A quest for redefining stem cell induction strategies: How to deal with ethical objections and patenting problems.

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A recent ruling of the European Court of Justice in Luxembourg (EU-CJ, 18 October 2011) on ES cell patenting has renewed the interest in attacking so-far unsolved ethical problems of stem cell research. In this contribution I will outline ethical and patenting problems that appear to arise in the modern field of induced pluripotent stem cell (iPS cell) technology. The focus will be on stem cell potentiality, and I will argue that potentiality rather than the act of sacrificing embryos will have to be a central point of concern in stem cell ethics and patenting in the future. Possible solutions will be discussed.

When somatic cells are reprogrammed to gain "full" pluripotency, they acquire (so to say as a byproduct) the capability to form viable embryos if tetraploid complementation (TC) is performed (addressed as "gold standard" by some authors). I argue that human cells possessing this capability cannot be patented. In analogy to the arguments used by the EU-CJ, this must apply not only to patenting cell lines themselves but also to patenting technologies using these cells. The fact that the problem is being created by the process of iPS cell induction itself asks for alternative strategies of stem cell derivation as well as for stringent criteria how to define and to test pluripotency vs. lower levels of potentiality. It will have to be discussed which genes should be seen here to be crucial (e.g. genes involved in early embryonic pattern formation processes). For ethical reasons it cannot be defended to use TC as a test for "full" pluripotency with human cells. It is thus necessary to discuss alternative test criteria.

Recent reports suggest that it may indeed be possible to directly induce multipotency while bypassing a pluripotent state, thus avoiding the addressed problems. It thus appears timely and prudent to redefine goals and strategies for stem cell derivation, in addition to stem cell quality testing criteria, in order to find an escape from the ethical and patenting dilemma.