TIMES OF MALTA

Banning commercial use of human embryos

Opinion

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On October 18, the European Court of Justice ruled in the case Oliver Brüstle v Greenpeace e.V. that, under European law, a patent cannot be issued for any technical process that involves the prior destruction of the human embryo.

This much anticipated judgement is a triumph of ethical standards over commercial interest. Many welcomed this landmark decision as an important step forward in the legal recognition of the dignity of the human embryo from its first moment of fertilisation. It settled a thorny legal battle by ruling that research involving the destruction of embryos cannot be patented.

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The case stems from a German patent filed by Prof. Brüstle who invented a method for converting human embryonic stem cells into nerve cells. Greenpeace first challenged his patent in 1997. A German court ruled the patent invalid and, upon appeal by Prof. Brüstle, the German Federal Court of Justice referred the case to the ECJ.

The ECJ gives a clear legal definition of the concept of “human embryo”, thus closing any loophole in the interpretation of the “morality clause” (article 6) of the 1998 EU Patent Directive (98/44/EU), which does not speak of embryonic stem cells because this technology did not yet exist when the directive was discussed.

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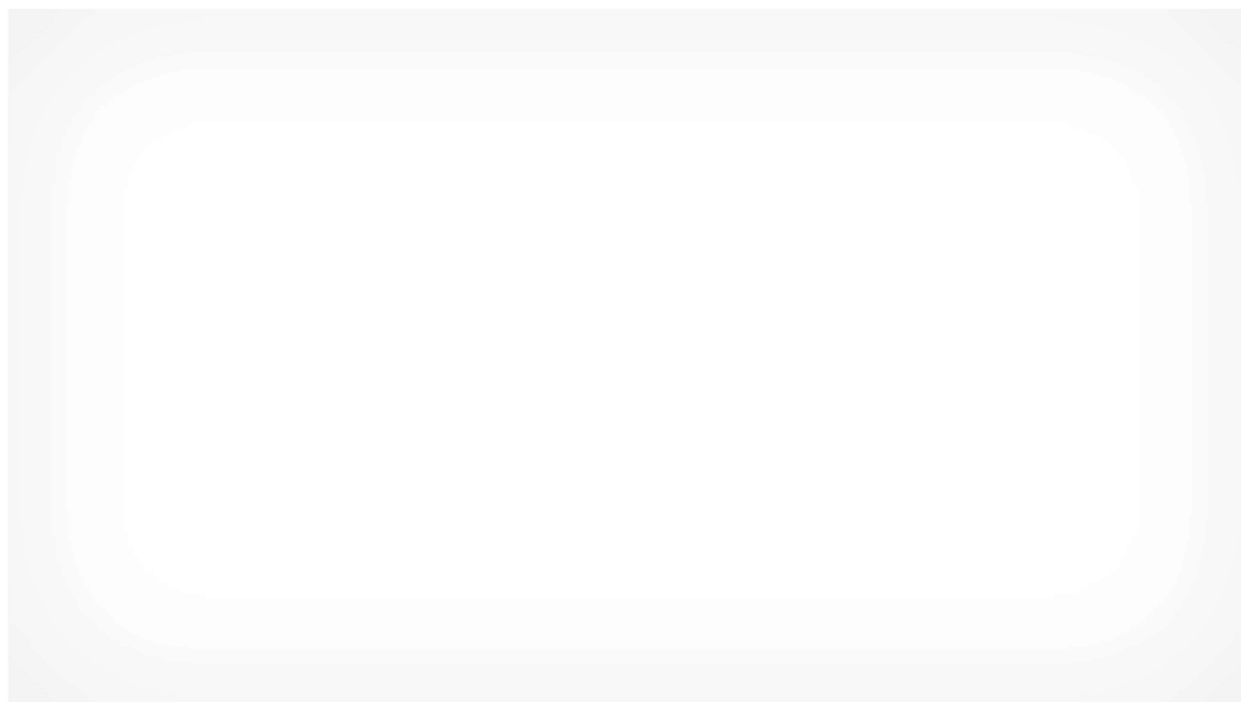

Any human ovum must, as soon as fertilised, be regarded as a “human embryo” if that fertilisation is such as to commence the process of development of a human being. A non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted (somatic-cell nuclear transfer – SCNT) and a non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis must also be classified as a “human embryo”.

This judgement makes it clear that fertilisation marks the beginning of the biological existence of a human being. Therefore, the human embryo, at every stage of development, must be considered a “human being with potential”, and not just a “potential human being”.

Earlier this summer, on the initiative of the Anscombe Bioethics Centre, hosted at Oxford University, the journal Nature (June 30) published a letter which I signed together with 23 other professors and centre directors from throughout Europe arguing that this case

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should be decided on the basis of ethics and not only on the basis of “European commercial interest”. The decision of the Court has vindicated our view.

The ruling came as no surprise in the light of the opinion of the ECJ Advocate General, Yves Bot, released on March 10. Though not binding on the Court, the Advocate General indicated the legal and moral solution of the Brüstle case by stating unequivocally that totipotent cells carrying within them the capacity to evolve into a complete human being must be legally classified as human embryos and must, therefore, be excluded from patentability.

Moreover, the Brüstle case follows the landmark decision on the patentability of human embryonic stem cells taken by the European Patent Office in Munich. In December 2008, the Enlarged Board of Appeal of the EPO refused in last instance an application for a patent from the Wisconsin Alumni Research Foundation for a method of deriving stem cells from human embryos. Although the US Patent and Trademark Office granted the patent, the EPO has rejected it on the basis that commercial exploitation of the patent would be “contrary to public order or morality” and, hence, not ethically permissible.

Way back in 2000, European Commission president Romano Prodi had asked the European Group of Ethics in Science and New Technologies (EGE) to prepare an opinion (n° 16) on the ethical aspects of patenting inventions involving human stem cells. Whereas the majority of the group agreed with the patentability of stem cells derived from destroyed human embryos, a minority report presented by one of its members expressed a dissenting view. It is interesting to note that this minority position of the EGE has been vindicated by both the EPO and the ECJ.

The decision of the European Court is very minimal. It does not prevent human embryos from being destroyed. It does not stop scientists from using human embryos in research. But it does make it more difficult for European commercial companies to profit from this destruction.

It is to be hoped that this decision will act as a “nudge”, encouraging scientists to turn away from embryonic stem cells and towards ethical and more effective alternative forms of stem cell research.

Till now, these have remained in the shadow of research on human embryonic stem cells. The use of adult stem cells, stem cells derived from umbilical cord blood and others offer,

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in some cases already, significant possibilities for regenerative medicine. These methods enjoy wide acceptance both on scientific and ethical grounds.

From the perspective of those who recognise the dignity of the human embryo, the Brüstle case is a small but significant step in the right direction.

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