Patents, Morality and Biosciences Innovation

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This paper will discuss the application of the morality exception from patentability presenting as examples Nanotechnology, Synthetic biology and Gene-editing. It will debate with particular incidence the topic of patentability of germ cells modification, and the interpretation of Article 6 (2) (b) of the Biotechnology Directive.

Bioscience innovation is bound to create generate heated ethical debates in society. The patent system is not immune to such discussions. The European Patent convention contains a morality and 'ordre public' exception in Article 53 (a) EPC, preventing patentability on grounds of lack of ethical compliance of the invention with prevailing standards. Many other jurisdictions have similar provisions or somehow impose restrictions on patentability based on similar ratio legis. The topic is further regulated in Article 6 of the Biotechnology Directive (which is also adopted in the EPC implementing rules). This *ratio legis* of this norm and the standards for its applicability are far from clear or consensual.

Innovation in *cutting edge* biosciences implies always a certain level of uncertainty concerning future technological possibilities. The same can be said in regards to any legislative attempt to regulate such technologies. The Biotechnology Directive was enacted in 1998 after a long legislative process. At the time, the academic and policy discussions were based on mere abstract scientific possibilities and imaginary dystopic eugenic futures. Today we are confronted with realistic possibilities for life saving genetic health interventions, that can be made possible provided there is enough incentive to innovation in genetic therapy. Science and technology has progressed considerably in the last 20 years. It will be argued that developments in scientific knowledge and technology are a factor to be taken into consideration in legal interpretation and *de lege ferenda* proposals.