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EU Directive on biotechnological inventions eventually implemented in Italy

Daniela Ampollini (Trevisan & Cuonzo) · Wednesday, October 6th, 2010

Along with a number of other relevant innovations to the Italian IP Code, last August the Italian legislator eventually passed the long awaited implementation into Italian law of Directive 44/1998/EC on biotechnological inventions (see legislative decree no. 131/2010 of 13 August 2010 [here](#)). Those who are familiar with the Italian political scene will know that the current Italian government on numerous other occasions showed to be extremely conservative as regards issues touching the sphere of human dignity and matters that may have religious implications. No surprise, therefore, that the new provisions of the IP Code contemplate a longer list of exclusions than that contained in Directive 44/1998. While new Art. 81 (quater) of the Italian IP Code substantially reproduces the list of what is patentable under Directive 44/1998, Art. 81 (quinques) IP Code specifies that a patent is not admitted on any invention for which the commercial exploitation is contrary, not only to the public order or morality (as is also stated by the directive), but also to “human dignity, the protection of the health, the environment, the life of humans and animals, the preservation of biodiversity and the prevention of serious environmental damages in conformity with the principles established by Art. 27.2 of the TRIPs agreement”. The same article then clarifies that this exclusion encompasses (besides what already listed by Directive 44/1998, i.e. processes for cloning human beings; processes for modifying the germ line genetic identity of human beings; uses of human embryos for industrial or commercial purposes; 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) any line of stem cells of human embryos, as well as any technical process which makes use of human embryonic cells. Art. 81 (quinques) IP Code also expressly excludes the patentability – on the assumption that it would be contrary to what above listed – of any genetic screening protocol the exploitation of which may lead to a discrimination or stigmatization of human subjects on genetic, pathological, racial, ethnical, social or economical basis, or which has eugenic rather than diagnostic objectives. Finally, the Italian legislator introduced the possibility for the Italian Patent Office, in processing patent applications on biotechnological inventions, of seeking the advice of the National Biosafety and Biotechnology Committee in order to guarantee the application of Art. 81 (quinques) of the IP Code.

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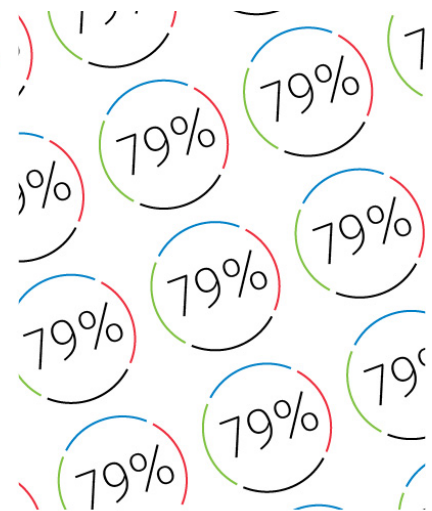
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