

**This chapter is a first draft and work in progress.  
The chapter is not to be cited or quoted without the permission of the authors.  
This chapter was written for a Research Handbook in EU Health Law and Policy co-  
edited by Tamara K Hervey and Calum A Young, Edward Elgar, 2016/2017.**

## **EU law and policy on new health technologies**

**Estelle Brosset<sup>1</sup>**

Senior lecturer and Jean Monnet Chair  
Center of International and Community Research<sup>2</sup>  
Faculty of Law  
University of Aix Marseille

**Aurélie Mahalatchimy<sup>3</sup>**

Research Fellow in biomedicine law  
Centre for Global Health Policy, School of Global Studies  
University of Sussex, the UK

### **Introduction**

The evocation of « new health technologies » takes us straight away into a strange world where reality and fantasies are intertwined, in which connected wristbands can be found next to gene therapy medicinal products, where bionic prosthetics herald 3D-printed prosthetics or in which human eggs are activated through parthenogenesis while human genome sequencing can be achieved within a few minutes. In order to review the state of European Union law on new health technologies and its prospects, we must first try to define these technologies and discuss a number of preliminary points regarding EU law which can apply before presenting the structure of this chapter.

**1- New health technologies: definitions.** First we must define what are « new health technologies ». The WHO and the World Health Assembly both use the same broad definition of health technology: “the application of organized knowledge and skills in the form of medicines, medical devices, vaccines, procedures and systems developed to solve a health problem and improve quality of life”.<sup>4</sup> At the EU level, the field of “Health Technology Assessment”<sup>5</sup> is the sole one where the European Commission gives a definition of this term, which is rather broad: “the ways scientific knowledge is used in healthcare and disease prevention”.<sup>6</sup> Thus the expression “health technology” is a vague concept, intended to be all-

---

<sup>1</sup> To find out about the activities of the “European health law” Chair: see the website : <http://droiteuropeen.wix.com/ceric-sante>.

<sup>2</sup> Joint Research Group “International, comparative and European Law” n° 7318.

<sup>3</sup> This work has been partially supported by REGenableMED, UK ESRC Project ES/L002779/1.

<sup>4</sup> World Health Assembly, Eleventh plenary meeting, 23 May 2007 – Commission B, Fourth Report: “Health Technologies”, WHA60.29.

<sup>5</sup> This involves assessing how science and technologies are used in the field of health in order to assist policy-makers in particular with regard to questions of reimbursement.

<sup>6</sup> [http://ec.europa.eu/health/technology\\_assessment/policy/index\\_fr.htm](http://ec.europa.eu/health/technology_assessment/policy/index_fr.htm). A more detailed definition is given by the International Network of Agencies for Health Technology Assessment (INATHA): “An intervention that may be used to promote health, to prevent, diagnose or treat acute or chronic disease, or for rehabilitation. Health technologies include pharmaceuticals, devices, procedures and organizational systems used in health care.” INATHA, Glossary, <http://htaglossary.net/health+technology>.

encompassing, in that it aims to include a variety of objects and practices as long as the purpose of their use or implementation is of a medical nature.

Among this vast array of health technologies, here we will be looking solely at « new » health technologies. How do we distinguish « new » technologies? New technologies are usually considered to be technologies that required an innovation. The concept of technological innovation means the emergence of novelty in the field of technology that substantially changes the way producers and/or users do things. We then speak of innovative technologies or emerging technologies. The concept of innovation does not however fully clarify the expression. First, one can wonder whether the expression « new technologies » is not wider than that of « innovative technologies » and whether it could include technologies that have emerged a while back. Furthermore, the idea of “novelty” as such is quite complex to handle. When can something be called new and when does it cease to be? Who decides what is new? For example when dealing with innovation relating to a health treatment, is it the scientist who looks mainly at the manufacturing process, the source or the nature of the substance, its structure or how it operates? Or is it the clinician who cares about therapeutic efficiency? This is most likely why the concept of « new health technologies » is generally defined using a non-exhaustive list. Thus, according to the European Commission, “New technologies, therapies and medicines are emerging; this includes regenerative medicine, more personalised treatments, as well as the development of nanomedicines. The Commission is committed to monitoring scientific progress and to constantly review Community legislation in the light of new developments so as to make safe, novel treatments available to patients as early as possible”.<sup>7</sup> In this chapter we will also approach new health technologies by listing the health technologies that they refer to. These mainly include, on the one hand, information and communication technologies applied to health, and on the other hand, biotechnologies applied to health. The former category of technologies overlaps with what is usually referred to as « e-health » which is discussed in another chapter of this book.<sup>8</sup>

This chapter will thus look more specifically at biotechnologies applied to health, and we must therefore define this term. Biotechnologies are defined as “any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use”.<sup>9</sup> The nature of biotechnologies changed when genetic engineering techniques emerged, which include an array of methods and concepts that lead to a modification of the genetic characteristics of a cell through the manipulation of its genes. Biotechnologies have multi-sectorial implications, including in the field of health, as evidenced for example by products or processes based on new therapeutic techniques such as gene<sup>10</sup> or cell therapy.<sup>11</sup> Many pathologies are impacted, such as rare genetic diseases and the most common serious pathologies (cancers, cardiovascular diseases and neurodegenerative conditions). There is also hope that there will be impacts on the diagnosis and prevention of illnesses. For example, advances in genetics contribute to the strengthening of stratified medicine by using genetic predisposition, in the context of targeted screening for diagnostic and preventive purposes beyond treatment purposes. Biotechnologies thus use material of

---

<sup>7</sup> DG Health website, Advanced Therapies: [http://ec.europa.eu/health/human-use/advanced-therapies/index\\_en.htm](http://ec.europa.eu/health/human-use/advanced-therapies/index_en.htm).

<sup>8</sup> See :

<sup>9</sup> Article 2, Convention on Biological Diversity.

<sup>10</sup> Gene therapy can be defined as a medical intervention that consists in inserting, deliberately, genetic material into the body of a patient in order to heal this patient.

<sup>11</sup> Cell therapy consists in injecting into the human body cells or tissues, transformed or manipulated (in particular cultured), to replace missing or damaged cells or tissues.

human origin for health purposes.<sup>12</sup> Conversely, human material can use technology in order to produce its effect on health, it is then excluded from “biotechnologies” or “new health technologies” for the purpose of this chapter. Indeed, elements of the human body used as such, as in the case of organ transplants, are governed by separate regulations and are discussed in another chapter.<sup>13</sup>

**2- The application of EU law: preliminary points.** First it must be pointed out that the European Union treaty (considered here as including the TEU and the TFEU) does not speak of new health technologies or of biotechnologies. Indeed, the European Union (and previously the European Communities) does not have express competence on these matters. Yet the review of secondary law does not leave room for doubt. New health technologies, health biotechnologies, are governed by a number of secondary law rules, which shows the importance of the means of fine-tuning competences. Fine-tuning was carried out through the official procedure of the revision and attribution of new competences to the EU that took place, with respect to the protection of public health, in 1992 with the Treaty of Maastricht (article 129 TEC now article 168 of the TFEU). But fine-tuning also resulted from the use of general competences such as the internal market competence (article 114 TFEU)<sup>14</sup> that has been used greatly in the field of health,<sup>15</sup> including in the field of new health technologies. It must also be pointed out that the authority of EU law on these matters was not founded solely on competences; it is based on principles, namely the principles of free movement. Indeed, the Court of Justice of the European Union (CJEU) has often confirmed that “the special nature” of certain health activities “does not remove them from the ambit of the fundamental principle of freedom of movement”.<sup>16</sup> The Court’s case law thus usefully supplements and clarifies the relevant rules of secondary law.

**3- Structure of this chapter.** The review will be carried out in two stages matching the two main phases of the life of any technology, which always includes a research phase followed by a production and marketing phase for the technology to be used for health purposes. Technology is first at the heart of research leading (or not) to an “invention” before taking the form of a product or a process intended for marketing. With respect to both the research phase (I) and the marketing phase (II), EU law must combine two well-known objectives: enabling the development of these technologies and guaranteeing the respect of fundamental rights,<sup>17</sup> which means achieving access, across the territory, to approved, safe and high quality health technologies.

## **I- EU law and the research on new health technologies**

The development of technology always comes after a research phase which depends first and foremost on economic factors including the availability of capital, i.e. funding. However, alongside these factors, regulatory intervention plays a key role in encouraging and promoting

---

<sup>12</sup> In the European biopharmaceutical sector, about 20% of existing medicinal products already come from biotechnologies and among them, up until 50% are new medicinal products.

<sup>13</sup> J. McHale and A. Mahalatchimy, *EU law and policy on human material, this book...*

<sup>14</sup> This article allows the adoption of secondary law measures for the approximation of national divergent provisions as long as they have “as their object the establishment and functioning of the internal market”. The use of this legal basis is certainly not unconditional. Indeed, the Court emphasised the European Union has no “general power to regulate the internal market”. The competence only arises when the existence of obstacles or potential obstacles « actually » affecting the internal market has been proved (ECJ, 5 October 2000, *Germany v Parliament and Council*, C-376/98, *Rec.* p. I-8419, points 83 et 84).

<sup>15</sup> E. Brosset (Ed), *Droit européen et protection de la santé*, Bruylant, 2015, 464 p.

<sup>16</sup> ECJ, 28 April 1998, *Raymond Kohll v Union des caisses de maladie*, C-158/96, *Rec.* 1998, p. I-01931, pt 20.

<sup>17</sup> Communication of the Commission, Life sciences and biotechnology - A Strategy for Europe, COM (2002)27 final, OJ C 55, 02/03/2002, pp. 3-32.

innovation. Given the huge amounts at stakes, it must be possible to exploit an invention for a sufficient amount of time and across a sufficiently large territory without fear of being copied by competitors. It requires the grant of a patent. Here we will discuss EU law on research funding (A) and on the use of patents to support research (B).

## **A- Research funding**

Research funding in the EU has been achieved through framework programs (1) together with the creation of structures promoting research (2).

### ***1- New health technologies in research framework programs***

The EU's support<sup>18</sup> for research and technological development typically involves the adoption of multiannual Framework Programs (FP). Encouraging research in the field of biotechnology is an objective long mentioned in framework programs in the field of research and technological development.<sup>19</sup> The third framework program applicable for the 1990-1994 period already included as one of its top priorities the question of life sciences and technologies.<sup>20</sup> In the regulation establishing Horizon 2020 - the latest framework program for research and innovation (2014-2020)-,<sup>21</sup> support for research projects in the field of so-called enabling technologies, including biotechnologies, is contemplated once again.<sup>22</sup>

As part of these framework programs, there has long been an obligation to comply with the ethical requirements raised by research on the genome or on human living organisms. The third framework program for research and technological development (1990-1994)<sup>23</sup> already referred to the ethical dimension of community research and development activities. The first references were still extremely general. Decisions progressively clarified the terms of this obligation. Thus, the regulation establishing Horizon 2020 – the latest framework program for research and innovation (2014-2020)<sup>24</sup> - specifies a number of prohibitions with respect to the financing of certain research activities.<sup>25</sup> There is also a general clause providing that “All the research and innovation activities carried out under Horizon 2020 shall comply with ethical principles and relevant national, Union and international legislation, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols. Particular attention shall be paid to the principle of proportionality, the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of a person, the right to non-discrimination and the need to ensure high levels of human health protection”.<sup>26</sup>

---

<sup>18</sup> According to article 181 of the TFEU, the EU and the Member States coordinate their research and technological development activities, in order to ensure the mutual consistency of national and community policies.

<sup>19</sup> Council Decision 90/221/Euratom, EEC of 23 April 1990 concerning the framework Programme of Community activities in the field of research and technological development (1990 to 1994), OJ L 117, 8.5.1990, p. 28–43.

<sup>20</sup> *Ibid.*

<sup>21</sup> Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC, OJ L 347, 20.12.2013, p. 104.

<sup>22</sup> Annex 1, section 2, Regulation (EU) No 1291/2013, *Ibid.*

<sup>23</sup> It was already clearly stated for biomedical research “Ethical, social and legal aspects of implementing the findings of research into the human genome will be carefully assessed”. Moreover, in the biotechnologies field, “all the necessary importance will be attributed to the ethical implications of such work”.

<sup>24</sup> Regulation (EU) No 1291/2013, *op. cit.*

<sup>25</sup> Article 19-3, Regulation (EU) No 1291/2013, *op. cit.*

<sup>26</sup> Article 19-1, Regulation (EU) No 1291/2013, *op. cit.*

There has been much debate over the question of the funding of research on human Embryonic Stem Cells (hESCs). hESCs are unique as they have the potentiality to form any cell of the human body and thus replace damaged or sick tissues. Research on hESCs could therefore lead to the development of treatments destined to treat illnesses that are currently incurable and/or potentially fatal, such as Parkinson's disease, diabetes, strokes, cardiovascular diseases or blindness. Yet at the same time, research on hESCs raises major ethical questions as obtaining them entails either the destruction of human embryos,<sup>27</sup> or the use of the cloning technique (i.e. the nuclear transfer of a somatic cell into an enucleated egg).<sup>28</sup> For a while the issue of funding was not addressed directly. There was only a prohibition on the modification of the genetic constitution of human beings and cloning.<sup>29</sup> Then, when it came up, it was of course vigorously debated and a compromise was therefore slow to emerge.<sup>30</sup> Funding was finally obtained with the adoption of the 7th FP (2007-2013)<sup>31</sup> and was maintained in the current "Horizon 2020". On the one hand, research activities on human cloning for reproductive purposes and research activities targeting the creation of human embryos solely for research purposes or for the supply of stem cells are excluded from any funding from the European Union.<sup>32</sup> On the other hand "the exclusion of funding of this step of research will not prevent Community funding of subsequent steps involving human embryonic stem cells".<sup>33</sup> In this context, the European Union has funded the creation of a European registry of human pluripotent stem cells lines in order to facilitate collaboration at a global level.<sup>34</sup> The program includes the same conditions in terms of extensive scientific and ethical assessment and strict compliance with the legal frameworks of Member States.

This debate is however far from being over. It is significant that a compromise was reached with regard to the restrictions and conditions of European funding. However, in practice this compromise does not impede Member States involved in European projects to fund the procurement of hESCs with their own resources. Indeed they have the ability to allocate their project's research activities on the basis of their national legal frameworks alongside European funding. It so happens that these activities involving the constitution of an embryo for research purposes are authorised in a number of Member States, notably the United Kingdom. The debate was in fact reopened by a citizens' initiative entitled « One of Us » which proposed a change to « Horizon 2020 » in order to prohibit the funding of research

---

<sup>27</sup> hESCs are usually harvested within embryos in the first stages of their development (blastocyst stage) coming from donations to research in the context of medically assisted procreation.

<sup>28</sup> Nowadays, a new technique can provide cells whose characteristics are similar to hESCs : Induced Pluripotent Stem cells (IPS cells). These cells are obtained through the reprogramming of an adult cell into a cell equivalent to a hESC by gene transfers.

<sup>29</sup> "No research modifying, or seeking to modify, the genetic constitution of human beings by alteration of germ cells or of any stage of embryo development which may make these alterations hereditary, nor research seeking to replace a nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo or subsequent development of an embryo, known as cloning, will be carried out under this framework programme". Decision No 1110/94/EC of the European Parliament and of the Council of 26 April 1994 concerning the fourth framework programme of the European Community activities in the field of research and technological development and demonstration, OJ L 126, 18.5.1994, p. 1-33.

<sup>30</sup> The question did however start to emerge with the adoption of the 6<sup>th</sup> FP (2002-2006). In the absence of a consensus, this framework was however adopted without reiterating the funding exclusion for research activities involving a cloning operation. In the end the debate led to a compromise expressed in an additional decision of the Council in which the funding of research on hESCs is subject to a number of conditions: Council Decision 2002/834/EC of 30 September 2002 adopting a specific programme for research, technological development and demonstration: "Integrating and strengthening the European Research Area" (2002-2006), OJ L 294, 29.10.2002, p. 1-43.

<sup>31</sup> Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013), OJ L 412, 30.12.2006, p. 1-43.

<sup>32</sup> Article 19-3, Regulation (EU) No 1291/2013, *op. cit.*

<sup>33</sup> Point 12 of the European Commission statement on article 19. For the principle, see Article 19-4, Regulation (EU) No 1291/2013, *op. cit.*

<sup>34</sup> Website of the European registry of human Pluripotent Stem Cells lines, 'hPSC registry' : <<http://hpscereg.eu/>>.

activities that destroy human embryos, including those aiming at obtaining stem cells as well as research activities requiring the use of hESCs in their later stages.<sup>35</sup>

## **2) Research infrastructures supporting new health technologies**

Together with framework programs, the implementation of research-specific European infrastructures contributes to the creation of a European Research Area. The creation of these infrastructures was made possible by the adoption of regulation (EC) No 723/2009 on the Community legal framework for a European Research Infrastructure Consortium.<sup>36</sup> On the basis of this regulation and as an example, three of the European research infrastructures created are susceptible to support the development of new health technologies, in particular biotechnologies applied to health. First of all, the Biobanking and BioMolecular Resources Research Infrastructure (BBMRI- ERIC)<sup>37</sup> aims to facilitate access to samples of biologic origin, to biomedical equipment, and support high quality biomedical and medical research in the field of biotechnologies. Second of all, the objective of the European Clinical Research Infrastructures Network<sup>7</sup> (ECRIN- ERIC)<sup>38</sup> is to promote and facilitate multinational clinical studies at the European level, necessarily frequent when biotechnologies are intended to treat rare diseases (orphan medicinal products). Third and last, the European Advanced Translational Research Infrastructure in Medicine (EATRIS)<sup>39</sup> aims to support collaborative projects regarding scientific issues at the interface between exploratory and clinical research some of which relate to biological products and advanced therapies, for example gene and cell therapies and regenerative medicine.

Reference must be made here to the Joint Technology Initiative on innovative medicines (IMI) established by regulation (EC) No 73/2008 setting up the joint undertaking for the implementation of the joint technology initiative on innovative medicines.<sup>40</sup> The goal is to combine private sector investment and national and/or European public funding in order to improve the process of developing medicines by supporting cooperation in the field of R&D between SMEs, the academic world and the biopharmaceutical industry. During the 2008-2013 phase, a two billion euro budget was raised for IMI.<sup>41</sup> IMI 2, seen as the European body that implements the world's largest public-private partnership in the field of life sciences,<sup>42</sup> is working with a budget of 3.3 billion euros over the 2014-2024 period.<sup>43</sup>

---

<sup>35</sup> The initiative was officially submitted to the Commission on 28 February 2014, after receiving the support of over 1.7 million citizens, the thresholds having been met in 18 Member States. The Commission decided not to follow the initiative but, in accordance with the provisions of the regulation on citizens' initiative, it was required to present the reasons behind this decision which lie in the guarantees already provided in « horizon 2020 »: Communication from the Commission on the European Citizens' Initiative "One of us", COM/2014/0355 final.

<sup>36</sup> Council Regulation (EU) No 1261/2013 of 2 December 2013 amending Regulation (EC) No 723/2009 concerning the Community legal framework for a European Research Infrastructures Consortium (ERIC), OJ L 326, 6.12.2013, p. 1–2.

<sup>37</sup> BBMRI- ERIC : <<http://bbmri-eric.eu/about>>.

<sup>38</sup> ECRIN- ERIC : <<http://www.ecrin.org/>>.

<sup>39</sup> EATRIS : <<http://www.eatris.eu/>>.

<sup>40</sup> Council Regulation (EC) No 73/2008 of 20 December 2007 setting up the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines, OJ L 30, 4.2.2008.

<sup>41</sup> European Commission, First Interim evaluation of the Innovative Medicines Initiative Joint Undertaking, Panel report, 2011; Second Interim Evaluation- IMI, 31 July 2013.

<sup>42</sup> Council Regulation (EU) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking, OJ L 169, 7.6.2014, p. 54–76.

<sup>43</sup> IMI, Introducing IMI, The budget: <<http://www.imi.europa.eu/content/mission>>. One half (1.638 billion euros) comes from the Horizon 2020 program and the other half from EFPIA companies (1.425 billion euros) and other life sciences industries or organisations (213 billion euros) that decided to contribute to IMI 2 as members or joint partners in individual projects.

## **B- Support for research: patent protection of new health technology inventions**

Support for research in the field of new health technologies was also demonstrated by the adoption of a directive on the legal protection of biotechnological inventions,<sup>44</sup> which must now be read in the light of several Court decisions.

### ***1) Directive 98/44/EC on the protection of biotechnological inventions***

After a heated debate that lasted ten years<sup>45</sup>, the directive on the legal protection of biotechnological inventions was adopted to ensure the secure legal protection of biotechnological inventions but also to guarantee the proper functioning of the internal market in this field. Two main characteristics stand out when reading the directive. On the one hand, the directive chose to include these inventions in the category of industrial property rights and in particular patent law.<sup>46</sup> On the other hand, the key goal of the directive is solely to adapt and supplement the national rules in order to take into account adequately the evolution of technology that uses biological material. The tone is set in recital 8: “legal protection of biotechnological inventions does not necessitate the creation of a separate body of law in place of the rules of national patent law”.<sup>47</sup>

Regarding the conditions for patentability, according to the directive, “inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used”.<sup>48</sup> The directive clearly specifies that the fact that biological material pre-existed “in a natural state” is not really relevant for the qualification of an invention; it is enough that this material has been “isolated from its natural environment or produced by means of a technical process”<sup>49</sup> for the innovation relating to such material to be qualified as an invention. Thus “an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element”<sup>50</sup> provided however that it is susceptible of an industrial application disclosed in the patent application<sup>51</sup> and that the person from whose body the material is taken have had an opportunity of expressing free and informed consent.<sup>52</sup> The directive does also provide a number of exclusions from patentability. First, “the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions”.<sup>53</sup> Methods of surgical or therapeutic treatment of the human body and diagnostic methods cannot constitute inventions

---

<sup>44</sup> Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, Official Journal L 213, 30/07/1998, pp. 13 – 21.

<sup>45</sup> The first proposal was from 1988 : COM (88) 196 final, 21 October 1988, JOCE C 10, 13/01/1989, p. 3.

<sup>46</sup> There was no doubt as to this approach as it had already been accepted by the American Supreme Court (*Diamond v. Chakrabarty*, 1980, 206 USPQ, 193) and by the European Patent Office (Technical board, *Ciba Geigy*, T49/83, 26 July 1983, OJ EPO, 1984, p. 112; Technical board, *President and Fellows of Harvard College*, T19/90, OJ EPO, December 1990, p. 476; Examining Division, *Relaxin*, 8 December 1994, OJ EPO 1995/6, p. 388).

<sup>47</sup> The same is provided by article 1 of the directive: “Member States shall protect biotechnological inventions under national patent law (...) This Directive shall be without prejudice to the obligations of the Member States pursuant to international agreements”. That is why article 95 TEC (114 TFEU) has been used as a legal basis, not article 235 TEC (352 TFEU).

<sup>48</sup> Article 3-1, Directive 98/44/EC.

<sup>49</sup> Article 3-2.

<sup>50</sup> Article 5-2.

<sup>51</sup> Article 5-3.

<sup>52</sup> Recital 26

<sup>53</sup> Article 5-1.

either,<sup>54</sup> as well as inventions involving plant varieties, animal races or processes that are essentially biological for the production of plants and animals. Finally, inventions whose commercial exploitation is contrary to *ordre public* and morality must be excluded from patentability.<sup>55</sup> These include processes to clone human beings, processes to modify the germ line genetic identity of human beings, the use of human embryos for industrial and commercial purposes and processes for modifying the genetic identity of animals “which are likely to cause them suffering without any substantial medical benefit to man or animal” as well as animals resulting from such processes.<sup>56</sup>

With regard to the scope of the protection afforded by a patent related to biological material, such protection extends to “any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics”.<sup>57</sup> Moreover, the protection afforded by a patent over a product containing or consisting of genetic information extends to all material in which the product is incorporated and in which the genetic information is contained and performs its function.<sup>58</sup> The directive also includes provisions related to the rules defining the obligations of the patentee such as the research exemption, which is the right for third parties to use the patented biological material freely for experimental purposes<sup>59</sup>.

## 2) Interpretation

The directive has given rise to important interpretations with regard to the legal framework applicable to research in the field of health biotechnologies. The first interpretation comes from a case dated 18 October 2011, the *Brüstle* case<sup>60</sup> which has been widely discussed. Dr Brüstle was the holder of a German patent related to a process for the production, isolation and purification of neural cells obtained from hESC. The patent covered in particular the culture processes of embryonic stem cells, the cells produced by these processes, the libraries of stem cells and their use for the treatment of neural defects in particular for patients suffering from Parkinson’s disease. While the direct use of human embryos was not claimed in the patent, it did however constitute a precondition of its application since the invention presupposed the removal of stem cells from the blastocyst and therefore the destruction of the embryos. Greenpeace brought invalidity proceedings against this patent based on the provisions of German law related to patents, transposing directive 98/44/EC, according to which inventions cannot be patented if their commercial use would be contrary to *ordre public* and morality and in particular “uses of human embryos for industrial or commercial purposes”. But this implied defining the concept of « human embryo » as set out in article 6.2 c) of the directive which was precisely the reason of the preliminary- reference procedure

---

<sup>56</sup> Article 6-2.

<sup>57</sup> Article 8-1. The same extension is provided for processes’ inventions by article 8-2: “The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics”.

<sup>58</sup> Article 9.

<sup>59</sup> Article 13-3 b) : (Access to the deposited biological material shall be provided through the supply of a sample) « The sample shall be supplied only if the person requesting it undertakes, for the term during which the patent is in force : (...) not to use it or any material derived from it except for experimental purposes (...) »

<sup>60</sup> C-34/10, *Rec.* 2011 I-09821.



before the Court. Against all expectations,<sup>61</sup> although clearly aware of the sensitive nature of the subject,<sup>62</sup> the Court stated that “any human ovum after fertilisation, any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted, and any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis constitute a ‘human embryo’”. Thus, according to the Court, it is because these various organisms, even non-fertilised ones, may be used to obtain totipotent cells (with the inherent ability, within themselves, to evolve into a complete individual) that they can be considered embryos.<sup>63</sup>

A second interpretation, given in the International Stem Cell Corporation decision («ISCC»), then came to supplement the first one.<sup>64</sup> The ISCC had introduced two requests for national patents with the United Kingdom Intellectual Property Office: one of them related to methods of production of human pluripotent stem cells lines from parthenogenetically activated eggs and of stem cells lines produced using these methods.<sup>65</sup> During the procedure to obtain the patent, the ISCC’s request was rejected on the basis that the requests were not patentable as the inventions described constituted non-patentable uses of human embryos. Admittedly, there was no reason for the question to be asked as the Court had already answered it in the aforementioned case. However, the question was based on at least two elements that explain why the Court looked into this matter once again. The first related to the interpretation of an important expression used by the Court in the Brüstle case, namely that the organism (the egg) must be “capable of commencing the process of development of a human being”. Did it have to be interpreted as meaning the ability of an organism to commence the process of a development of a human being or solely the ability to proceed to term and develop into a full human being? The second element was determined by the scientific elements related to parthenogenesis. It had been demonstrated that, according to current scientific knowledge, human parthenotes did not have the ability to develop to term.<sup>66</sup> In this context, the Court decided to answer these questions. Yet, contrary to the Brüstle case, the Court concluded that “an unfertilised human ovum whose division and further development have been stimulated by parthenogenesis does not constitute a ‘human embryo’”,<sup>67</sup> an interpretation contrary to the one given three years before. To reconcile this conclusion with its previous interpretation, the Court specified “the mere fact that that organism commences a process of development is not sufficient for it to be regarded as a ‘human embryo’”.<sup>68</sup> In other words, what matters is that

---

<sup>61</sup> Indeed, up until then, the Court had often avoided the subject: ECJ, 26 February 2008, *Sabine Mayr*, C-506/06, Rec. 2008, p. I-01017. According to the Advocate general, the “medico-ethical debate on the origins of life, which would be both unnecessary and inappropriate in the present context.” Opinion of Advocate General M. Damaso Ruiz-Jarabo Colomer, C-506/06, *Sabine Mayr*, delivered on 27 November 2007.

<sup>62</sup> The Court uses much caution in this case. It points out, on the one hand, that it is not called upon in this case to broach questions of a medical or ethical nature as to the concept of « human embryo », but will restrict itself to a legal interpretation of the relevant provisions of the directive (pt. 30). On the other hand, it states that the text of the directive did not define human embryo, nor does it contain any reference to national laws. The absence of a uniform definition of human embryo would impede the proper functioning of the internal market, which is the aim of the directive (Pts 26 et 27).

<sup>63</sup> In this case, the patent did not concern these totipotent cells but pluripotent cells obtained from a blastocyst. A subsequent question therefore arose: did the scope of the patentability exclusion exclude a claimed technical teaching, on the grounds that it does not mention the use of human embryos, but implies their prior destruction? According to the Court “the Directive excludes an invention from patentability where the technical teaching (...) requires the prior destruction of human embryos or their use as base material, whatever the stage at which that takes place and even if the description of the technical teaching claimed does not refer to the use of human embryos” (pt 52).

<sup>64</sup> Judgment of the Court (Grand Chamber) of 18 December 2014, *International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks*, C- 364/13.

<sup>65</sup> Including a request related to the methods of production of synthetic cornea or corneal tissue, involving the isolation of pluripotent stem cells from eggs activated parthenogenetically, and of synthetic cornea or corneal tissue obtained using these methods.

<sup>66</sup> Point 30, C- 364/13.

<sup>67</sup> See the enacting terms of the case.

<sup>68</sup> Point 29, C- 364/13.

the process must be carried through to completion and therefore that the relevant organism must have the inherent ability to develop into a human being. The Court also explained that because “the list provided by article 6 (2) obviously cannot presume to be exhaustive”, the directive does not prevent a Member State from excluding parthenotes from patentability on the basis of article 6, paragraph 1, of the directive<sup>69</sup> which allows the exclusion from patentability of inventions contrary to *ordre public* and morality.

## **II- EU law and the marketing of new health technologies**

EU law regulates the marketing of new health technologies used for medical purposes in order to promote their development with an objective that is twofold: ensuring the proper functioning of the internal market and guaranteeing a high level of protection of public health. Their medical purpose implies that these health technologies can be used for therapeutic, preventive or diagnostic purposes.

In this context, new health technologies are regulated either as medicinal products (A) or as medical devices (B). The main difference between medicinal products and medical devices is how they operate. Indeed, medicinal products exert a pharmacological, immunological or metabolic action. On the contrary, the main action of a medical device is not obtained by pharmacological, immunological or metabolic means but its function can be helped by these means. It should be pointed out here that elements of the human body used as such for medical purposes are not part of this article as they are not “technologies” in the strict sense. Elements of the human body are therefore considered here only when they are transformed into products that are legally classified as medicinal products or medical devices.

### **A- New health technologies classified as medicinal products**

The harmonisation of European rules on medicinal products started in 1965 with the directive on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products.<sup>70</sup> This directive gave the first definition of the term “medicinal product” which subsequently evolved.<sup>71</sup> This term is now defined as “Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis”.<sup>72</sup> Since regulation (EEC) No 2309/93, all new medicinal products presenting a significant biotechnological dimension must be submitted to a centralised assessment carried out by the European Medicines Agency (EMA).<sup>73</sup>

---

<sup>69</sup> Point 37, C- 364/13.

<sup>70</sup> Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products, OJ 022, 09/02/1965, pp. 369 - 373.

<sup>71</sup> Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products, OJ 022, 09/02/1965, pp. 369 - 373.

<sup>72</sup> Article 1§2 and annex I of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67; as modified by directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, OJ L 136, 30/04/2004, pp. 34- 57.

<sup>73</sup> Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products, OJ L 214, 24/08/1993 p.1 – 21.

Among these medicinal products based on biotechnological processes, EU law has put in place specific legal regimes for orphan medicines and advanced therapy medicines, which are specific and cumulative legal categories applicable to new health technologies. These regimes are based mainly on regulation (EC) No 141/2000 for the former<sup>74</sup> and regulation (EC) No 1394/2007 for the latter.<sup>75</sup> In both cases, regulations have been adopted, which are the best tools to harmonise EU law in particular compared to the directives applicable to standard medicinal products, which require transposition into domestic law. While specific European legislation on orphan medicines was adopted long after their US and Japanese counterparts<sup>76</sup> (1), the EU has been ahead regarding advanced therapy medicines (2).

### ***1- Orphan medicinal products***

Orphan medicinal products (OMP) aim to treat orphan diseases, which are diseases, including inherited ones, which are life-threatening or chronically debilitating, the prevalence of which is so low<sup>77</sup> that specific combined efforts are needed to fight them in order to reduce the number of people contracting the diseases, to prevent significant morbidity or perinatal or premature death or a significant reduction of the quality of life or of the socio-economic potential of sufferers.<sup>78</sup> These orphan diseases, of which 6,000 to 8,000 have been identified, affect around 30 million people in the European Union. Yet the low prevalence of each of these conditions implies very narrow markets for new molecules that could be marketed, so much so that firms are discouraged by the scientific and financial risks incurred. To alleviate these reservations towards these research lines that are little or not profitable at all, regulation (EC) No 141/2000 on orphan medicines<sup>79</sup> was adopted on 16 December 1999 in order to encourage the pharmaceutical industry to develop and market such medicinal products. Because of the mostly genetic origin (80% of orphan diseases are of genetic origin)<sup>80</sup> and the low prevalence of orphan diseases, this is a key area for therapeutic innovation, in which research is predominant in the sector of biotechnologies, and more specifically of gene therapy.

Regulation (EC) No 141/2000 subjects OMP to a centralised marketing authorisation procedure (MA) and establishes a procedure to obtain the « orphan medicinal product » designation and registration with the OMP register, under the responsibility of the committee for orphan medicinal products (COMP) which it created within EMA. It is supplemented by regulation (EC) No 847/2000 of the Commission dated 27 April 2000 laying down the provisions for implementation of the criteria for designation of a medicinal product as an OMP.<sup>81</sup> In order to obtain this designation, the relevant product must fit into the legal definition of a “medicinal product for human use”. Furthermore, sponsors must demonstrate one of the following two alternative criteria: the medicinal product must be destined to treat a life-threatening or chronically debilitating condition affecting not more than 5 in 10,000 persons in the European Union when the application is made or it must be considered as non-

---

<sup>74</sup> Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products, OJ L 18 du 22/01/2000, pp. 1- 5.

<sup>75</sup> Regulation (EC) n°1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004, OJ L324 10/12/2007, pp. 121-137.

<sup>76</sup> While the European regulation on orphan medicinal products has been adopted on 16 December 1999, specific regulations on orphan drugs have been adopted in 1983 in the USA and in 1993 in Japan.

<sup>77</sup> Less than 5 persons out of 10.000 in the European Union.

<sup>78</sup> [http://ec.europa.eu/health/ph\\_threats/non\\_com/rare\\_diseases\\_fr.htm](http://ec.europa.eu/health/ph_threats/non_com/rare_diseases_fr.htm)

<sup>79</sup> Regulation (EC) No 141/2000, *op. cit.*

<sup>80</sup> See notably: Eurordis, Factsheet, What is a rare disease, 2007 : <http://www.eurordis.org/content/what-rare-disease>.

<sup>81</sup> OJ L 103 28/04/2000, pp. 5- 8.

profitable in the EU, meaning that “without incentives it is unlikely that the marketing of the medicinal product in the Community would generate sufficient return to justify the necessary investment”.<sup>82</sup> Finally, one additional criterion must be satisfied: the absence of a satisfactory method of diagnosis, prevention or treatment already authorised in the EU or the existence of a significant benefit.<sup>83</sup> The latter criterion of a “significant benefit” seems to be vague, but in fact it prevents the exclusion of new medicinal products and this provision from being an obstacle to new and more effective treatments. Obtaining the “orphan medicinal product” designation from the COMP means benefitting from several measures destined to encourage their development: a ten-year market exclusivity period,<sup>84</sup> assistance with the elaboration of protocols for medicinal products designated as “orphan medicinal products”<sup>85</sup> with a partial or total waiver of the fees payable to EMA,<sup>86</sup> eligibility for EU and Member States incentives to support the R&D of OMP,<sup>87</sup> total or partial reduction of the fees due to EMA<sup>88</sup>. Since 2000, the number of applications for designation has been increasing and about one hundred OMP have received a marketing authorisation.<sup>89</sup>

## ***2- Advanced therapy medicinal products (including GMO)***

Regulation (EC) No 1394/2007 of the European Parliament and of the Council dated 13 November 2007 came to supplement the regulation on orphan medicinal products and constitutes without doubt the main regulation with regard to new health therapies. Indeed it governs what is referred to as « Advanced Therapy Medicinal Products » (ATMPs).<sup>90</sup> ATMPs are considered to be “biological medicinal products”, i.e. “product[s], the active substance of which is a biological substance”; such substance being “a substance that is produced by or extracted from a biological source and that needs for its characterisation and the determination of its quality a combination of physico-chemical-biological testing, together with the production process and its control”.<sup>91</sup> ATMPs include gene therapy medicinal products, cell therapy medicinal products, tissue engineered products and combined ATMPs that integrate a medical device.<sup>92</sup> These ATMPs are developed for the purpose of preventing or treating more or less rare diseases, acquired diseases such as cancer, central nervous system degenerative conditions (such as Alzheimer’s and Parkinson’s disease); and genetic diseases, which currently include an estimated 5000 hereditary diseases that can be “monogenic” or “multifactorial”. Having said that, medicinal products that fall within the scope of the legal definitions of ATMPs but “which are prepared on a non-routine basis according to specific quality standards, and used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient” are excluded from

<sup>82</sup> Article 3 (1) a) Regulation (EC) n°141/2000.

<sup>83</sup> Article 3 (1) b) Regulation (EC) No 141/2000.

<sup>84</sup> During this period, no MA or MA extension can be granted for any similar medicinal product used for the same orphan indication and which competes directly, save for a number of exceptions (consent from the holder of the original authorisation; insufficient supply of the medicinal product to patients; safer, more effective or otherwise clinically superior medicinal product). However, this ten-year exclusivity period can be reduced to six years if it is established, at the end of the fifth year, that the criteria for an orphan medicinal product are no longer met, or if the product is sufficiently profitable not to justify the maintenance of market exclusivity. Article 8, Regulation (EC) n°141/2000, *op. cit.*.

<sup>85</sup> Article 6 Regulation (EC) n°141/2000.

<sup>86</sup> Article 7§2 Regulation (EC) n°141/2000.

<sup>87</sup> Article 9 Regulation (EC) n°141/2000.

<sup>88</sup> EMA, Fee reductions for designated orphan medicinal products, 19 November 2013, EMA/622074/2013.

<sup>89</sup> EMA, Orphan Medicines Figures 2010- 2014.

<sup>90</sup> A. Mahalatchimy, [The impact of European Union law on the regulation of advanced therapy medicinal products in the France and the United Kingdom], PhD thesis, March 2015, University Toulouse 1- Capitole, France.

<sup>91</sup> Other biological medicinal products are notably immunological medicinal products and medicinal products derived from human blood and human plasma. Annex I Part 1 Pt. 3.2.1.1 b), directive 2001/83/EC.

<sup>92</sup> Regulation (EC) n°1394/2007, *op. cit.*

the scope of regulation (EC) No 1394/2007.<sup>93</sup> This “hospital exemption” was adopted so as not to prevent non-profit entities (universities, hospitals) from developing ATMPs within the scope of the hospital exemption as they do not have the necessary human and financial resources to comply with the EU pharmaceutical legislation. But the differences in how this exemption is applied by Member States have made it the most controversial provision as it could be used broadly in certain States, enabling the avoidance of the requirements imposed by the regulation.<sup>94</sup>

Based on elements of the human body transformed into medicinal products or used for a different function by the recipient, these medicinal products, which rely on complex scientific techniques, offer new therapeutic perspectives and great profit potential. But they also raise concerns about the little-understood risks that they could create. This is why this regulation creates a unified and specific legal regime (*lex specialis*) that is stricter than the one applicable to standard medicinal products. First of all, their marketing authorisation falls within the scope of the centralised procedure (EMA opinion and European Commission decision) and involves a committee of experts on these techniques: the committee for advanced therapies (CAT). This committee is in charge, among other things, of issuing recommendations on the classification as advanced therapy medicinal products. Given the complexity of the innovative scientific techniques on which these medicinal products rely, these recommendations currently constitute the main activity of the CAT. Moreover, this regulation set up a procedure to certify quality as well as non-clinical information in order to facilitate the development of these medicinal products through partnerships between the academic world, SMEs and big pharmaceutical companies. This procedure is based on the idea that academics and SMEs develop the proofs of concept (or feasibility studies) but have not necessarily the means to carry out clinical trials. In this case, the certificate obtained from EMA constitutes added value for their techniques, which they can sell to larger companies with the capacity to carry out clinical trials that are costly but comply with EU pharmaceutical legislation. This procedure is not well known and has been used very little. Furthermore, there are more stringent safety requirements in the clinical trial, pharmacovigilance and traceability stages. In this regard, many guidelines of the EMA and of the European Commission have been adopted, updated or are in the process of being adopted in this area. Finally, this regulation includes a 90% reduction for SMEs and a 65% reduction for other applicants with regard to the fees payable to EMA for the provision of scientific advice.

Since the adoption of this regulation, only 6 marketing authorisations<sup>95</sup> have been granted while one of them was withdrawn by its holder for commercial reasons and another one suspended for lack of an authorised production site on the EU territory. The European Commission reviewed the application of this regulation in its 2014 report<sup>96</sup> and confirmed that few ATMPs have received a marketing authorisation. But it also reported an increase in the activity of the CAT, revealing the dynamics of this sector, and suggested a clarification of the legislation in order to help the translation of research into medicinal products available to patients in the EU. Finally it highlighted several possibilities to improve the current framework, including the clarification of the definitions of ATMPs and of the scope of the hospital exemption, the extension of the certification procedure, the revision of marketing

---

<sup>93</sup> Article 28§2 Regulation (EC) n°1394/2007.

<sup>94</sup> European Biopharmaceutical Enterprises position paper on the Hospital Exemption, 2013.

<sup>95</sup> The six marketing authorisations have been granted to ChondroCelect, Glybera, MACI, Provence, Holoclar and Imlygic. Provence’s one has been withdrawn while MACI’s one has been suspended.

<sup>96</sup> Report from the Commission to the European Parliament and the Council in accordance with Article 25 of Regulation (EC) No 1394/2007 of the European Parliament and of the Council on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004, 28/03/2014, COM (2014) 188 final.

authorisation requirements and the adoption of measures to avoid disparities in the classification of ATMPs in the EU.<sup>97</sup>

## **B- New health technologies classified as medical devices**

The European legislation currently in place with regard to medical devices mostly stems from directive 93/42/EEC concerning medical devices (MDs)<sup>98</sup>, directive 90/385/EEC regarding active implantable medical devices<sup>99</sup> and directive 98/79/EC regarding in vitro diagnosis medical devices<sup>100</sup>. These directives specify key quality and safety requirements that must be met by the manufacturer in order to affix the CE mark which is required to place MDs on the European market. There are several procedures for the assessment of MDs' conformity to these key requirements, depending on the risks they create. Primarily, directive 93/42/EEC classifies MDs on the basis of technical criteria into a risk level which determines how they are assessed: duration (transient, short or long term), invasive devices (partial or full penetration inside the body, either through a body orifice or through the surface of the body, with the aid or in the context of a surgical operation, or an implantable device), reusable, dependent on a source of energy outside the human body, intended for treatment or for diagnosis, acting on the central circulatory system or the central nervous system.<sup>101</sup> On the basis of these criteria, classification rules based “on the vulnerability of the human body taking account of the potential risks associated with the technical design and manufacture of the devices” lead to grouping the devices into four classes:<sup>102</sup> conformity assessment procedures are carried out either through self-certification, or certification by a notified body. Self-certification is carried out under the sole responsibility of the manufacturers, for class I devices which create low risks, whereas the intervention of a notified body, a third party body designated by the competent Member States authorities, is required at the production stage of class IIa devices, and at the design and manufacturing stages of class IIb and III devices which constitute a high risk potential. These conformity assessment procedures are based on the deliverance of CE mark certificates by notified bodies for class III dedicated to high risk devices, such as all active implantable MDs. New health technologies classified as MDs generally fall within class III as their novelty and the complexity of the techniques on which they rely involve risks that are little or not known.

This legal framework is currently being revised, especially after the French authorities discovered the violation of an authorisation by a breast implant manufacturer (Poly Implant Prosthesis- PIP). Thus, in 2012, the European Commission made two proposals for regulations, one regarding all MDs and active implantable MDs,<sup>103</sup> the other specific to in vitro diagnosis MDs,<sup>104</sup> in order to clarify and to strengthen the health safety regulations applicable to MDs. In these proposals, while the classification rules still rely on the same criteria, they are adapted to technical advances. Furthermore, and most importantly, the scope of these rules is widened to cover new health technologies, in particular biotechnologies like

---

<sup>97</sup> *Ibid.* p. 15.

<sup>98</sup> Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ L 169, 12.7.1993, p. 1.

<sup>99</sup> Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, OJ L 189, 20.7.1990, p. 17–36.

<sup>100</sup> Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, OJ L 331, 7.12.1998, p. 1–37.

<sup>101</sup> Annex IX of directive 93/42/EEC as modified, *op. cit.*

<sup>102</sup> Recital (15) of directive 93/42/EEC as modified, *op. cit.*

<sup>103</sup> Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) n° 178/2002 and Regulation (EC) n° 1223/2009, 26/09/2012, COM/2012/542 final.

<sup>104</sup> Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices, 26/09/2012, COM/2012/0541 final.

the MDs produced with non-viable cells and tissues of human origin when they are not considered to be medicinal products. Notified bodies, whose powers are increased in particular as they have the ability to carry out unannounced inspections, are controlled more closely by national authorities. Similarly, the identification, traceability and clinical investigation requirements are subject to stricter rules. The rights and responsibilities of manufacturers and of their agents, of importers and distributors are clarified. Finally, a coordination group on MDs including representatives of the relevant national authorities is created to guarantee a better coordination between Member States. The Council of the Union agreed, on 5 October 2015, on a general approach with regard to both proposals to revise the legislation on MDs. On that basis, discussions are currently taking place between the Commission, the Council and the Parliament, but no provisional adoption date has yet been announced.<sup>105</sup>

## Conclusion

Through its policies and regulations, the EU currently brings major support to the development of new health technologies. We must however highlight the complexity of this field due to the accumulation of European texts, the specificities of these technologies – constantly evolving because of scientific progress – and the material that they involve: human biological material.

In this context, we can see the outline of the future developments and/or discussions in EU law.

### - *First, regarding research*

Besides the issues raised by the adoption of the European patent with unitary effect, which is a new tool to support innovation and thereby the development of new health technologies,<sup>106</sup> the main issues relate to exclusions from patentability. The prohibition of industrial and commercial uses of human embryos in the context of inventions is one of them, which is still ongoing. Thus we can wonder what will be the consequences of the ISCC case. Is this case an exception or a step towards a relaxation of the Brüstle case?<sup>107</sup> How to strike a balance between the freedom of research and patent law, which is essential both in the interest of society and for the industrial players, also remains an open question. Admittedly, a research exemption is provided in the directive but it only applies to the research phase. As a consequence, if a researcher improves a patented biological material or if he or she uses all or part thereof for a new invention, he or she will not be able to market it for the duration of the patent, unless the holder of the patent grants him a cross-licence in exchange for payment.

---

<sup>105</sup> Employment, Social Policy, Health and Consumer Affairs Council meeting on 7 December 2015 Proposal for a Regulation of the European Parliament and of the Council on medical devices and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices - Information from the Presidency on the state of play, ST 14215 2015 INIT - 2012/0267 (OLP).

<sup>106</sup> Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection, OJ L 361, 31.12.2012, p. 1–8; Council Regulation (EU) No 1260/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements, OJ L 361, 31.12.2012, p. 89–92. See notably: A. Plomer 'A Unitary Patent for a (Dis)United Europe: the Long Shadow of History' : <http://link.springer.com/article/10.1007/s40319-015-0356-6>.

<sup>107</sup> Indeed it appears that the ISCC case could be extended to other techniques used in the field of health technologies, such as iPS cells or the nuclear transfer of somatic cells which do not have – in and of themselves – the inherent ability to develop into a human being.

With regard to all these ethical questions, to which must be added the issue of the funding of hESC research, while the competence is primarily up to Member States (who decide for example whether or not to authorise hESC research), the “One of Us” citizens’ initiative demonstrates the need for dialogue with the civil society.

- *Regarding the use of new health technologies*

The legislation on this matter is changing. The implementation of ATMPs regulation still raises many challenges. While a revision of the regulation should be envisaged following the many possible improvements presented by the Commission, no such action has yet been announced. Nine years after the adoption of regulation (EC) No 1394/2007, few ATMPs have been marketed and the guidelines necessary for the application of this regulation are still in the process of being adopted. A vast project is also underway in the field of MDs where the revision of the regulation on medical devices launched in 2012 and hoped for 2016 should change the European landscape with respect to notified bodies for ever greater security. Finally, while the EU largely supports the marketing of new health technologies, whether they are legally classified as MDs, orphan medicinal products and/or ATMPs, these are not easily accessible to European patients. Not only is their cost often high given the need to control health expenditures, but Member States are the ones who decide whether or not such technologies are reimbursed.<sup>108</sup> In this matter, the intervention of the EU is particularly necessary to facilitate patients’ full accessibility to new health technologies.

---

<sup>108</sup> A. Mahalatchimy, Reimbursement of cell- based regenerative therapy in the UK and France, *Medical Law Review*, 2016, In press.