection in place**



- **WTO Members may exclude from patentability inventions if their commercial exploitation would violate ordre public or morality (protection of human, animal or plant life or health or environment) mere prohibition of exploitation not sufficient – in any case, commercialisation of such inventions may not be allowed!!!**

[Art. 27 (2)]

EU & EPC Common Playground



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- **Directive on the Legal Protection of Biotechnological Inventions 98/44**
- **Implementing Regulations to the EPC - as amended in 1999**
- **EPO not an EU institution!**
- **EPC not an EU legal instrument!**



- **No patents for inventions the commercial exploitation of which would be contrary to *ordre public* or morality;**

However,

- **exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States.**



In Particular Not Patentable

- **The human body, at various stages of its formation and development [Art. 5 (1) Dir.; R 29 (1) EPC]**
- **Uses of human embryos for industrial or commercial purposes [Art. 6 (2) (c) Dir.; R 28 (c) EPC]**



Patentable

- **An element isolated from the human body or otherwise produced by means of a technical process..., even if the structure of that element identical to that of the natural element [Art. 5 (2) Dir.; R 29 (2) EPC]**
- **Inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it [Recital 42 Dir.]**



- **Confirmed the legality of the Directive**
- **Found fundamental Rights to **human dignity** and **integrity** observed and guaranteed** [Art. 5 (1) (2), Art. 6]
- **Observed that the prior free and informed consent of the donor and recipient outside the scope of the Directive and to be dealt by other laws**
- **Clarified that the Directive does not preclude **legal limitations** and prohibitions applying to research into patentable products or the exploitation of patented products – i.e., research exemption**

Opinion No. 16 of the EU Group on Ethics in Science and New Technologies (EGE) of May 2002



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- **It would be contrary to public (especially patients') interests, if patenting of SCs or SCLs would be forbidden**
- **Unmodified SCLs can hardly be considered as a patentable product - have no specific use but large range of potential undescribed uses**
- **Patenable SCLs modified by in-vitro treatment, or genetically modified → acquired specific characteristics**

EU Member States Allowing Research in hESC



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- **Belgium – Research & therapeutic cloning (SCNT)**
- **Czech Republic ~ UK**
- **Denmark – Research & procurement of hESC from shE**
- **Finland – Research & procurement of hESC from shE**
- **Greece – Research & procurement of hESC from shE**
- **Netherlands – Research & procurement of hESC from shE**
- **Sweden – Research & procurement of hESC from shE & SCNT**
- **Spain – Research & therapeutic cloning**
- **UK – Research & development of hESC from shE & therapeutic cloning (SCNT)**

UK Practice Notice of April 2003 on “Inventions Involving Human Embryonic Stem Cells”



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- **Not patentable:** Human totipotent cells because of their potential to develop into an entire human body
- **Patentable:** Human embryonic pluripotent stem cells because they lack such potential

At least 14 Patents issued, e.g.:

- **GB 2407822 B: Oligodendrocytes derived from hESCs for remyelination and treatment of spinal cord injury – of 22.02.06**
- **GB 2394723 B: Culture System for rapid expansion of hESCs of 20.07.05**
- **GB 2385054 B: Host cells obtained by introducing and expressing VHL gene in cancer cells or embryonic stem cells of 27.04.05**
- **GB 2396623 B: Methods of derivation and propagation or undifferentiated human embryonic stem (hes) cells on feeder-free materials and human feeder layers of 05.04.06**

Human Embryonic Stem Cells Thomson's WARF - Application



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Claim 1

"A cell culture comprising primate embryonic stem cells which (i) are capable of proliferation *in vitro* [sic] culture for over one year, (ii) maintain a karyotype in which all chromosomes normally characteristic of the primate species are present and are not noticeably altered through culture for over one year, (iii) maintain the potential to differentiate to derivatives of endoderm, mesoderm, and ectoderm tissues throughout the culture, and (iv) are prevented from differentiating when cultured on fibroblast feeder layer."

EP Appl. No. 96903 521.1



...

2. ... does Rule 28(c) EPC forbid the patenting of claims directed to products (here: human embryonic stem cell 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 derived, if the said method is not part of the claims?
3. ... does Art. 53 (a) EPC forbid patenting such claims?
4. ... is it of relevance that after the filing date the same products could be obtained without the destruction of human embryos (e.g. derivation from available human embryonic cell lines)?

Biotech Patents - EU/EPC Implications

The Warf - Embryonic Stem Cell Case



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Legal Basis

- **Rule 28 (c) - under Art. 53a) EPC - no patents for "uses of human embryos for industrial or commercial purposes"**
- **Rule 29 (1) - the human body, at the various stages of its formation and development - no patentable invention**
- **Rule 29 (2) - an element isolated from the human body or otherwise produced by technical means - patentable**



Rules of Interpretation & EBA Decision

- **EPC Rules binding & Directive incl. recitals supplementary interpretation means**
- **Art. 53(a) EPC - controls**
- **Request for referral for a preliminary ruling of ECJ - inadmissible**



Question 2

- **Rule 28 (c) prohibits patenting if a human embryo used for industrial or commercial purposes**
- **Term "embryo" not defined - to be understood broadly - e.g. including a fertilized egg**
- **Decisive the technical teaching as a whole - not the explicit wording of the claims**
- **Here the only teaching - to perform the invention - the use (including their destruction) of human embryos**



EBA WARF Decision

Question 2

- **Product must first be made before it can be used - such making the ordinary way commercially to exploit the claimed invention - falls within the monopoly granted.**
- **Making the claimed product remains commercial or industrial exploitation of the invention even where further research is intended**
- **The use involving destruction - thus an integral and essential part of the industrial or commercial exploitation of the claimed invention - thus prohibited under Rule 28(c) EPC**



EBA WARF Decision

Question 2 - Which Standard to Apply?

- **Discussion of standards of *ordre public* or morality - European or national, etc. - inappropriate**
- **National & European laws concerning research on human embryo - of no significance - due to the decision of the legislator**



Question 4

- **Subsequent possibility to perform the invention without the need to destruct embryos - irrelevant**
- **Decision not concerned with the patentability in general of inventions relating to human stem cells or human stem cell cultures.**
- **Affected only inventions concerning products (here: human stem cell cultures) which can only be obtained by destruction of human embryos**
- **Thus pluripotent human embryonic stem cells generated by the technology of, e.g. *K. Takahashi* and *J. Yamanaka* (iPS cells) could be patented**

Consequences of the WARF EBA Decision



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- **No EP Patents available for any stem cells or stem cell lines of human embryonic origin**
- **For pluripotent human embryonic stem cells, stem cell lines, etc., national patents available in UK and probably in Belgium, Denmark, Finland, the Netherlands, Sweden, Spain**
- **Last word - keyrole - European Court of Justice**
- **EBA decision hardly supported by the wording and preparatory documents - ignoring regulatory rules on R&D and commercialization**

Time for action of ALLEA - HUGO as model?



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- **Lack of any protection for results of research in compliance with regulatory rules - not acceptable and discriminatory**
- **Especially where the obligation exists to protect them under the funding requirements and**
- **The fact that they may be commercialized - in violation of TRIPS rules**



Take HUGO as Model



HUGO INTELLECTUAL PROPERTY COMMITTEE STATEMENT ON PATENTING ISSUES RELATED TO EARLY RELEASE OF RAW SEQUENCE DATA

May 1997

HUGO, having reviewed recent developments in the field and, in particular, having taken note of the Principles agreed at the International Strategy Meetings on Human Genome Sequencing*¹ in Bermuda in February 1996 and February 1997, and of the practice of the U.S. Patent and Trademark Office (PTO) on granting patents on Expressed Sequence Tags (ESTs) as recently reported in *Science* 275: 1056:

- **reaffirms** its Statements on Patenting of DNA Sequences of 1992 and 1995, clarifying the fact that HUGO does not oppose patenting of useful benefits derived from genetic information, but does explicitly oppose the patenting of short sequences from randomly isolated portions of genes encoding proteins of uncertain functions;
- **regrets** the decision of some patent offices, such as the U.S. PTO, to grant patents on ESTs based on their utility “as probes to identify specific DNA sequences”, urging these offices to rescind these decisions and, pending this, to strictly limit their claims to specified uses, since it would be untenable to make all subsequent innovation in which EST sequence would be involved in one way or other dependent on such patents;
- **urges** all large-scale sequencing centres and their funding agencies to adopt the policy of immediate release, without privileged access for any party, of all human genome sequence information in order to secure an optimal functioning of the international network, as well as to avoid unfair distortions of the system;
- **stresses** that only the policy of rapid publication and free availability of human genomic sequence information will secure further international co-operation of large-scale sequencing centres;
- **emphasises** the differences between the U.S. patent law, which provides for a so-called one year “grace period”, allowing the authors of published data to subsequently file patent applications for inventions based on such information, and the patent laws of practically all other countries, which do not contain such a provision and where therefore no protection for, or based on, published data can be acquired;

Take HUGO as Model



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HUGO INTELLECTUAL PROPERTY COMMITTEE STATEMENT ON PATENTING ISSUES RELATED TO EARLY RELEASE OF RAW SEQUENCE DATA

May 1997

- **calls upon** the law makers to enter negotiations aimed at reaching an agreement on the introduction of a “grace period” along the lines of the U.S. law, which should precede the Paris Convention Union priority term, and which will eventually provide conditions putting all participants in the international network on an equal footing;
- **expresses** the hope that the free availability of raw sequence data, although forming part of the relevant state of the art, will not unduly prevent the protection of genes as new drug targets, which is essential for securing adequate high risk investments in biology, and will not result in a shift of activities of the pharmaceutical industry to searching for compounds that give marginal advantages against known targets rather than taking risks with new targets.

This Statement was prepared by the Intellectual Property Rights Committee of HUGO and approved for release by the Council of HUGO, May 1997

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¹ Sponsored by The Wellcome Trust



» Thank you!