



CPME/AD/EC/03052012/053/EN

On 3 May 2012, the CPME Executive Committee adopted the “CPME Statement on Ethical and Fair Patents” (EC 2012/053)

CPME Statement on Ethical and Fair Patents

CPME welcomes the proposal for a regulation¹ on the creation of enhanced cooperation to implement unitary patents² and firmly affirms its belief in the need for new innovative treatments with an evidence base to assure highest quality patient safety through effective treatment. Such new treatment needs to be accessible and allow for further advances, ensuring fair competition on the medicine market and complying with previous European legislation on medicinal products for human use³ and biotechnological inventions⁴ as well as other relevant laws setting limits to patentability.

Notwithstanding the positive and long awaited results from granting unitary patents, European doctors remind policy-makers and legislators that:

1. The patenting of the human genome is prohibited.
2. Any direct or indirect barrier to the development and fair pricing of new treatment should be prohibited as it is a barrier to better healthcare.

CPME urges that the current proposal for a regulation should introduce a clearly specified exemption in the scope of the regulation on the human genome and natural substances, in particular under the limitations listed under Article 8 of the proposal⁵.

References:

1. Statement of CPME on the analysis of the human genome ([CP 1989/210](#))
2. Letter from the Polish Medical Association on Patents, 1997 ([CPME 1997/060](#))
3. Letter to MEPs put forward by the German Medical Association, 2000 ([CPME 2000/038](#))

¹COM(2011)215 Proposal for a regulation OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL implementing enhanced cooperation in the area of the creation of unitary patent protection, http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=EN&type_doc=COMfinal&an_doc=2011&nu_doc=215

² "European patent" means a patent granted by the European Patent Office under the rules and procedures laid down in the EPC;

"European patent with unitary effect" means a European patent which benefits from unitary effect in the territories of the participating Member States by virtue of this Regulation;

³ Directive 2001/83, Directive for medical products intended for human use;

⁴ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ 1998 L 213, p. 13);

⁵ Ibid1, Art 8



4. The European Patent Convention, 1973 <http://www.epo.org/law-practice/legal-texts/html/epc/1973/e/ma1.html>
5. European Commission (2005). *Report from the Commission to the Council and the European Parliament (COM (2005) 312 final)*. Retrieved April 24th, 2012 from: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2005:0312:FIN:EN:PDF>
6. European Commission (1996). *Ethical aspects of patenting inventions involving elements of human origin*. Retrieved April 24th, 2012 from: http://ec.europa.eu/bepa/european-group-ethics/docs/opinion8_en.pdf
7. Hawkins. N (2010). Human gene patents and genetic testing in Europe: A reappraisal. *SCRIPTed*, 7 ((3)), 453. Retrieved April 24th, 2012 from: <http://www.law.ed.ac.uk/ahrc/script-ed/vol7-3/hawkins.pdf>
8. Convention for the Protection of Human Rights and Dignity of Human Beings with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, 1997, <http://conventions.coe.int/Treaty/en/Treaties/html/164.htm>
9. WMA Statement on Genetics and Medicine, adopted October 2005 and last amended in October 2009, [http://www.wma.net/en/30publications/10policies/g11/index.html.pdf?print-media-type&footer-right=\[page\]/\[toPage\]](http://www.wma.net/en/30publications/10policies/g11/index.html.pdf?print-media-type&footer-right=[page]/[toPage])
10. WMA Statement on Patenting Medical Procedures, adopted October 1999 and last amended October, <http://www.wma.net/en/30publications/10policies/m30/index.html>