III. Legal Provisions Applicable to the Patent Eligibility of hESC-Related Inventions

A. EPC

The EPC[22] governs a centralized examination procedure which results in the grant of a bundle of national patents. At the very beginning, this procedure starts with the assessment whether an invention is patent eligible. This is the question preceeding the patentability of an invention, which requires the fulfillment of other conditions, namely novelty, inventive step and industrial applicability. The EPC has a negative approach by determining the exclusions from patent protection especially as provided in Art. 53. The first exclusion under literae (a) is based on the grounds of *ordre public* and morality, inventions the commercial exploitation of which would be contrary to *ordre public* or morality would not be patent eligible. Literae (b) sets forth exclusions for plant or animal varieties or essentially biological processes for the production of plants or animals. At the end, there is also the exclusion for methods of treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body. However, these exclusionary provisions also contain exceptions: Art. 53(b) and 53(c) state respectively, that microbiological processes or the products thereof and products in particular substances or compositions for use in surgery, therapy and diagnostic methods could be patent eligible. So far, the exclusionary provision based on *ordre public* and morality grounds has proved to be the most oft encountered barrier to the patent eligibility of biotechnological inventions in the EPC.

22 Convention on the Grant of European Patents ratified, Oct. 5, 1973, revised Dec.13, 2007.

B. TRIPs

Art. 27 of TRIPs[23] draws the contours of the patentable subject-matter. This article is significant because its first paragraph points out that patents should be available for all inventions "without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced." As stated by Straus, this is a "historical event" for the international industrial property protection because "almost all" inventions would be treated similarly to other trade objects throughout borders.[24] However, this generous rule is followed by some allowed exclusions in the second and third paragraphs of the said article. The second paragraph of Art. 27 provides for the WTO Member States an option to exclude from patent protection, inventions, "the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality." As it might be seen, this provision is similar to the EPC Art. 53(a). This might be the evidence that the EPC influenced drafting specific provision of TRIPs.[25] The same inference is true for Art. 27(3) but one must be aware that EPC's exclusions have a narrower scope in comparison with the provisions of TRIPs. The latter allows also exclusions in other fields of technology or for other types of inventions.[26] It is suggested that the legislator of TRIPs needs to review its position with regard to exclusions from patentability depending on the technological and scientific developments.[27] The similar result could be true for the EPC as well. As pointed out by Straus[28], since TRIPs does not contain "negative catalogue of creations of the human intellect," the patentability issue of biological materials such as DNA, cell lines, etc. is not clearly guided by TRIPs. This result is also valid in regard to the focal point of our research, namely, hESC-related inventions. There-

23 Agreement on Trade Related Aspects of Intellectual Property, Apr. 15, 1994 (*hereinafter* TRIPs.).

24 Joseph Straus, *Implications of the TRIPs Agreement in the Field of Patent Law*, in From GATT to TRIPs the Agreement on Trade Related Aspects of Intellectual Property Rights 160, 180 (Friedrich-Karl Beier&Gerhard Scricker eds., VCH, 1996).

25 United Nations Conference on Trade and Development-The Information and Communication Services Division, Resource Book on TRIPS and Development 376 (Cambridge University Press 2005).

26 Straus, *supra* note 24, at183.

27 *Id.,* at 185.

28 *Id.,* at 187.

after, the debate concerning hESC-related inventions would be mainly within the boundaries of ethical issues.

C. EC 98/44 Directive

Since the "biotechnology and genetic engineering are playing an increasingly important role in a broad range of industries, … the protection of biotechnological inventions … [is] of fundamental importance…"[29], the Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions has been adopted on July 6, 1998. (hereinafter the Biotech Directive). The essentiality for Member States of the effective and harmonized protection of biotechnological inventions throughout the EU Member States was an incentivising factor to draft the Biotech Directive.[30] The patent eligibility of hESC-related inventions is covered under the following provisions: Art. 5(1) provides for the exclusion from the patent protection of "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." On the contrary, "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" is the patent eligible subject matter under Art. 5(2). Additionally, similar to the language of TRIPs and the EPC, Art. 6(1) of the Biotech Directive draws an exclusion based on moral grounds. In the Art. 6(2), some examples of biotechnological inventions excluded from the patent protection based on the reasons related to the *ordre public* and morality are enumerated such as "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."

Although we already described the applicable provisions within the context of the EPC, it is necessary to draw attention to the link between the Biotech Directive and the EPC: After the adoption of the Biotech Directive, on June 16, 1999, the EPO implemented the rules laid down in the Directive into the EPC Implementing Regulations under a new chapter entitled

29 Council Directive 98/44 Directive, recital 1, 1998 O.J. (L 213) (EC) (*hereinafter* Biotech Directive.).

30 *Id.,* Recital 3.

'Biotechnological Inventions'.[31] In the Notice Concerning the Amendment of the Implementing Regulations, the EPO draws attention to the fact that this implementation has been done to create harmonisation and uniformity in the European patent law.[32] These new rules are intended be used to interpret EPC provisions in conformity with the Biotech Directive.[33] Thus, by virtue of Art. 164(1) of the EPC, Rule 26-29 constitute an integral part of the Convention. As a result, a link is generated between two legislative bodies and one could assert that the application of the Biotech Directive has to be closely followed by the EPO for a better functioning of the EPC for the purpose of consistency among Contracting States.

31 EPO Notice Concerning the Amendment of the Implementing Regulations to the European Patent Convention, 8-9/1999 O.J EPO, ¶1, at 573.
32 *Id.,* ¶3, at 573.
33 *Id.,* ¶9, at 575.