

Bioethics Issues of Stem Cells Patents

ביו-אתיקה: מדע, כלכלה וחברה

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BOUTIQUE IP FIRM

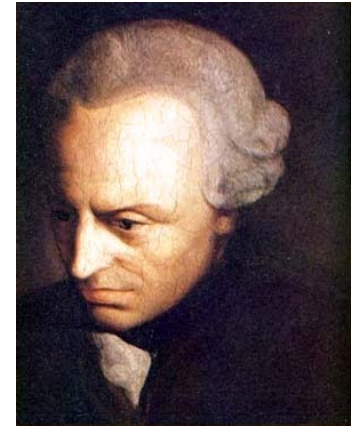
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**WE
CLAIM
SUCCESS™**

Total Morality

Immanuel Kant: *Fiat iustitia, et pereat mundus*

May justice happen, even if the world decays.

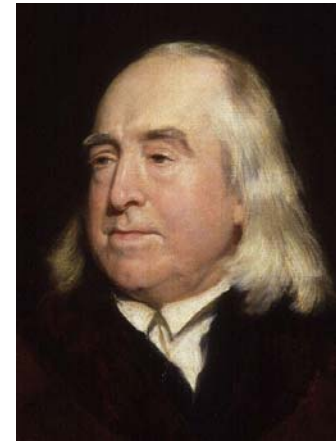


Utilitarianism

Jeremy Bentham: moral worth of an action determined by its contribution to overall utility :

"the greatest good for the greatest number of people"

Rule utilitarianism: *"If the rule produces more happiness than otherwise, then follow it always".*



Patent

Monopoly rights are granted to the owner preventing others from using the patented technology for a limited period in a specific country *in return for a full public disclosure of the technology*

Ordre Public

Patent system has been justified by Natural Law (1791, France);
Exchange for secrets (England, 1734)

Monopoly

Adam Smith: Reward by Monopoly



In the USA:

Tension between Sherman Act and Patent Law:

“A delicate balance must be brought between the two regulatory schemes”

Schering Plough (402 F3d)

Article 27 TRIPS

Patentable Subject Matter

Patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are **new**, involve an **inventive step** and are capable of **industrial application**.

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.

Morality of Patents

EPO

The European Patent Convention – EPC

"European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step"

(Article 52 P1 of the EPC).

However, patents shall not be granted on "plant or animal varieties or essentially biological processes for the production of plants or animals"

(Art. 53 lit. b, EPC),

as well as for ***"discoveries"***

(Art. 52, EPC).

European Parliament and Council Directive

EC/98/44 6 July 1998

The following inventions include those that are unpatentable where their exploitation would be **contrary to public policy or morality**:

1. processes for **cloning human beings**;
2. processes for **modifying the germ-line genetic identity of human beings**;
3. **uses of human embryos** for industrial or commercial purposes;
4. processes for **modifying the genetic identity of animals** which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

USPTO

35 U.S.C. 101 Inventions patentable

Whoever invents or discovers any **new** and **useful** process, machine, manufacture, or composition of matter, or any new and **useful** improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Diamond v. Chakrabarty, 447 U.S. 303 (1980)

A live, human-made micro-organism is patentable subject matter under [Title 35 U.S.C.] 101.

Respondent's micro-organism constitutes a "manufacture" or "composition of matter" within that statute

J. E. M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc., 534 U.S. 124 (2001) and other decisions we know that patentability **extends** to:

- New **methods of modulating biochemical processes** which are carried out in a human, animal or plant.
- Newly **identified DNA**
- Newly created **useful DNA sequences**
- **New organisms** and parts of organisms such as seeds, for example those containing modified DNA.
- **New vectors**, such as plasmids.
- New research techniques and in some cases at least the products obtained from using these techniques.

ILPTO

7. סייג למתן פטנטים

[בעריכה לשונית א.ב.]

בעל אמצאה כשירת פטנט זכאי לבקש, לפי הוראות חוק זה, שיינתן לו פטנט עליה. על אף האמור לא יוענק פטנט על -

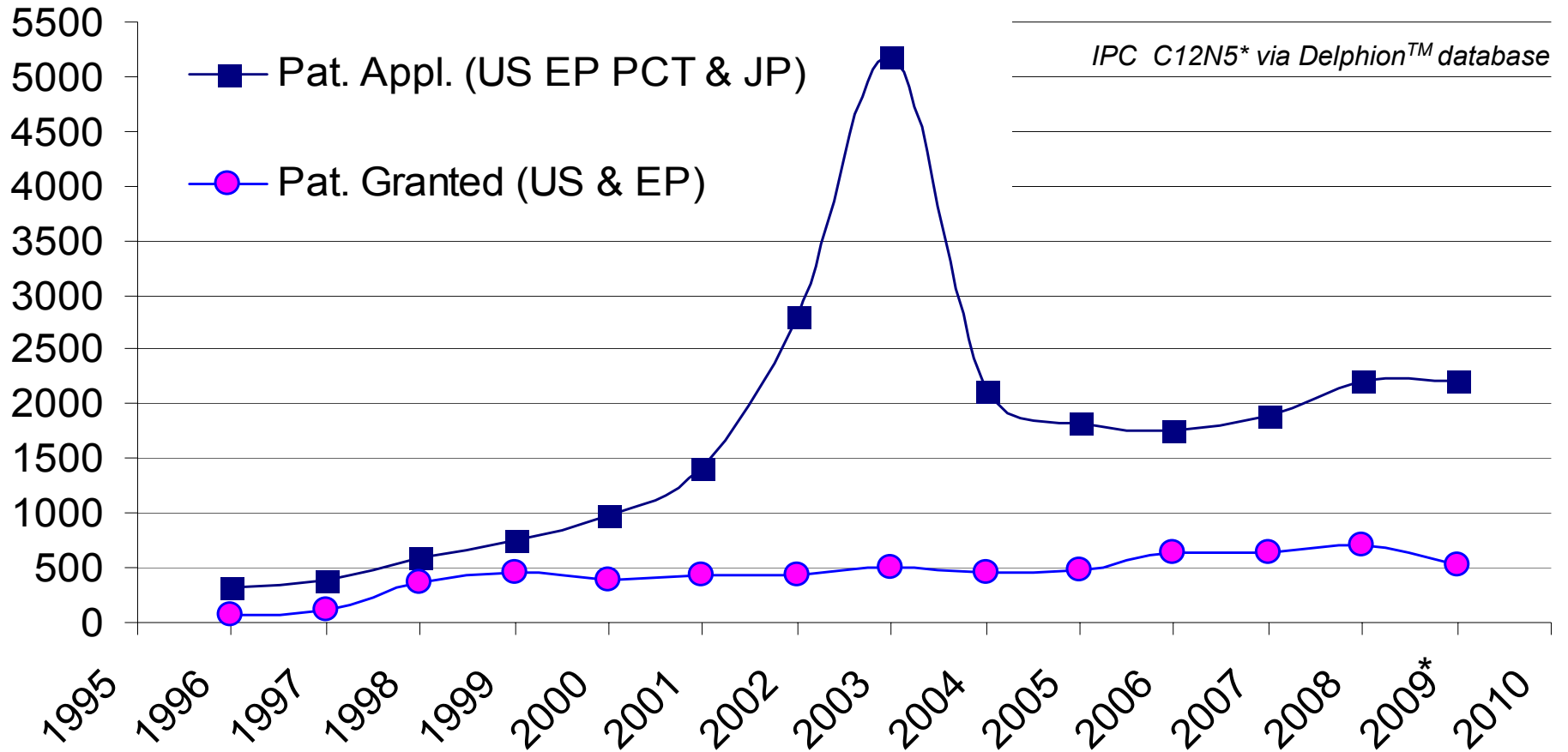
(1) תהליך לטיפול רפואי בגוף האדם;

(2) זנים חדשים של צמחים או בעלי-חיים, זולת אורגניזמים מיקרו-ביולוגיים שלא הופקו מהטבע.

Patents in Stem Cells

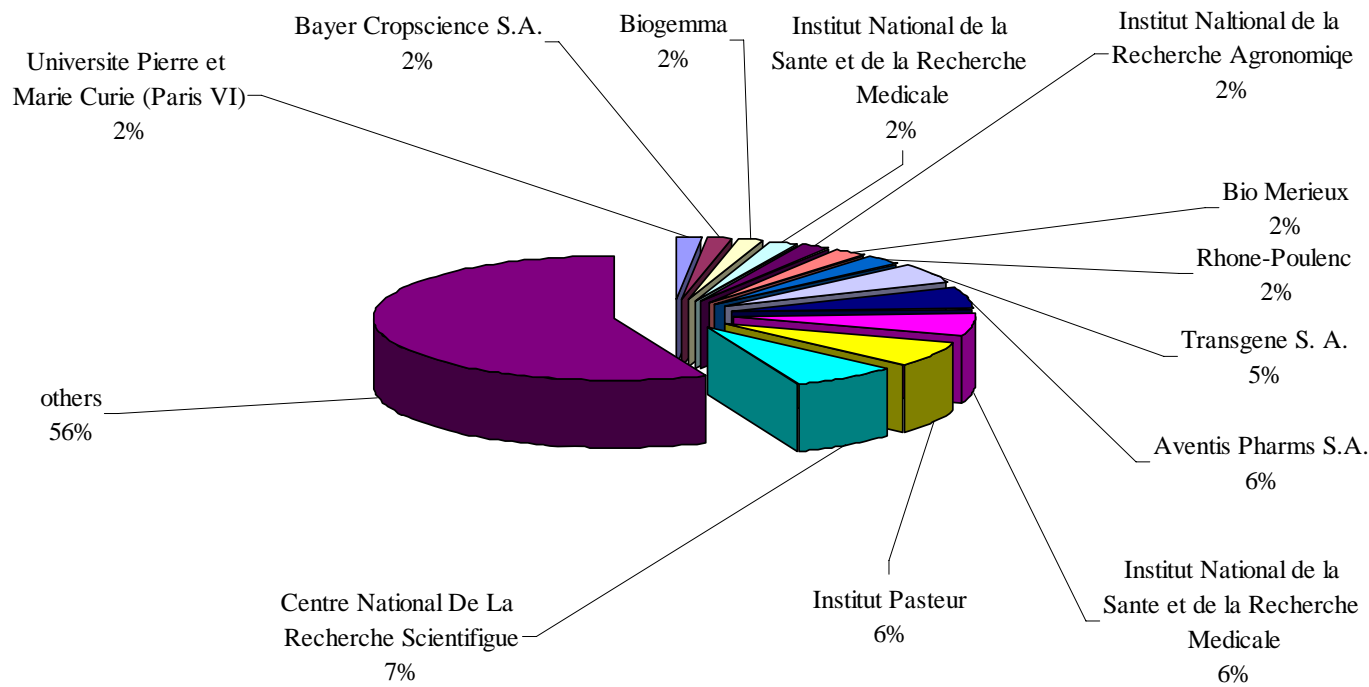
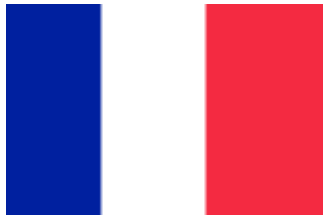
Undifferentiated human, animal or plant cells, e.g. cell lines;

Tissues; Cultivation or maintenance thereof; Culture media therefore

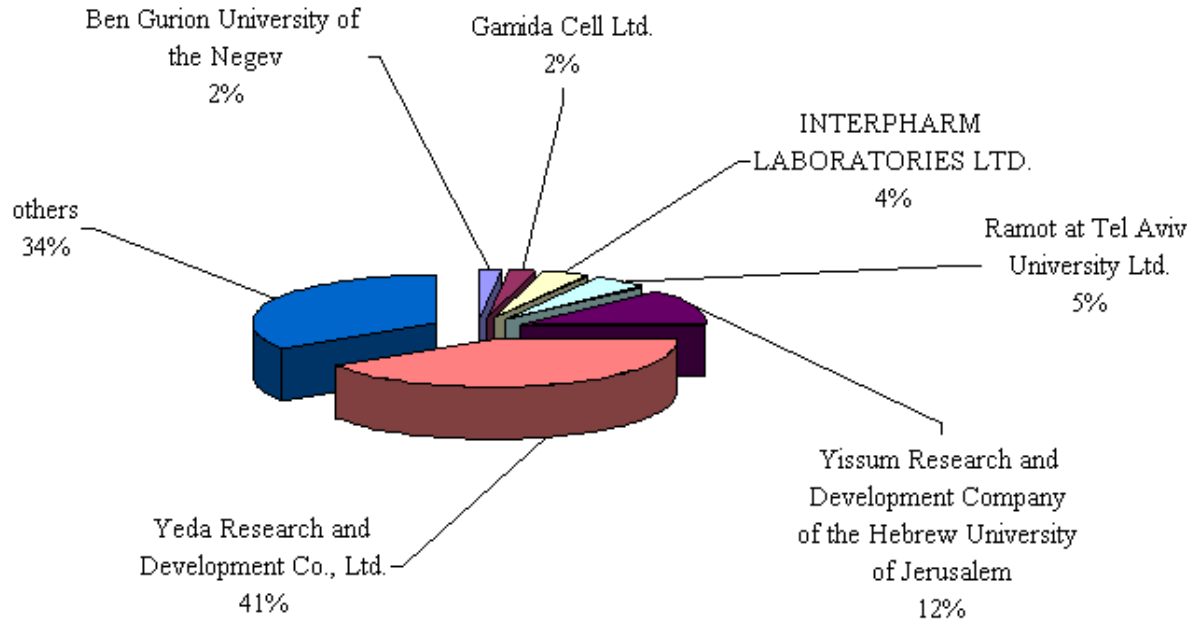


*Calculated on base of Jan-June 2009

More than 25,000 Patent Applications on Stem Cells,
About 6,000 Granted Patents (US & EP).



US & EP Granted Pats., 682
[about 6% of patents in Stem Cells]
GDP (2009) \$ 2500 billion
Population 65 M



US & EP Granted Pats., 145
[about 2% of patents in Stem Cells]
GDP (2009) \$ 201 billion
Population 7.4 M
US 89% , IL/US 1:1 per Capita

Human Relaxin (1991)

- Green Party : gene existed in body
- EPO : complementary DNA, + 2nd Form was unknown
- Green Party: DNA isolation not inventive
- EPO : Isolation method immaterial, Novel Product was revealed.
- Green Party : Only a discovery
- EPO : Newly isolated, technically applicable solution to a technical problem
- Green Party: contrary to *ordre public*
- EPO: Not abhorrent to the public
- Green Party: Dignity : gene isolated from preg. women, then used for profit.
- EPO : Tissue taken with consent.
- Green Party: “*form of modern slavery ...dismemberment of women and their piecemeal sale ...*”
- EPO: Gene patents do not confer rights over individual humans...point of the invention was to synthesize the hormone.
- Green Party : patenting human genes tantamount to patenting human life, intrinsically immoral.
- EPO : Cannot reconstitute a human being from the sum of it's genes.

WHAY IF WE COULD RECONSTITUE A HUMAN FROM A GENE?