

# TOWARDS AN INTERNATIONAL CONVENTION AGAINST HUMAN REPRODUCTIVE CLONING

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#### A. Introduction

Human cloning raises profound ethical and legal concerns. This is true always, whether the main technique in question, somatic cell nuclear transfer, will one day be used for reproductive or for therapeutic purposes. While "reproductive cloning" would mean the creation of a genetically identical copy of an existing human being, the term "therapeutic cloning" alludes to a possible revolutionizing of regenerative medicine by providing means for investigating and curing genetically inheritable diseases that cannot be cured with the presently available scientific tools.

But is everything which may be technically possible at the same time permissible? Discussions mainly revolve around the fact that the technique, according to the present state of the art and irrespective of the ultimate biomedical purpose, always involves the production and use of embryos, the early form of human life. With respect to the two main biomedical purposes of cloning, the ethical-legal implications could be characterized as two-fold: The protection of *human dignity* which is exposed when the technique is applied for reproductive purposes; the protection of *human life* when therapy, through which the embryo is destroyed, is the ultimate goal.

Germany and France were concerned about reported ongoing research efforts around the world which were aiming at perfecting the cloning technique since they were undertaken without internationally binding rules. The German foreign minister Joschka Fischer and his then French counterpart Hubert Védrine on 26 June 2001 therefore agreed on an initiative to be presented to the United Nations. Both of them hoped this would lead to a wide-ranging project. On 14 September 2000, ahead of the 55<sup>th</sup> UN General Assembly, Fischer had already called for an international Convention to be drawn up concerning the ethical and human rights issues raised by genetic

technology.<sup>1</sup> The French President, Chirac, had repeatedly called for the drawing up of a comprehensive bioethics Convention under the auspices of UNESCO.

However, Fischer and Védrine were careful to concentrate their efforts in the UN General Assembly on seeking to effectuate a legally binding ban on human reproductive cloning. Preliminary work done by UNESCO had clearly shown which parts of the overall issue were ripe for international decision-making and which were not. For instance, the politically influential but legally non-binding Universal Declaration on the Human Genome and Human Rights<sup>2</sup> prohibits practices that violate human dignity and explicitly names reproductive cloning in this connection. But it was not possible to achieve international consensus regarding a similar prohibition of therapeutic cloning and other biomedical issues.

In October 2001, Ida Ryuichi, Chairman of the UNESCO International Bioethics Committee, stated: "In view of world-wide differences in values, even on such fundamental matters as concepts of life and death, it is hard to envisage any universally valid set of standards". This statement alludes to value systems in which the embryo does not enjoy absolute protection. This may be because protection of the embryo is weighed against therapeutic benefits (the idea of the ethically justifiable sacrifice), because the embryo is not regarded as a human being when it is only a few days old, e.g. the dominant Islamic idea that an embryo does not become human until the soul enters the body, which is deemed to happen only after many

<sup>&</sup>lt;sup>1</sup> See http://www.auswaertiges-amt.de/www/de/infoservice/presse/index\_html? bereich\_id=11 &type\_id=3&archiv\_id=309&detail=1; see also the speech by foreign minister Fischer at the 6<sup>th</sup> German-Dutch Conference in Potsdam, 28 February 2002, on the subject of "The Beginning and End of Life": "My thesis is that in the sphere of genetics and biotechnology we need international, as far as possible universally legally binding rules. (...) By presenting the German-French initiative against reproductive cloning, we have attempted to take an initial step in that direction."

<sup>&</sup>lt;sup>2</sup> See UNESCO (1997).

days, or because – as in Buddhism, for example – life is not seen as a gift of God.

Even Europe, a region of relative cultural homogeneity, is far from achieving consensus. The spectrum ranges from the United Kingdom, which approves of research into therapeutic cloning within a framework of legal controls, to Germany and Spain, which prohibit the cloning of human embryos regardless of the biomedical purpose for which they are produced.

It is true that Europe is the only region of the world that has binding legal norms concerning this matter. In 1998, the Council of Europe supplemented its Biomedicine Convention with an Additional Protocol prohibiting the cloning of human beings.<sup>3</sup> The "Right to Freedom from Injury" (article 3) of the EU Charter of Basic Rights<sup>4</sup> also makes express mention only of the prohibition of reproductive cloning.

On 3 and 4 June 2002, the German foreign ministry (*Auswärtiges Amt*) and the Quai d'Orsay organized a symposium entitled "On the Path to Global Bioethics?" in Berlin. Its purpose was to establish the extent to which global consensus exists on bioethical issues. The conclusion reached by 70 independent experts from every continent, as well as by the Ethics Councils of Germany and France, was again that there is consensus concerning the need to prohibit the reproductive cloning of human beings, but not concerning therapeutic cloning.<sup>5</sup>

The outlined discussion regarding the *scope* of a prohibition on human cloning was later mirrored in the negotiations that Germany and France initiated at the United Nations. There, it turned out to be

<sup>&</sup>lt;sup>3</sup> See *Council of Europe* (1997), see http://conventions.coe.int/treaty/en/treat ies/html/186.htm.

<sup>&</sup>lt;sup>4</sup> See *European Union* (2000), see http://europa.eu.int/eur-lex/pri/en/oj/dat/20 00/c\_364/c\_36420001218en00010022.pdf.

<sup>&</sup>lt;sup>5</sup> See *German-French Forum* (2002).

its Achilles' heel: Over three years after being introduced, their UN initiative of 2001 calling for a far-reaching, legally binding ban on the reproductive cloning of human beings has died, leaving the international community of states without any tangible legal implications.

Deep divisions over whether not only reproductive cloning - which the world community rejects seemingly unanimously - should be prohibited, but also therapeutic cloning, or whether the latter should merely be subject to controls were the sole subject of the diplomats' talks. In November 2004, the General Assembly finally acknowledged that the controversy was for the time being shelved and, in order not to lose its face in front of the world community, resorted to a legally non-binding political Declaration on human cloning. Factually speaking, this decision put the German-French initiative of a legally-binding instrument to an end.

Hence, now is an opportune juncture for taking stock of developments so far and for attempting to investigate the strong and the weak points of the German-French initiative. Progress out of the current deadlock can only be made when envisaging a Convention on human cloning, if we learn from past experiences and understand the various underlying interdisciplinary premises that have so far been steering the debate.

For that purpose, the *status quo* of the international debate regarding a regulation of human cloning will be outlined in the following. We will assess the scientific procedure of human reproductive and therapeutic cloning and its risks and promises from the perspective of science. Then, we will analyze the current legal framework at the international level, followed by a case study of the law in jurisdictions particularly involved in the UN initiative. In a final step, we will detail a report of the course of the negotiations that Germany and France had sparked at the UN in 2001. On the basis of this multifacetted analysis, we will draw conclusions for future legislative attempts.

# B. An assessment of the *status quo:* The science of human cloning and current legal regulation

Today, the ongoing research aiming at human reproductive and therapeutic cloning provokes disussions particularly focused on the question if and how reported attempts at the cloning of human beings should be prohibited.<sup>6</sup>

In order to address the question of a prohibition, we shall first learn of the basic scientific mechanisms that are used for human cloning. The following description therefore tries to provide the necessary background to the human cloning procedures and their biomedical purposes. Following that, the assessment of current international and national legislation shall serve as an indicator for existing world-wide consensus and room for possible compromise in multi-lateral talks.

### I. The science of human cloning

The purpose of this chapter is to provide background on the basic scientific aspects of human reproductive and therapeutic cloning. Also, we will consider related implications for the practical feasibility of a prohibition of reproductive cloning only, separate from a regulation of therapeutic cloning.

## 1. Natural reproduction

To understand the difference in mechanisms between natural reproduction and reproduction through cloning, we shall begin with basic facts about early embryonic development.

A human cell contains a nucleus that holds chromosomes, which carry genes, and deoxyribonucleic acid (DNA) is the substance of the

<sup>&</sup>lt;sup>6</sup> See, for example, *Kass* (1998); *Humber/Almeder* (eds.) (1998); *McGee* (ed.) (1998); *Lauritzen* (ed.) (2001); *Mackinnon* (2000); *Annas* et. al. (2002) at 151-178; *Kahn* (1997) at 119-124; *Macking (1994)*.

gene.<sup>7</sup> Moreover, almost the entire DNA in a cell is contained in the nucleus, and virtually every cell in the human body contains a human being's complete genetic code.<sup>8</sup> The rest of the DNA of a human cell resides in small organelles called mitochondria.<sup>9</sup> Mitochondria contain a small piece of DNA that specifies the genetic instructions for making several essential mitochondrial proteins. During fertilization, sperm mitochondria are selectively degraded inside the zygote. Thus, the developing embryo inherits solely or principally mitochondria and mitochondrial DNA from the egg.<sup>10</sup>

A healthy human egg (ovum) and a human sperm each have twentythree chromosomes.<sup>11</sup> During fertilization, a process point ("syngamy") occurs where the egg and the sperm unite to become an entity.<sup>12</sup> After the point of syngamy, the nuclei of the male and female gametes begin to unite resulting in the formation of a zygote which has a full complement of chromosomes for a human nucleus.<sup>13</sup> The produced "zygote" contains a nucleus with the adult cell complement of 46 chromosomes, half from each parent. Once a zygote exists, the embryonic genome is completely formed and embryonic development begins.<sup>14</sup> The zygote traverses the gradual process of cell division, growth, and differentiation.

When the one-celled zygote develops into other distinct cells, the new cells are called blastomeres. Because they divide mitotically, all blastomeres contain identical chromosomes and genetic information as the original one-celled zygote.<sup>15</sup> As a zygote divides, the new cells become specialized or they will not be able to divide to become new

<sup>&</sup>lt;sup>7</sup> See *Larsen* (2001) at 1.

<sup>&</sup>lt;sup>8</sup> See *id*.

<sup>&</sup>lt;sup>9</sup> On mitochondrial DNA, see Johns (1996) at 1065-1067.

<sup>&</sup>lt;sup>10</sup> See *The President's Council on Bioethics* (2002) at 59.

<sup>&</sup>lt;sup>11</sup> 22 pairs plus two X chromosomes if the adult is female, or 22 pairs plus one X and one Y chromosome if the adult is male.

<sup>&</sup>lt;sup>12</sup> See *Larsen* (2001) at 1.

<sup>&</sup>lt;sup>13</sup> See *id*.

<sup>&</sup>lt;sup>14</sup> Although the embryonic genome is complete, it is not activated until four to eight cells are present, see *O'Rahilly/Muller* (1996) at 29.

<sup>&</sup>lt;sup>15</sup> See *Forsythe* (1998) at 476.

embryos.<sup>16</sup> In addition, the new cells, like the zygote, are somatic cells as opposed to germ cells. A somatic cell is any cell of the embryo, fetus, child, or adult which contains a full complement of two sets of chromosomes; in contrast with a germ cell, i.e. an egg or a sperm, which contains only one set of chromosomes.<sup>17</sup> As is apparent, in natural reproduction, the new life that comes into being has a full complement of the chromosomes of the human egg and the human sperm.

Human reproduction, in cases hampered by one or another cause of infertility, has been accomplished with the help of *in vitro* fertilization (IVF) of an egg by a sperm and the subsequent transfer of the early embryo to a woman for gestation and birth. Though such union of egg and sperm requires laboratory assistance and takes place outside of the body, IVF reproduction is still sexual in the biological sense: The new human being arises from two biological parents through the union of egg and sperm.<sup>18</sup>

#### 2. Cloning techniques

Today, we know of two cloning techniques, *embryo splitting* and *somatic cell nuclear transfer*.

#### a) Embryo splitting

For embryo splitting, an embryo is divided into several separate cells which each are totipotent, i.e. can potentially develop and transdifferentiate into an individual.<sup>19</sup> The totipotent cells are genetically identical with each other and with the original embryo.

<sup>&</sup>lt;sup>16</sup> See *id.* at 477.

<sup>&</sup>lt;sup>17</sup> See *The President's Council on Bioethics* (1997) at 1 No. 2.

<sup>&</sup>lt;sup>18</sup> See *The President's Council on Bioethics* (2002) at 59.

<sup>&</sup>lt;sup>19</sup> See National Academy of Sciences et. al. (2002) at 25-27; Deutsche Forschungsgemeinschaft (1999) at 8; Hillebrand/Lanzerath (2001) at 12. Totipotentiality of cells split from the embryo exists at least up until the four cell stadium, see Kersten (2004) at 8 with further references.

"Identical" means that both the DNA of the nucleus and the DNA of the mitochondria, and thus the complete genome, match.<sup>20</sup>

The technique of embryo splitting as a means of cloning has already been applied in animal breeding, for the production of farm animals.<sup>21</sup> The initial intent there was to produce identical working animals with special properties. However, embryo splitting is of little practical interest since the offspring has to be produced before knowledge about the specific properties of the developing animal becomes evident.<sup>22</sup> It showed however the possibility of the development and birth of an embryo produced through embryo splitting. The U.S. scientists Jerry Hall and Robert Stillman in 1993 tried the embryo splitting technique with human embryos.<sup>23</sup> Although the experiment failed prematurely, the scientists could show that the single cells, until the end of the experiment, were displaying the usual ability to further split and develop. The conclusion was drawn that the cloning of human beings through embryo splitting was theoretically possible.

#### b) Somatic cell nuclear transfer

The limitations encountered in embryo splitting are hoped to be exceeded through the somatic cell nuclear transfer technique.

Somatic cell nuclear transfer is an extension of research that has been going on for over 40 years with nuclei derived from nonhuman embryonic and fetal cells.<sup>24</sup> It has first been successfully applied at the Roslin Institute in Scotland which announced the successful

<sup>&</sup>lt;sup>20</sup> For the legal implications that are bound up with the term "identical", see for instance the discussion of Germany's ESchG, outlined at B.II.2.c) aa). See also the Additional Protocol of the Council of Europe outlined at B.II.1.b) bb). <sup>21</sup> See *Rendtorff* et al. (1999) at 7-8. For the cloning of primate offspring through

<sup>&</sup>lt;sup>21</sup> See *Rendtorff* et al. (1999) at 7-8. For the cloning of primate offspring through embryo splitting see *Chan* et. al. (2000) at 317-320.

<sup>&</sup>lt;sup>22</sup> See *Winnacker*, in: Vöneky/Wolfrum (2004) at 55.

<sup>&</sup>lt;sup>23</sup> See *Hall* et. al. (1993), suppl. at 1. See also *Jones* (1994) at 205-207; *Robertson* (1994) at 6-14.

<sup>&</sup>lt;sup>24</sup> For a history on research of somatic cell nuclear transfer see *Gurdon/Byrne* (2002) at 35-50.

cloning of a sheep.<sup>25</sup> The technique involved transplanting the genetic material of an adult sheep, obtained from a somatic cell with a full chromosomal complement, into an egg from which the nucleus had been removed (called oocyte). The somatic cell's nucleus with its forty-six chromosomes was altered<sup>26</sup> and then placed into the enucleated cell of the egg. Thus, the egg was tricked into reacting as if the nucleus of a sperm cell had merged with its egg nucleus.<sup>27</sup> The egg was then re-implanted into a womb and began developing.

The result of this procedure was the birth of a sheep, named Dolly, on 5 July 1996, which contained the genetic material of only one parent and was therefore a "delayed" genetic twin of a single adult sheep. As is apparent, this cloning technique does not combine the genetic material of two parents, but uses only that of one. In that, it is fundamentally different to the result of natural reproduction – the "process of genetic diffusion"<sup>28</sup> is suspended through a deliberate scientific effort.

This first successful attempt of somatic cell nuclear transfer was a revolutionary finding.<sup>29</sup> Until then, scientists had assumed that a differentiation of cells was irreversible. The Dolly experiment proved that the genetic information of a nucleus stemming from a fully differentiated adult cell in combination with the cytoplasma of a denucleated egg can merge to become a new totipotential cell, totipotentiality being the starting point for the differentiation into a new independent organism. Before, scientists thought that the differentiation of human cells was only one-dimensional – the development evolving from the embryo towards an adult cell type, and never vice-versa. The experiment "Dolly" proved that clones could be created at a time when the numerous features and

<sup>&</sup>lt;sup>25</sup> See *Wilmut* et. al. (1997) at 810-813; *Wilmut* et. al. (2001) at 270.

<sup>&</sup>lt;sup>26</sup> For the process of alteration see in detail *Cantrell* (1998-1999) at 70.

<sup>&</sup>lt;sup>27</sup> See *Forsythe* (1998) at 481-482.

<sup>&</sup>lt;sup>28</sup> See *Winnacker* (2002) at 4 ("genetischer Schüttelvertrag").

<sup>&</sup>lt;sup>29</sup> See *Deutsche Forschungsgemeinschaft* (2001) at 11-12; *Stiegler* (1997) at 62-64; *Winnacker* (2000) at 14.

characteristics of the cell nucleus are already known - which is of course not the case with an embryo.<sup>30</sup>

Until now, somatic cell nuclear transplantation experiments have been successful with many species, but never with primates. The cloning of several mammalian species however shows that cloning by nuclear transfer is highly inefficient.<sup>31</sup> According to the overall success rate, 1% of manipulated eggs currently develop to adults.<sup>32</sup> Failures in the process of somatic cell nuclear transfer and the low success rate originate in "incorrect reprogramming"<sup>33</sup>, a process that has to take place in natural reproduction as well. Here, the egg cytoplasm must, following fertilization, reprogram the genetic material of both egg and sperm with the resulting activation of the embryonic genome. The egg cytoplasm which is designed to accomplish this reprogramming, and the fact that both sperm and egg genomes are inactive at the time of fertilization may contribute to its success.<sup>34</sup>

Following the transfer of a somatic cell nucleus, the egg cytoplasm encounters a transcriptionally active genome it is not designed to reprogram. Whatever pattern of gene expression specific for a particular somatic cell is present it needs to be shut down and a pattern specific for the zygotic genome must be established. Since this part of the process is highly complex, it is no wonder that the majority of clones does not succeed and fails before implantation.<sup>35</sup> Also, failures in reprogramming result in fetal and perinatal loss<sup>36</sup> and

<sup>&</sup>lt;sup>30</sup> See above at B.I.2.a).

<sup>&</sup>lt;sup>31</sup> See *Solter* et. al., in: Gethmann (2003) at 66; *National Academy of Sciences* et. al. (2002) at 40-43 and 114-116; *Hillebrand/Lanzerath* (2001) at 14, 24.

 $<sup>^{32}</sup>$  See the research results of *Chung* et. al. (2002), *Heindryckx* et. al. (2001), *Ono* et. al. (2001). The cloning of cows seems to make an exception, it can reach 50 % and more, see *Winnacker*, in: Vöneky/Wolfrum (2004) at 56.

<sup>&</sup>lt;sup>33</sup> Enquete-Kommission Deutscher Bundestag (2001) at 11; Solter et. al., in: Gethmann (2003) at 66; National Academy of Sciences et. al. (2002) at 41-43, 52, 64; Kersten (2004) at 12, 13; Winnacker (2004) at 57.

<sup>&</sup>lt;sup>34</sup> See *Solter* et. al., in: Gethmann (2003) at 66.

<sup>&</sup>lt;sup>35</sup> See *id*.

<sup>&</sup>lt;sup>36</sup> See *Renard* et. al. (1999) at 490; *Solter* (1999) at 312.

phenotype abnormalities in adult clones, such as obesity<sup>37</sup>, pneumonia and liver failure resulting in premature death<sup>38</sup> and arthritis observed in Dolly<sup>39</sup>. Also, it is not clear whether the "genetic age" of the clone is higher than expected and is actually the same as the age of the donor cell.<sup>40</sup>

As regards the successful application of somatic cell nuclear transfer on human beings,<sup>41</sup> some scientists take the successful cloning of animals<sup>42</sup> as an indication that cloning should be possible in all species including humans. We may however note that the new individual created through somatic cell nuclear transfer would not be a clone in a biological sense. The genome of the clone consists of DNA from the nucleus and DNA from the mitochondria. While the DNA of the nucleus stems from the donor of the nucleus, the DNA of the mitochondira comes from the donor of the egg. If the definition of "clone" is understood as a 100% genetic identity, then the nucleus of the somatic cell nuclear transfer clone must have stemmed from the donor of the egg cell.<sup>43</sup> In all other cases, the clone "shares" the genetic information of the genome of its nucleus with the donor of the nucleus while its mitochondrial DNA is identical with the donor of the egg. Then, the genetic heritage of the clone differs at 0,01 to 0.02% in comparison with the donor if the nucleus.<sup>44</sup>

<sup>&</sup>lt;sup>37</sup> See *Tamashiro* et. al. (2002) at 264, 265.

<sup>&</sup>lt;sup>38</sup> See *Ogonuki* et. al. (2002) at 253.

<sup>&</sup>lt;sup>39</sup> See *Williams* (2002) at R78; *Winnacker*, in: Vöneky/Wolfrum (2004) at 56. Moreover, Dolly died prematurely after six years.

<sup>&</sup>lt;sup>40</sup> See *Shiels* et. al. (1999), quoted in *Rentorff* et. al. (1999) at 9.

<sup>&</sup>lt;sup>41</sup> On the process see detailed *National Academy of Sciences* et. al. (2002) at 7; *The President's Council on Bioethics* (2002) at 59-65.

<sup>&</sup>lt;sup>42</sup> Sheep (*Campbell* et. al. 1996), cattle (*Lanza* et. al. 2001), pigs (*Betthauser* et. al. 2000; *Onishi* et. al. 2000; *Polejaeva* et. al. 2000), goats (*Keefer* et. al. 2001), mice (*Wakayama* et. al. 1998), cats (*Shin* et. al. 2002), rabbits (*Chesne* et. al. 2002), zebrafish (*Lee* et. al. 2002), and rhesus monkey (*Mitalipov* et. al. 2002), quoted in *Solter* et. al., in: Gethmann (2003) at 104.

<sup>&</sup>lt;sup>43</sup> The discussion on the precise meaning of the term "identical" was re-visited in the interpretation of the German ESchG, see below at B.II.2.c)aa).

<sup>&</sup>lt;sup>44</sup> See *The President's Council on Bioethics* (2002) at 59.

Proof has not yet been produced of the successful cloning of human beings.<sup>45</sup> On the contrary, voices in the scientific community question whether human cloning through somatic cell nuclear transfer will ever be possible.<sup>46</sup> Though there have, for instance, been some reports suggesting that adult animal clones are phenotypically normal<sup>47</sup>, the preponderance of abnormalities suggest that no clone is entirely normal.<sup>48</sup> Besides these and other uncertainties<sup>49</sup> and the tremendous loss of embryos<sup>50</sup> in animal cloning, it seems very likely that cloned humans would, if at all, be born abnormal.<sup>51</sup> A final prognosis on the success of reproductive cloning seems premature, considering that the technique has not been optimized.<sup>52</sup> It may only be said so much: Successful human reproductive cloning through somatic cell nuclear transfer is not wholly foreclosed.<sup>53</sup>

The empiric experiment of cloning a human being to find out *whether* the technique and its ultimate purpose can be applied successfully is, however, not an option.<sup>54</sup> At this point in time, scientists question that the somatic cell nuclear transfer technique is sophisticated enough to be experimented with in the context of human life as opposed to animal life.<sup>55</sup> The look at the current development of non-human animal reproductive cloning technology gives reason for caution. The technique of reproductive cloning applied so far is so rudimentary that the procedure has resulted, as was described, in an extremely

<sup>&</sup>lt;sup>45</sup> See in detail on the following *Fitzgerald* (1998) at 218-223.

<sup>&</sup>lt;sup>46</sup> See *Müller-Jung* (2003a) at 38; *Wewetzer* (2003) at 15. Some however deem it possible, see *Silver* (2000) at 59, 61-63; *Kersten* (2004) at 14 with further references. *Winnacker* regards the cloning of human beings through somatic cell nuclear transfer as feasible, see *id.*, in: Vöneky/Wolfrum (2004) at 58.

<sup>&</sup>lt;sup>47</sup> See *Lanza* et. al. (2002) at 1171, 1172.

<sup>&</sup>lt;sup>48</sup> See *Wilmut* (2002a) at 61.

<sup>&</sup>lt;sup>49</sup> See *Solter* et. al., in: Gethmann (2003) at 66 with further references.

 <sup>&</sup>lt;sup>50</sup> For instance, the attempts at cloning Dolly included the creation of 277 embryos.
 <sup>51</sup> So Jaenisch, cited in *Müller-Jung* (2003b) at 34.

<sup>&</sup>lt;sup>52</sup> See *McGee/Wilmut*, in: McGee (1998) at 93-94.

<sup>&</sup>lt;sup>53</sup> See *Deutsche Forschungsgemeinschaft* (2001) at 13; *Deutsche Bundesregierung* (1998) at 11; *Lanza* et. al. (1999) at 975. See also *Jaenisch/Wilmut* (2001) at 2552 who, with their claim "Don't clone humans!" must also deem it at least not wholly unthinkeable.

<sup>&</sup>lt;sup>54</sup> See *Kersten* (2004) at 15 with further references.

<sup>&</sup>lt;sup>55</sup> See Annas (1997) at 77-83 with further references.

high occurrence of severe physical and genetic defects and premature aging in cloned offspring.<sup>56</sup> Also, the age of a cloned individual is uncertain because the aging process is so complex. As the chromosomes in a cell age, they shorten. An individual beginning life with shortened chromosomes may be born older than sexually reproduced individuals.<sup>57</sup> Further, the cloned individual may risk inheriting genetic diseases and conditions from donor DNA.<sup>58</sup> Embryologists estimate that a single successful human cloning might come at the cost of hundreds of failed attempts.<sup>59</sup> In view of the above, human reproductive cloning is, at this point in time, not considered to be a safe and reasonable practice for humans.<sup>60</sup>

Beyond the health of the clone, there appear to exist some risks to the health of the egg donor, particularly risks to her future reproductive health caused by the hormonal treatments required for egg donation, and risks to the health of the surrogate mother, for instance, animal experiments suggest a higher than average likelihood of overweight offspring, which can adversely affect the health of the birth-mother.<sup>61</sup>

## **3.** Selected biomedical purposes and possible applications of the cloning techniques

In the following, we will focus our deliberations on the two biomedical purposes which are relevant for the discussions at the UN, namely reproduction and therapy. We will use these two notions in the same sense that Germany and France, and with them a supposed majority of UN delegations, interpreted and understood them.<sup>62</sup>

<sup>&</sup>lt;sup>56</sup> See *Westphal* (2001), Cloned monkey embryos are a "gallery of horrors", see *id.* at 4; *Wilmut* (2002) at 215. 216.

<sup>&</sup>lt;sup>57</sup> See Andrews (1998) at 643, 651.

<sup>&</sup>lt;sup>58</sup> See *Eskridge/Stein* (1998) at 95, 106.

<sup>&</sup>lt;sup>59</sup> See *Jaenisch/Wilmut* (2001) at 2552.

<sup>&</sup>lt;sup>60</sup> See *Gurdon/Colman* (1999) at 743, 746; *Brock* (2002) at 314, 316; *Check* (2002) at 351, 352.

<sup>&</sup>lt;sup>61</sup> See Working Paper # 2 of the *President's Council on Bioethics* (1997), Appendix A.

A. <sup>62</sup> A divergence in the interpretation of the cloning terminology mainly lies in "therapeutic cloning", see the disputed definition as used here and by Germany and France below at B.I.3.b). For the discussions held by UN member states in the

#### **Reproduction** *a*)

One purpose for the use of the cloning techniques is reproduction, i.e. the creation of a viable human being.<sup>63</sup>

As regards embryo splitting, the technique of embryo splitting could be used in *in vitro* fertilization.<sup>64</sup> An IVF embryo can be split into several totipotent cells. From among these new embryos, several could be placed in the uterus at once, thus increasing the chance of initiating a pregnancy. A gradual implantation of the cloned embryos is likewise possible. Should a first attempt of initiating a pregnancy fail, more embryos for implantation are available. Extra embryos could, even in the case of a successful birth, be implanted for the purpose of giving birth to cloned siblings of the first-born.<sup>75</sup>

While embryo splitting is a prenatal form of cloning, somatic cell nuclear transfer offers the theoretical possibility to create a clone which caries the same genes as a living or an already dead human being.

As such, somatic cell nuclear transfer could be applied to prevent a hereditary disease of the offspring.<sup>76</sup> For instance, if a potential father had a genetic defect in his genes which would lead to Chorea

venue of the Sixth Committee on the term "therapeutic cloning", see below at C.II.5.

<sup>&</sup>lt;sup>63</sup> On the motives and purposes for reproductive cloning, see *Rendtorff* et. al. (1999) at 12-14; Andrews (1997) at F-9 to F-12; Kersten (2004) at 17-27; Wu

<sup>(1998)</sup> at 1479-1485; *Buchanan* et. al. (2000) at 200, 201. <sup>64</sup> See *Hillebrand/Lanzerath* (2001) at 18, 23; *Rendtorff* et. al. (1999) at 9.

<sup>&</sup>lt;sup>65</sup> See *Havry* (2003) at 447, 450.

<sup>&</sup>lt;sup>66</sup> On the motives and purposes for reproductive cloning, see *Rendtorff* et. al. (1999) at 12-14; Andrews (1997) at F-9 to F-12; Kersten (2004) at 17-27; Wu

<sup>(1998)</sup> at 1479-1485; *Buchanan* et. al. (2000) at 200, 201. <sup>67</sup> Example drawn from *Rendtorff* et. al. (1999) at 12.

<sup>&</sup>lt;sup>68</sup> On a "non-individualisation" through cloning, see Andrews (1998) at 657.

<sup>&</sup>lt;sup>69</sup> See UCLA (1998).

<sup>&</sup>lt;sup>70</sup> See *Peters*, in: Cole-Turner (1997) at 12, 21.

<sup>&</sup>lt;sup>71</sup> See *Rendtorff* et. al. (1999) at 14.

<sup>&</sup>lt;sup>72</sup> See *id*.

<sup>&</sup>lt;sup>73</sup> See *Kersten* (2004) at 18.

<sup>&</sup>lt;sup>74</sup> See Hillebrand/Lanzerath (2001) at 18, 23; Rendtorff et. al. (1999) at 9.

<sup>&</sup>lt;sup>75</sup> See *Rendtorff* et. al. (1999) at 14.

<sup>&</sup>lt;sup>76</sup> See *Rhodes* (1995) at 287.

Huntington, there would be a 50% probability that his descendants would inherit the defect in the case of natural procreation. Would however only a somatic cell of the mother be used for the purpose of cloning, the child would not inherit the defect.<sup>77</sup> Alternatives to cloning in this case could only be prenatal methods of genetic diagnosis, such as "preimplantation genetic diagnosis" (PGD), or germ-line therapy, both of which are ethically heavily disputed.

Also, somatic cell nuclear transfer could be used to remedy infertility.<sup>78</sup> Infertility can, for instance, have its origin in an incapacity of germline development. In such cases, the wish for children can only be fulfilled through adoption or heterologic insemination. Should the wish of a couple lie in a child that does not have a "foreign", i.e. family-dispatched origin<sup>79</sup>, it could be fulfilled through somatic cell nuclear transfer, if the husband is infertile and combines one of his somatic cells with the denucleated egg of his wife.

Finally, the technique could replace a famous person, presumed to be based on their desirable or superior genetic make-ups, or a dead child.<sup>80</sup> Contrary to common belief, however, somatic cell nuclear transfer will not produce an identical twin of an existing human being in every sense of the word.<sup>81</sup> Genetically speaking, it comes, as was described, very close to the later copy of a living human being. However, psychologically and socially speaking, it produces an entirely new individual, whose biological features just happen to be quite similar to someone else's. As can be seen with "natural twins", their almost identical gene set does not predetermine the

<sup>&</sup>lt;sup>77</sup> See *Robertson* (1994) at 6-14.

<sup>&</sup>lt;sup>78</sup> See *id.* (1994) at 8-11; *id.* (1998) at 1378-1385.

<sup>&</sup>lt;sup>79</sup> Supposedly, in most of the world, there is generally a strong desire for human couples to have biologically related children, see *de Melo-Martín* (2002) at 264, 254.

<sup>&</sup>lt;sup>80</sup> "Cloning of loved ones", see *Robertson* (1994) at 6-14. See also *Jonas* (1990) at 186.

<sup>&</sup>lt;sup>81</sup> See *Hayry* (2003) at 447, 449.

development of their personalities.<sup>82</sup> On the contrary, it is dependent on the environment that they grow up in.<sup>83</sup>

Beyond the outlined serious biomedical purposes, there are a number of imaginable repulsive applications of the reproductive cloning technique which may be the reason for the term "cloning" generally having a negative connotation.<sup>84</sup> Some of these applications should be attributed to an overambitious media and opponents of human cloning creating future scenarios in an attempt to warp the lawmaking process towards strict prohibitions.

Among these, we may count the scenario of the production of an unlimited number of genetically identical human beings. Theoretically, it would for instance be possible to create specifically strong, athletic men to be trained as fighters for the case of self-defence.<sup>85</sup> This could even be turned into a general intention to control our own evolution and manipulate the biological nature of our species.<sup>86</sup> Insofar, reproductive cloning can be linked to a vision of transferring our natural evolution to a man-made evolution.<sup>87</sup> Society may also prepare for the unpredictable nature of the future: For example, extreme circumstances may require the re-creation of certain desirable genomes. Reproductive cloning could thus be regarded as the gateway to the genetic self-improvement of mankind<sup>88</sup>, and the desirable continuation modern civilization's mastery of nature for the relief of man's estate. Whether all this

<sup>&</sup>lt;sup>82</sup> For instance, the age difference at the time of the death of non-identical (fraternal) twins is twice as big as that of identical twins, which allows the conclusion that the genome plays a major role for life expectancy. On the other hand, the intelligence quotient between identical twins who are growing up separately is less similar than the one between non-identical twins growing up separately, which allows the conclusion that an identical genome is not predominant for the development of intelligence but that the milieu in which twins grow up in is decisive, see *Winnacker* (2002) at 7.

<sup>&</sup>lt;sup>83</sup> See *de Melo-Martín* (2002) at 246, 249.

<sup>&</sup>lt;sup>84</sup> See Kersten (2004) at 18.

<sup>&</sup>lt;sup>85</sup> Example drawn from *Rendtorff* et. al. (1999) at 12.

<sup>&</sup>lt;sup>86</sup> On a "non-individualisation" through cloning, see *Andrews* (1998) at 657.

<sup>&</sup>lt;sup>87</sup> See UCLA (1998).

<sup>&</sup>lt;sup>88</sup> See *Peters*, in: Cole-Turner (1997) at 12, 21.

would be a serious scientific undertaking in view of the current knowledge and experience with cloning is highly questioned within the scientific community.<sup>89</sup>

The same can be said for the purported future scenario of cloning viable human beings in order to use their organs for transplantation. In transplantation medicine, a chronic lack of transplantable organs exists, which could be assuaged through cloning humans to serve as organ donators. Also, due to a lack of identical tissue, the transplant of organs often leads to rejection reactions after implantation. Using the somatic cell of an affected patient, a clone could be created that would donate his organ to the patient. This could theoretically include vital organs, such as the heart, and would correspondingly put the clones' life to an end.<sup>90</sup> Some therefore further discussed to create such clones without a brainstem. Thus, the clone would lack consciousness and could in the long term not live independently.

All of the purposes of reproductive cloning mentioned above are generally imaginable, however only under the general reservations that scientists hold towards the successful use of the techniques in human beings.

#### b) Therapy

Another purpose for the use of the cloning techniques would be therapeutic in its intent: The term "therapeutic cloning" circumscribes the use of the somatic cell nuclear transfer technique to produce transplantable cells, tissues, and organs for therapeutic purposes without the danger of an anti-immune reaction: An *embryonic clone* is created for medical research aimed at scientific investigation of early human embryo development and, ultimately, the development of treatments for disease, mainly of new tissue and organ replacement

<sup>&</sup>lt;sup>89</sup> See *Rendtorff* et. al. (1999) at 14.

<sup>&</sup>lt;sup>90</sup> See *id*.

therapies on the basis of material derived from embryonic cells or fetal tissues.<sup>91</sup>

The very idea was drawn from the Dolly experiment, where scientists understood that the nucleus of a fully differentiated somatic cell in combination with a denucleated egg cell can form a totipotential cell. Therefore, such cells could be produced *in vitro* with the intent to cultivate cell-, tissue-, and organ-replacement for the donor of the nucleus. The replacement tissue would thus have an almost identical gene set as the patient, i.e. the donor of the nucleus; an anti-immune reaction could be bewared. The technical procedure is that of somatic cell nuclear transfer. The inner cell mass of blastocysts produced after transfer of a somatic cell nucleus from the patient into an enucleated oocyte is used to isolate embryonic stem cells. The following cell or tissue replacement therapy would, since the patients own cells were used, at least ideally, eliminate the problem of immune rejection.<sup>92</sup>

Stem cells have important characteristics that distinguish them from other types of cells.<sup>93</sup> They are unspecialized cells that renew themselves for long periods through cell division. Serving as a sort of repair system for the body, they can theoretically divide without limits to replenish other cells for as long as the person is still alive. Under certain physiologic or experimental conditions, they can be induced to become cells with special functions such as the beating cells of the heart muscle, the insulin-producing cells of the pancreas,

<sup>&</sup>lt;sup>91</sup> The term is however used in a more narrow sense by some: "Therapeutic cloning" is *only* the cell and tissue replacement therapy which involves the patients' cells. Research aiming at the perfection of the techniques with the aim of therapy would not be covered by the definition, see *Smith* (1998) at R802-804. Others understand the term much broader and find that even reproductive cloning is therapeutic if it allows couples to have children whose physical disposition bars them from natural reproduction. On the terminology and its diverse interpretations, see *Kersten* (2004) at 17-18 with further references. See also *Simitis*, in: Vöneky/Wolfrum (2004) at 179; *Rendtorff* et. al. (1999) at 11-13; *National Academy of Sciences* et. al. (2002) at 20; *Eser/Koch* (2003) at 25-27; *The President's Council on Bioethics* (2002) at 37-57; *Wright* (1999) at 352. For the debate among UN member states on the "correct" terminology, see below at C.II.5. <sup>92</sup> See *Drukker* et. al. (2002) at 9864-9869.

<sup>&</sup>lt;sup>93</sup> For a definition of stem cells, see *Deutsche Forschungsgemeinschaft* (1999) at 3.

or a brain cell.<sup>94</sup> Some scientists believe that these cells therefore hold the potential to revolutionize medicine by providing a source of replacement tissue for patients with degenerating diseases that might one day restore their health suffering from a variety of debilitating conditions.<sup>95</sup>

Embryonic stem cells, as was just described, are derived from embryos.<sup>96</sup> The stem cell with the greatest potential, i.e. the totipotential, is the fertilized egg, which is capable of developing into a complete organism. According to the usual explanation, the fertilized egg cell has the totipotential up to the stage of division into eight cells, and in later stages the cells retain only the pluripotential. That is, they can form many different types of tissues, but not the complete organism.<sup>97</sup> Embryonic stem cells, meaning those 50 cells within a blastocyst, which then continue to develop into the embryo proper, may have this pluripotential. In the course of further specialization, stem cells of individual tissues are formed, such as that of bone marrow, from which all the other kinds of blood cells develop.

While having great therapeutic potential, the use of embryonic stem cells faces technical challenges. Scientists must learn how to control their development into all the different types of cells in the body. At this stage, it is for instance not clear how the quality of the transplantation material is affected through errors in the reprogramming of the genetic information of the transplanted

 <sup>&</sup>lt;sup>94</sup> For the successful implantation of embryonic stem cells in a rats' brain which could remedy brain defects, see *Deutsche Forschungsgemeinschaft* (2001) at 6. On other possible use of stem cells, see *Enquete-Kommission Deutscher Bundestag* (2001) at 17-20 with further references.
 <sup>95</sup> See *Committee on the Biological and Biomedical Applications of Stem Cell*

<sup>&</sup>lt;sup>95</sup> See Committee on the Biological and Biomedical Applications of Stem Cell Research et. al. (2001) at 14.

<sup>&</sup>lt;sup>96</sup> So far, embryonic stem cells are derived from embryos that develop from eggs that have been fertilized *in vitro* and then donated for research purposes with the informed consent of the donors.

<sup>&</sup>lt;sup>97</sup> Agreeing *Beier* (2002) at 27 and *Deutsche Forschungsgemeinschaft* (1999) at 6. This is however scientifically disputable, for the scientific discussion see *Kersten* (2004) at 22 with further references in footnote 31.

nucleus.<sup>98</sup> Embryonic stem cells might not be suitable for transplantation because of the genetic instability of cloned cells.<sup>99</sup> Also, the cells now available for research may be rejected by a patient's immune system.<sup>100</sup>

Another serious consideration is that the idea of using stem cells from human embryos or human fetal tissue troubles many on ethical grounds. Therapeutic cloning requires a gross use of eggs.<sup>101</sup> Women donating their eggs for use in the cloning process would be required to take superovulatory drugs and receive numerous hormone treatments before undergoing the invasive extraction procedure. Such a procedure carries rare yet serious health risks, including ovarian rupture, severe pelvic pain, bleeding into the abdominal cavity, acute respiratory distress, pulmonary embolism, possible increased risk of ovarian cysts and cancers, and potentially infertility.<sup>102</sup> Estimates are that treatment of a single patient via therapeutic cloning would require "thousands of [human] eggs on an assembly line."<sup>103</sup> As a result, certain groups of women, such as those economically disadvantaged, would be at great risk of exploitation, a danger of

<sup>&</sup>lt;sup>98</sup> See Enquete-Kommission Deutscher Bundestag (2001) at 11, 19, 50.

<sup>&</sup>lt;sup>99</sup> Cloned animals give the outward appearance of full health, but the probability of their having numerous genetic defects is very high. One of the reasons has been discovered by the German scientists *Rudolf Jaenisch* at the Institute for Biomedical Research at the Massachusetts Institute of Technology, and his colleague, *Ryuzo Yanagimachi*. Their conception is that in cloning – when the nucleus of a somatic cell is inserted into a denucleated egg cell – the reprogramming of the genes does not proceed properly, so that not all of the genes that are necessary to the early phase of embryonic development are activated. *Jaenisch* performed his experiments with mice that had been cloned using embryonic stem cells in place of the somatic cells, which produces better results. But the reprogramming of the inserted genetic material by the embryonic cells proceeded in a very unregulated way. There were no two clones in which the same pattern of gene activation was found, and *Jaenisch* is convinced that the use of embryonic stem cells was clearly responsible, see his statement at http://www.21stcenturysciencetech.com/articles/winter01.stem\_cell. html.

<sup>&</sup>lt;sup>100</sup> The cytoplasm of the enucleated recipient egg (oocyte) contains mitochondria which, in turn, carry a small genome of their own. The protein products of this genome are not products derived from the patients own genome but are foreign to them, see *Winnacker* (2004) at 58 and above at B.I.2.a).

<sup>&</sup>lt;sup>101</sup> See Deutsche Forschungsgemeinschaft (2001) at 14; Winnacker (2004) at 59.

<sup>&</sup>lt;sup>102</sup> See International Center for Technology Assessment (2002). See also Venn et. al. (1999) at 1586, 1590.

<sup>&</sup>lt;sup>103</sup> See *Gellene* (2002) at 9.

biomedical research that existing ethical codes are designed to prevent.

Moreover, some experimental evidence suggests that embryonic stem cells, especially those obtained from cloned embryos, might constitute harm to patients who receive therapies derived from such cells.<sup>104</sup> For the preceding reasons, an increasing number of scientists doubt that therapeutic cloning will ever yield the balance of benefit over harm that some anticipate.<sup>105</sup>

Beyond these notions, the dominant bioethical dilemma that arises with respect to using embryonic stem cells relates to the fact that they are taken from a developing embryo at the blastocyst stage, which destroys the embryo: A totipotential moment is passed and the isolation and derivation of the embryonic stem cells causes the sacrifice of an otherwise viable embryo.<sup>106</sup> Scientists therefore strive for technical solutions that would transdifferentiate somatic cells without passing through the point of totipotentiality.<sup>107</sup>

Also, as an alternative to embryonic stem cells, the use of "adult stem cells" is being investigated.<sup>108</sup> Adult stem cells can be found in many, if not all adult organs. They can be isolated, studied and used in cell and tissue therapy. Should their presumed transdifferentiation capacity<sup>109</sup> and other necessary properties prove overall appropriable, this would mean that each human being possesses cells in his own body that can be used to replace any cell in the body that needs

<sup>&</sup>lt;sup>104</sup> See *Oderico* et. al. (2001) at 193, 204.

<sup>&</sup>lt;sup>105</sup> See *Kersten* (2004) at 23; *Aldhous* (2001) at 622, 625.

<sup>&</sup>lt;sup>106</sup> See Kersten (2004) at 24; Enquete-Kommission Deutscher Bundestag (2001) at

<sup>49.</sup> <sup>107</sup> See *Lanza* et. al. (1999) at 976; *Winnacker* (2004) at 60; *Rendtorff* et. al. (1999) at 17, 20. See also the latest research proposal of Chinese and French scientists to create "quasi embryos", as described at B.II.2.e) bb). <sup>108</sup> For a complete overview on adult stem cells and their potential see *Solter* et. al.,

in: Gethmann (2003) at 73 with further references. See also Deutsche Forschungsgemeinschaft (2001) at 10, 11; Enquete-Kommission Deutscher Bundestag (2001) at 13-17.

<sup>&</sup>lt;sup>109</sup> The first reported transdifferentiation case was, for instance, that adult neural stem cells can give rise to several blood cell types, see Bjornson et. al. (1999) at 534-537.

replacement. Since adult stem cells are not related to the totipotent state, their use would render the bioethical debate revolving around the use of embryonic stem cells superfluous – altogether, the production and use of embryonic stem cells would be outdated. Science is however, far from making a definite claim at this stage.<sup>110</sup> The discussion on which stem cells, embryonic or adult stem cells, hold greater therapeutic potential is evolving. Altogether, however, it seems that embryonic stem cells are more promising.<sup>111</sup>

Until today, therapeutic cloning has not been wholly successful.<sup>112</sup> The widely celebrated scientific finding of a South Korean group of scientists which tried to confirm the cultivation of one embryonic stem cell line derived from a cloned blastocyst<sup>113</sup> turned out to be a lie.<sup>114</sup> While some experts had then estimated that the successful and efficient production of healthy cloned human embryos suitable for therapy might be months or at most a few years away<sup>115</sup>, such a timeframe now seems unrealistic.

#### 4. Feasibility of a partial ban on reproductive cloning

The question remains, whether a partial ban on reproductive cloning, as Germany and France had envisionaged it in their 2001 UN initiative, is feasible.<sup>116</sup> As is apparent, "reproduction" and "therapy" define the purpose of the research and the final objective of the use of the somatic cell nuclear transfer technique.<sup>117</sup> The point of

<sup>&</sup>lt;sup>110</sup> See *Winnacker* (2004) at 60.

<sup>&</sup>lt;sup>111</sup> The discussion on the potential of adult stem cells is ongoing, see *Kersten* (2004) at 22 with further references in footnote 26.

<sup>&</sup>lt;sup>112</sup> On various unofficial reports see *Jaenisch* (2002) at 1.

<sup>&</sup>lt;sup>113</sup> See *Hwang* et.al. (2004) at 1. For a report and evaluation see also *Ganten* (2004) at 39; *Winnacker* (2004a) at 33.

<sup>&</sup>lt;sup>114</sup> All in all, the use of the term "therapeutic" for research aiming at the development of therapy and treatment is only justified if the focus is laid on the therapeutic *potential* that these necessary intermediate research results hold for future applications, see *Kersten* (2004) at 25 and the debate revolving around the correct terminology, outlined above at B.I.3.a).

<sup>&</sup>lt;sup>115</sup> See Boiani et. al. (2002); Solter (2002) at 1163, 1166.

<sup>&</sup>lt;sup>116</sup> See *Kahn* (2002) at 103 and in more depth, *The President's Council on Bioethics* (2002) at 144-149 and 219 (for related policy considerations).

<sup>&</sup>lt;sup>117</sup> See Enquete-Kommission Deutscher Bundestag (2001) at 48.

intersection lies in the common technique and its immediate product - a cloned human embryo which serves as the "cellular intermediate"<sup>118</sup> for both final results. Either, the intermediate is transplanted into the uterus of a female organism; or, it is cultured in vitro to grow out into embryonic stem cell lines.

Once an embryo is created through somatic cell nuclear transfer, it can be used to develop a human being by implanting it into a woman's womb. Many argue that it would prove difficult to uphold the mandate that cloned human embryos which were created in the laboratory for research purposes only, should not be implanted or otherwise allowed to progress toward birth.<sup>119</sup> Also, once pregnancy has begun, there is no real remedy except forced abortion, something neither reproductive rights advocates nor pro-life advocates could accept.120

This is a serious concern, taking into consideration the many declarations of intent to carry out human reproductive cloning. The Raelian sect and its biotechnological Clonaid company as well as a group of reproduction biologists led by Severino Antinori have reiterated ongoing research activities aiming at cloning. The latter group alleges that it has been commissioned by two hundred infertile couples to produce cloned babies using cells from infertile fathers and it already has established clinical experience in reproductive biology.<sup>121</sup>

If cloned embryos were available for research, appeals to compassion within the privacy of the physician-patient relationship would likely lead to their implantation. Such violations of a partial ban would surely often go unnoticed. If laboratory creation of cloned human

<sup>&</sup>lt;sup>118</sup> See *Winnacker*, in: Vöneky/Wolfrum (2004) at 60.

<sup>&</sup>lt;sup>119</sup> See, for instance, the German regulation in section 6, paragraph 2 ESchG: "Likewise anyone will be punished who transfers into a woman an embryo ...", discussed below at B.II.2.c) aa).

<sup>&</sup>lt;sup>120</sup> For a discussion of a purported "obligation to kill", see again below at B.II.2.c) aa). <sup>121</sup> See *Black* (2002).

embryos was permitted but implantation of such embryos for the purpose of reproduction was banned, it would be infeasible to monitor the fate of each and every cloned embryo. To prevent a single embryo from being implanted within the private context of the patient-physician relationship would surely prove to be impossible.<sup>122</sup>

A policy that prohibited cloning for reproduction while permitting cloning for therapeutic purposes may actually facilitate the means to achieving what it intended to prevent. To permit therapeutic cloning as a legitimate activity of science may, some argue, result in an increased number of human clone births. Ongoing embryological research is poised to overcome many of the remaining technical obstacles to human cloning. If this methodology is perfected and IVF practitioners are trained in its use, the implantation of cloned human embryos would no longer be the distant prospect of a few laboratories in possession of specialized resources, but could become a simple and brief procedure within reach of most fertility clinics that perform labor-intensive forms of fertilization. Insofar, from the viewpoint of science, a partial ban on reproductive cloning seems difficult to be upheld.

# II. The current legal framework: An overview of international legal instruments and selected national regulations

As we have seen in our previous chapter on the science of human cloning, the technique is not developed to the extent necessary to be used for any practical purpose in humans, neither for reproduction nor for therapy. Considering ongoing research efforts, research on the various techniques of cloning therefore needs a clear legal framework for researchers to know the extent of permissible engagement aiming at perfecting human cloning. This should also include a framework of permissible purposes for which, once perfected, the technique may be used in the future.

<sup>&</sup>lt;sup>122</sup> See *Schwaegerl* (2004) at 5.

If cloning is illegal *per se* regardless of the purpose, it would seem consistent that research aiming at the development and perfection of the cloning technique is also prohibited. However, if the technique is not considered illegal *per se* but only specific applications of it are, for instance reproductive cloning, then research on the technique of cloning should be permitted, at least with respect to somatic nuclear cell transfer.<sup>123</sup>

In the following, we will examine whether existing legal instruments both on the international and on the national level prohibit cloning techniques *per se* or if they prohibit only single applications of these techniques. We will thus be able to draw conclusions on the current legal framework for researchers.

Beyond understanding the current legal framework we will also be able to better evaluate any attempts at drafting legally binding instruments regarding the techniques of cloning, in particular for the case of efforts of the UN member states to draft an international Convention. Past drafting experiences with legal texts at a multilateral level will further an understanding of the diplomats' challenges for future attempts. We will therefore start with an analysis of two documents from the Council of Europe and UNESCO. A closer look at different national laws will further define the leeway for a possible compromise that individual states are able to offer to the community of states.

Altogether, our analysis shall help us gain a deeper understanding of the factors that particularly affect the possibility of harmonization of differing laws around the world and serve as an indication for what, at this stage in time, is a realistic aspiration for the outcome of negotiations in the venue of the UN.

<sup>&</sup>lt;sup>123</sup> As the scientific debate shows, the technique of embryo splitting has no therapeutic potential so that permitting research on embryo splitting might be questionable, see above at B.I.2.a) and B.I.3.a).

#### **1.** International legal instruments

The emerging global consensus on bioethics is minimalist and so is the consensus on the relatively new technique of cloning human beings.<sup>124</sup> However, the Council of Europe (CoE) and the United Nations' Education, Scientific and Cultural Organization (UNESCO) have made significant efforts over the last years to reach a consensus on some basic principles relating to biomedicine and to cloning in particular. The work of both bodies was preceded by initiatives of various international organizations which served as a basis for their efforts on otherwise virgin soil. We will first briefly consider these initiatives.

#### a) Preceding initiatives of international organizations

Some preceding documents do not deal with cloning in particular since, at the time, the technique was still unknown; we can therefore draw only limited guidance for our current problem. Also, the inherent policies are not legally binding and of a declaratory character which procures neither rights nor duties.

Under the impression of the Nazi medical experiments in concentration camps and elsewhere, the *Nuremberg Code* of 1945 stipulates that, "...no experiment should be conducted where there is an *a priori* reason to believe that death or disabling injury will occur ...<sup>4125</sup> The *Geneva Convention Code of Medical Ethics* of 1949 asserts the traditional principle of medical professional ethics by which doctors promise to "...maintain the utmost respect for human life from the time of conception." The *Helsinki Declaration*<sup>126</sup>, first

<sup>&</sup>lt;sup>124</sup> See Adorno (2002) at 959.

<sup>&</sup>lt;sup>125</sup> For a discussion of the Code see *Deutsch*, in: Broda et. al. (1985) at 69-81.

<sup>&</sup>lt;sup>126</sup> The *World Medical Association Declaration of Helsinki* (2000) deals with medical research on human beings, including biomedical experimentation on humans in the sphere of genetics. After its first publication in 1964, it has been revised four times and was finally fundamentally amended and released under the title "Ethical Principles for Medical Research Involving Human Subjects" in October 2000, see http://www.wma.net/e/policy/b3.htm. The Declaration has the legal nature of a non-binding international professional ethics which is meant to provide ethical guidance to physicians and also help to guide national medical

published in 1964, is a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. Experiments and treatments in which the risk is uncontrollable or exceeds the possible benefits are regarded as unethical.<sup>127</sup> The general principles expressed in these documents, carefully put, say only so much: Research is not permitted without limitations and the moment of conception marks a line that is, from a legal perspective, at least not passed wholly unnoticed.<sup>128</sup>

More recent international documents directly deal with the cloning techniques. Such documents have been issued by the World Health Organization which recognizes that all cloning raises ethical and medical issues. In its 1997 resolution WHA 50.37129 "Cloning in Human Reproduction" however and in a subsequent resolution<sup>130</sup> the WHO was only able to reach an agreement on reproductive cloning which was condemned.<sup>131</sup> The World Medical Association in its resolution on reproductive cloning of November 1997<sup>132</sup> calls on researchers to abstain from engaging in reproductive cloning until all scientific, ethical, and legal problems have been fully considered, and necessary controls are put in place. Finally, the European Union explicitly condemns the reproductive cloning of human beings as contrary to the right to the integrity of the person in article 3.2 of the

associations, governments and international organizations throughout the world, i.e. the Declaration needs to be implemented by national law, see *Deutsch/Taupitz*, in: Winter et. al. (2001) at 213.

<sup>&</sup>lt;sup>127</sup> See *Lilie*, in: Vöneky/Wolfrum (2004) at 127, more generally, on the Declaration as a whole, see Deutsch/Taupitz, in: Winter et. al. (2001) at 205-215.

<sup>&</sup>lt;sup>128</sup> Beyond this general notion, the principles may be assumed to be applicable in genetics, i.e. research on human cloning, see with regard to the Helsinki Declaration *Deutsch/Taupitz*, in: Winter et. al. (2001) at 541.

<sup>&</sup>lt;sup>130</sup> See WHO (1998).

<sup>&</sup>lt;sup>131</sup> The Fiftieth World Health Assembly "...affirms that the use of cloning for replication of human beings is ethically unacceptable and contrary to human integrity and morality..." (no. 1). The text contains a condemnation of cloning but not an explicit prohibition. It is understood to refer to reproductive cloning. With regard to therapeutic cloning, it is not clear that the resolution goes as far as to condem it as well, see Kersten (2004) at 218, 220. The resolution is legally nonbinding, see Enquete-Kommission Deutscher Bundestag (2001) at 21.

<sup>&</sup>lt;sup>132</sup> See World Medical Association (1997).

Charter of Fundamental Rights of the European Union of 7 December 2000.<sup>133</sup>

### b) The Council of Europe: The Convention on Human Rights and Biomedicine

The Council of Europe with its "Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine" (Biomedicine Convention) might have set a trend in Europe thrifting towards the codification of regulations on biomedical research.<sup>134</sup> It drafted the most wholistic legal scheme on human cloning and has principally lead and influenced other drafting attempts of supranational legal instruments, most notably UNESCO's Human Genome Declaration.<sup>135</sup>

#### aa) Background to the Convention

Certainly, the Council of Europe is an apt forum in which to develop the first internationally binding rules in biomedicine. The Council of Europe was set up "to defend human rights, parliamentary democracy and the rule of law, develop continent-wide agreements to standardize member countries' social and legal practices, promote awareness of a European identity based on shared values and cutting across different cultures."<sup>136</sup> It is supposed to discuss questions of common concern, find agreements and common action. According to article 1(b) of the Statute of the Council of Europe, the fields of common concern lie in "economic, social, cultural, scientific, legal

<sup>&</sup>lt;sup>133</sup> See Charter of fundamental rights of the European Union (2000) at 1.

From The European Union, see also *European Parliament*, Resolution on Human Cloning (2000). *European Parliament*, Resolution on Human Cloning (1998). *European Council*, Declaration on Banning the Cloning of Human Beings (1997); *European Parliament*, Resolution on Cloning (1997); *European Parliament*, Resolution on the Cloning of the Human Embryo (1993); *European Parliament*, Resolution on the Ethical and Legal Problems of Genetic Engeneering (1989), see all at http://www.mpil.de/de/ hp/embrdoc.cfm.

<sup>&</sup>lt;sup>134</sup> See *Winter* (2001a) at 59; *Kersten* (2004) at 49.

<sup>&</sup>lt;sup>135</sup> See *Rudolf-Schäffer* (1999) at 326; *Taupitz/Schelling*, in: Eser (1999) at 102. On the Human Genome Declaration, see below at B.II.1.c).

<sup>&</sup>lt;sup>136</sup> See mission statement of the Council of Europe at http://www.coe.int/T/e/Com/ about\_coe/.

and administrative matters and in the maintenance and further realization of human rights and fundamental freedoms."<sup>137</sup>

In general, European Conventions are prepared and negotiated within the institutional framework of the Council of Europe. Negotiation culminates in a decision of the Committee of Ministers establishing *ne varietur* the text of the proposed treaty. It is then agreed to open the treaty for signature by member states of the Council.<sup>138</sup>

All member states of the European Union are members of the Council of Europe but beyond these states the Council of Europe has among its 45 member states also central and eastern European states such as Albania, Bulgaria, Croatia, Georgia, Turkey, the Russian Federation, and Switzerland. The Council is a mere platform for negotiations among its member states on multi-lateral Conventions which hence are, technically speaking, not statutory acts of the organization itself; they owe their legal existence simply to the expression of the will of those states that may become parties thereto, as manifested *inter alia* by the signature and ratification of the treaty.<sup>139</sup>

The first step of the Council of Europe with regard to the protection of Human Rights in relation to health dates back to 1971, when the Parliamentary Conference on Human Rights of the Council of Europe identified important themes for further protection in the particular field.<sup>140</sup> Over the years, the Council has further issued a substantial

<sup>&</sup>lt;sup>137</sup> See Statute of the Council of Europe, London 5 May 1949. The Statute of the Council of Europe has been numbered "1" in the European Treaty Series. Amendments of a statutory character adopted later have been numbered 6, 7, 8, and 11. The text of the Statute reproduced at http://conventions.coe.int/Treaty/EN/Treaties/Html/001.htm incorporates all successive amendments.
<sup>138</sup> For a more detailed description of the treaty making within the venue of the

<sup>&</sup>lt;sup>138</sup> For a more detailed description of the treaty making within the venue of the Council of Europe, see *Polakiewicz* (1999) at 19-26.

<sup>&</sup>lt;sup>139</sup> See *Herdegen* (2002) at 11-14. See also in more detail *König/Haratsch* (2003) at 7-8; *Oppermann* (1999) at 29-39.

<sup>&</sup>lt;sup>140</sup> See *Council of Europe* (1972). Some of these issues identified in 1971 were taken care of in the Biomedicine Convention, for instance, human rights aspects of transplantation medicine. Others were not, for instance, the right to dispose of a dead body and the juncture at which death shall be considered to supervene, human rights aspects of abortion, further protection of the right to life by determining when it begins and when it ends.

number of important recommendations in the field of public health and health care in relation to Human Rights.<sup>141</sup>

In the course of this development, the Biomedicine Convention<sup>142</sup> emerged as the first legal instrument setting important principles to be respected with regard to the application of development in the sciences of biology and medicine.<sup>143</sup> It provides new standards, in particular regarding the protection of the embryo and foetus, and in elaborating upon some of the legal norms and principles contained in general human rights treaties<sup>144</sup> in one particular area.<sup>145</sup> It was adopted by the Committee of Ministers of the Council of Europe on 19 November 1996 and submitted for approval to and ratification by the member states in Oviedo on 4 April 1997. So far, 17 out of 45 member states of the Council of Europe have ratified the Convention, which entered into force on 1 December 1999. Although adopted in a European framework, the Convention is an international instrument because it is accessible to non-member states of the Council of Europe framework.

<sup>&</sup>lt;sup>141</sup> Some examples which have proven to be important sources of interpretation of human rights standards are recommendations dealing with HIV/Aids, on safety of blood, in protection of personal medical data, on medical treatment of prisoners, on genetic screening and on the quality of health care services. The (non-updated) list of Council of Europe resolutions and recommendations is published by the *Council of Europe*, see *id.* (1990) and *id.* (1993).

<sup>&</sup>lt;sup>142</sup> For the text of the Convention, see *Council of Europe* (1997) or http://legal.coe.int/bioethics/gb/html/txt adopt.htm.

<sup>&</sup>lt;sup>143</sup> On the Convention, see *Taupitz*, in: id. et. al. (2002a) at 2-8; *Rudolf-Schäffer*, in: Winter et. al. (2001) at 63-78; *Roscam-Abbing* (1996) 201-205; *de Wachter* (1997) at 13-23; *Winter* (1997) at 73-77.
<sup>144</sup> See only the *United Nations*' Universal Declaration of Human Rights, 1945 and

<sup>&</sup>lt;sup>144</sup> See only the *United Nations*' Universal Declaration of Human Rights, 1945 and the *Council of Europe's* European Convention for the Protection of Human Rights and Fundamental Freedoms, 1950. In 1961, these were followed by the *Council of Europe's* European Social Charter and in 1966 by the *United Nation's* International Covenants on Civil and Political Rights and on Economic, Social and Cultural Rights.

<sup>&</sup>lt;sup>145</sup> The Convention codifies standards which give expression to important human rights principles in the particular field covered by the Convention: non-discrimination (e.g. equitable access to health care), protection of physical integrity (e.g. information and consent procedures in various distinct situations) and privacy (e.g. respect for private life, including the right not to be informed).

<sup>&</sup>lt;sup>146</sup> Therefore, the Council of Europe in its summary of the Convention names it the "...first internationally binding human rights document in the field of the

After ratification, signatory states are obliged to adapt national law to the provisions of the Convention.<sup>147</sup> The Council of Europe thus safeguards that signatory states effectively honor their duties under the Convention. At the same time, a supra-national Convention will ensure that ethically questionable research would not be carried out in neighboring states.<sup>148</sup>

#### Provisions regulating human cloning and embryo bb) research

The Convention originates from the desire for harmonization of standards for the protection of the individual in the context of scientific and technological developments in medicine and health care. Explicitly, the cloning of human beings is not prohibited in the Convention. A prohibition, however, has implicitly been inferred from article 1, which guarantees the protection of the "dignity and identity of all human beings"; from article 13, which prohibits genetic modifications and thus in any case also encompasses the technique of somatic cell nuclear transfer<sup>149</sup>; and from article 18.2 which prohibits the creation of human embryos for research purposes.<sup>150</sup>

The uncertainty in the Convention, however, has been clarified by an Additional Protocol issued shortly after the Convention on 12 January 1998. It is the usual practice of binding multi-lateral human rights documents, that the "mother document" - the Convention itself - is conceived as a mere framework containing general principles.<sup>151</sup> Laying out detailed rules is reserved for so-

application of biology and medicine", see the Council's Summary of the Treaty (1997a). <sup>147</sup> See *König/Haratsch* (2003) at 8.

<sup>&</sup>lt;sup>148</sup> However, the Convention does not supersede national law. In Germany, for instance, the Convention becomes binding only according to article 59 paragraph 2 of the Constitution (GG).

<sup>&</sup>lt;sup>149</sup> Whether cloning by using somatic nuclei as a genetic source will produce an "identical" human being is still in question, see B.I.2.a) and also the debate in Germany regarding the term "identical" at B.II.2.c) aa). It could hence not be within the meaning of article 1.

<sup>&</sup>lt;sup>150</sup> See Winter (2001a) at 81; Tinnefeld (1999) at 321; Honnefelder (1997) at 313. <sup>151</sup> See *Council of Europe* (ed.) (2001) at 3-11 and 77-82.

called "Additional Protocols" thus allowing for a swift drafting process of the mother document which can focus on the consensus elements of the subject matter.<sup>152</sup> These Additional Protocols derive their legal authority from express provisions in the Convention which was granted by the Biomedicine Convention in article 31.<sup>153</sup>

The "Additional Protocol to the Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine, on the prohibition of cloning human beings" (Additional Protocol) addresses the techniques of cloning as such. Thus, article 1(1) of the Additional Protocol explicitly prohibits the techniques of cloning per se by providing that "...any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited." Article 1(2) makes clear that the technique of somatic cell nuclear transfer is embraced by the prohibition by defining "identical" as "a human being sharing with another the same nuclear gene set". This means that the small part of mitochondrial DNA located in the cell plasma does not bar the genome from qualifying as "identical" which could have been doubtable under article 18 of the Convention.<sup>154</sup>

<sup>&</sup>lt;sup>152</sup> The drafting of "Additional Protocols" is generally considered to be a great strength of Conventions of the Council of Europe; precisely so in the case of the Biomedicine Convention, see *Rudolff-Schäffer*, in: Winter et. al. (2001) at 67; *Winter*, in: id. et. al. (2001a) at 81.

Here, the Additional Protocol against reproductive cloning, for instance, allowed the member states of the Council of Europe to agree on what is a separate, legally binding document to the Biomedicine Convention, obtain the respective national agreement, and open it for signature in a breathtaking pace, namely only one year after Dolly. Also, only shortly after this Additional Protocol was laid out for signature, the Council of Europe started preparing another draft "Additional Protocol to the Convention on Human Rights and Biomedicine concerning transplantation of organs and tissue of human origin" which was opened for signature already in January 2002, see http://conventions.coe.int/Treaty/en/Treaties/Html/186.htm.

<sup>&</sup>lt;sup>153</sup> See article 31 of the Convention. Additional Protocols were foreseen "to clarify, strengthen and supplement the overall Convention", see *Council of Europe* (1997a). <sup>154</sup> See *Winter*, in: id. et. al. (2001b) at 83. See also the similar general opinion to the interpretation of § 6 ESchG in Germany, below at B.II.2.c) aa).

One might assume that because the techniques of cloning are prohibited per se, therapeutic as well as reproductive cloning and hence all research on cloning human beings is prohibited. This is not the case. As the explanatory report to the Additional Protocol makes clear, it is left to the single signatory state to define the meaning of the term "human being" as used in article 1 of the Biomedicine Convention and thus to define the scope of protection under the Convention and its Additional Protocol.<sup>155</sup> If a signatory state decides. e.g., that the term human being shall apply only some time after nidation,<sup>156</sup> cloning an embryo *in vitro* and using it for research and later for therapeutic purposes would not be prohibited under the Biomedicine Convention.<sup>157</sup> Hence, in the end, the Convention as clarified by the Additional Protocoll effectively only prohibits the use of cloned embryos for reproduction, leaving research on cloning techniques and, when technically possible, the consumption of cloned embryos for therapeutic purposes up to the signatory states.<sup>158</sup>

The specific issue of research on non-cloned embryos has already given rise to serious dissent among the countries in negotiating the text of the Convention itself. In particular, a debate flared up between

<sup>&</sup>lt;sup>155</sup> See Council of Europe (1998a) at 6. In general, an explanatory report cannot constitute a source of authoritative interpretation of the text of a given treaty, only the parties to a treaty have the right to give an authoritative interpretation of its terms, see the Permanent Court of International Justice in its Advisory Opinion of 6 December 1923 ("Jaworzina" case, PCIJ, Series B No. 8, at 37): "The right to give an authoritative interpretation of a legal rule belongs to the person or body who has the power to modify or suppress it.", quoted in *Polakiewicz* (1999) at 27, Fn. 46. In the case of our Protocol, the explanatory report expressly does not constitute an instrument providing authoritative interpretation of the text of the Protocol, see Council of Europe (1998a) at II. However, given the fact that the treaty and the explanatory report are negotiated simultaneously, the latter constitutes at least a supplementary means of interpretation, see article 32 of the VCLT. Furthermore, the idea of leaving it up to member states' domestic legislation to define the term "human being" is also in accordance with the overall approach taken in the drafting process of the Convention itself and should thus be weighed accordingly.

<sup>&</sup>lt;sup>156</sup> As for instance in the United Kingdom, see below at B.II.2.a).

<sup>&</sup>lt;sup>157</sup> On the other hand, since the Convention seeks to establish a minimum of protection, national legislation that grants a higher level of protection or is planning to do so can keep or introduce national laws and regulations accordingly, see article 27 of the Convention.

<sup>&</sup>lt;sup>158</sup> See *König* (2003) at 148; *Kersten* (2004) at 60-66.

the United Kingdom (in favour of the creation of human embryos for research purposes) and Germany, who, together with Belgium and Poland, abstained from voting.<sup>159</sup> Therefore, in the end, the Convention requires no less than an "adequate protection of the embryo"<sup>160</sup> in states where national law allows research on embryos *in vitro* and does hence not explicitly prohibit embryo research which does not serve the embryo's own good.

## c) UNESCO: The Human Genome Declaration

The UNESCO, a specialized agency of the United Nations, played a major role in laying the foundations for future international bioethical regulations by drafting the "Universal Declaration on the Human Genome and Human Rights" (Human Genome Declaration).<sup>161</sup> Due to its constitution and general commitment, UNESCO was probably the most competent agency to be given the mandate to elaborate the first instrument in which universally-accepted ethical principles were laid down: UNESCO is required by its constitution to promote "collaboration among the nations through education, science and culture",<sup>162</sup> a principle that evokes the terms of ethical reflection.<sup>163</sup> Also, UNESCO has a permanent commitment to combat racism and discrimination of all kinds which ties in with a main challenge to genetics.<sup>164</sup>

<sup>&</sup>lt;sup>159</sup> See *Manuel* et. al. (1999) at 55, 58.

<sup>&</sup>lt;sup>160</sup> See article 18.1.

<sup>&</sup>lt;sup>161</sup> See UNESCO (1997).

<sup>&</sup>lt;sup>162</sup> See UNESCO Constitution, article 1 (1).

<sup>&</sup>lt;sup>163</sup> It was therefore in that context that in 1974, UNESCO adopted a recommendation on the status of scientific researchers, which asserted the principle of the researcher's independence and also pointed to the necessary ethical dimension of research, see *UNESCO* (1974) at 6-7.

<sup>&</sup>lt;sup>164</sup> This field makes it possible to identify biologically-determined factors, and could thereby foster the resurgence of ideologies advocating to exclusion based on genetics. To counter such theories, UNESCO adopted a Declaration on Race and Racial Prejudice, see *UNESCO* (1978). See article 2 (1): "Any theory which involves the claim that racial or ethnic groups are inherently superior or inferior, thus implying that some would be entitled to dominate or eliminate others, presumed to be inferior, or which bases value judgments on racial differentiation, has no scientific foundation and is contrary to the moral and ethical principles of humanity." Altogether, it took the drafting of this 1978 Declaration 28 years.

The Human Genome Declaration was elaborated at UNESCO over a period of four years between 1993 and 1997.<sup>165</sup> It was first drafted by UNESCO's Bioethics Committee (IBC)<sup>166</sup>, then discussed and approved by the UNESCO General Conference, and finally by the UN General Assembly.<sup>167</sup>

As for the legal nature of the document, the IBC decided to propose a Declaration<sup>168</sup> for the General Conference's approval, rather than a Convention and thus followed the general practice in the United Nations: The document sought to serve as an incentive for national legislation and future preparation of a binding instrument.<sup>169</sup> The non-binding nature of the document should help overcome states' reluctance to be bound by legal obligations in sensitive areas and help achieve international consensus.<sup>170</sup>

<sup>&</sup>lt;sup>165</sup> The mandate for the elaboration of a draft Declaration was laid down in resolution 27 C/5.15 (15 November 1993) in which the General Conference of UNESCO asked the Director-General to prepare an international instrument for the protection of the human genome. For a background to the Declaration and a history of origin, see more detailed *Fulda* (2001) at 195-201; *Lenoir* (1999) at 537, 550.

<sup>&</sup>lt;sup>166</sup> The International Bioethics Committee (IBC) is an independent body which was created in 1998. It originally comprised some 60 members appointed in their personal capacity by the Director-General of UNESCO. It was deeply transformed by a new statute adopted in 1998, see http://www.unesco.org/ibc/uk/ presentation/statutes.html. The IBC "provides the only global forum for in-depth bioethical reflection by exposing the issues at stake. It does not pass judgment on one position or another. Instead, it is up to each country, particularly lawmakers, to reflect societal choices within the framework of national legislation and to decide between the different positions", see IBC mission statement at http://portal.unesco.org/shs/en/ev.php@URL\_ID=1879&URL\_DO=DO\_TOPIC& URL SECTION=201.html

<sup>&</sup>lt;sup>167</sup> For a detailed report of negotiations of the Declaration which spells out, *inter alia*, the dynamics in the course of four years of negotiations and the main opposing views, see *Lenoir*, chair of UNESCO's International Bioethics Committee 1993-1998, (1999) at 538-587.

<sup>&</sup>lt;sup>168</sup> UN doctrine considers a "Declaration" to be a formal and solemn instrument that is chosen when principles of major importance and lasting validity are being stated with stress laid on moral authority; it is not subject to ratification, see Report of the *Commission on Human Rights* (1962) at paragraph 105. See also *Hailbronner/Klein*, in: Simma (2002) at article 10, margin no. 41. For this particular Declaration, see *Rothman* (2000) at 89, 90. <sup>169</sup> See *Lenoir* (1999) at 549 who believes that future instruments could either be

<sup>&</sup>lt;sup>169</sup> See *Lenoir* (1999) at 549 who believes that future instruments could either be one treaty, comprised of general principles like the Human Genome Declaration, or a series of separate Conventions relating to specific practices, such as experimentation on human beings or cloning.

<sup>&</sup>lt;sup>170</sup> See *Lenoir* (1999) at 550. On the normative (legally non-binding) status of the Declaration, see *Herdegen* (2000) at 640; *Benda* (1997) at 17.

The IBC was concerned "to focus on the fundamental ethical issues at stake". It did not aim "to regulate, authorize, or restrict specific scientific processes which may soon be obsolete … The text has been designed to establish lasting ethical principles at a universal level."<sup>171</sup> In the course of the four years of work, it prepared nine successive versions.<sup>172</sup> At the end of this process, in January 1997, the governments of UNESCO's member states received a preliminary draft and were given the opportunity to reply and propose amendments. Already in this early draft of the Declaration – which was understood to be a statement of bioethical principles and not as a detailed statement on specific practices<sup>173</sup> – only one practice was singled out and defined as being contrary to human dignity, namely the reproductive cloning of human beings. The proposal to also prohibit germ-line modifications<sup>174</sup> including germ-line therapy, were rejected by other states.<sup>175</sup>

The text of the Human Genome Declaration was finally adopted unanimously and by acclamation by the UNESCO General Conference on 11 November 1997.

#### aa) Provisions on reproductive cloning

Other than the Biomedicine Convention of the Council of Europe, the Human Genome Declaration focuses exclusively on genetics. The chief principle of the Human Genome Declaration is that of human

<sup>&</sup>lt;sup>171</sup> So IBC President Noelle Lenoir, quoted in *Marble/Key* (1997).

<sup>&</sup>lt;sup>172</sup> According to *Lenoir* (1999) at 554, each version was submitted for discussion and criticism at the international level. In addition, a questionnaire was sent to about 500 correspondents from national ethics committees, academic centers, universities, research institutions, international and regional intergovernmental organizations such as the WHO, the Council of Europe, the European Union, nongovernmental organizations, and UNESCO National Commissions. The replies were collected in a summary report, which was submitted for debate and whose contents helped shape the Human Genome Declaration, see the results of the Discussions on Bioethics at *UNESCO* (1995).

<sup>&</sup>lt;sup>173</sup> See *Lenoir* (1999) at 555.

<sup>&</sup>lt;sup>174</sup> Germ-line modification refers to any modification of the human genetic heritage at the embryonic or pre-embryonic stage (intervention of the gametes), either for therapeutic purposes, or to improve some physical traits of a future child.

<sup>&</sup>lt;sup>175</sup> See *Lenoir* (1999) at 556.

dignity.<sup>176</sup> It affirms the primacy of the individual by making the principle of dignity fundamental, stating that no other consideration, whether scientific, economic or social, should "prevail over respect for ... human rights, fundamental freedoms and human dignity ..."<sup>177</sup> In the context of human reproductive cloning, article 11 states that "...Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international organizations are invited to co-operate in identifying such practices and in taking, at the national or international level, the measures necessary to ensure that the principles set out in this Declaration are respected."

Since only the "reproductive cloning of human beings" is prohibited, the cloning of human cells is not prohibited, so long as no human being is created hereby.<sup>178</sup> As with the Biomedicine Convention and its Additional Protocol, it therefore is decisive for the scope of the prohibition, at what stage in the process of human development we speak of "human being", i.e. if pre-natal development is also covered. This question is left untouched by the Declaration.<sup>179</sup> It is for the member states to decide, in their implementation of article 11 of the Declaration, on the scope of the prohibition.<sup>180</sup>

<sup>&</sup>lt;sup>176</sup> This is not surprising if we consider that human dignity is one of the few common values in the world of pluralism and that the "dignity of all members of the human family" (Universal Declaration of Human Rights, preamble) is the ground of human rights and democracy.

<sup>&</sup>lt;sup>177</sup> See UNESCO (1997), article 10.

<sup>&</sup>lt;sup>178</sup> So *Kersten* (2004) at 225. See also *Trute* (2001) at 401.

<sup>&</sup>lt;sup>179</sup> Kersten therefore reaches the conclusion that the term "human being" is open to the extent that it could include pre-natal developmental stages. The IBC Commission itself, however, had left this controversial question of whether the Declaration also wants to protect the embryo open, see *UNESCO IBC* (1996) at 4, quoted in *Kersten* (2004) at 227. On the scope of article 11 of the Declaration as understood to be limited to reproductive cloning, see also *Herdegen/Spranger* (2000) at margin no. 15; *Taupitz* (2001) at 3439. <sup>180</sup> See article 11, sentence 2 of the Declaration: "States and competent international

<sup>&</sup>lt;sup>180</sup> See article 11, sentence 2 of the Declaration: "States and competent international organizations are invited to co-operate in identifying such practices and in taking, at the national or international level, the measures necessary to ensure that the principles set out in this Declaration are respected."

#### bb) The current status of the Declaration

By resolution 29 C/I7 entitled "Implementation of the Universal Declaration on the Human Genome and Human Rights", the UNESCO General Conference laid out the methods for the follow-up of the implementation of the Declaration. Interestingly, this is the first time a Declaration adopted by member states of UNESCO has lead to the establishment of a monitoring mechanism.

The mechanism, *inter alia*, calls on states to identify appropriate measures for the promotion of the principles of the Declaration, whether through the setting of standards or the provision of incentives.<sup>181</sup> In addition, the IBC is assigned to make recommendations in accordance with UNESCO's statutory procedures, addressed to the General Conference and give advice concerning the follow-up of this Declaration.<sup>182</sup>

<sup>&</sup>lt;sup>181</sup> See article 22: "States should make every effort to promote the principles set out in this Declaration and should, by means of all appropriate measures, promote their implementation"; and article 23: "States should take appropriate measures to promote, through education, training and information dissemination, respect for the above-mentioned principles and to foster their recognition and effective application. States should also encourage exchanges and networks among independent Ethics Committees, as they are established, to foster full collaboration."

<sup>&</sup>lt;sup>182</sup> See article 24: "The International Bioethics Committee of UNESCO should contribute to the dissemination of the principles set out in this Declaration and to the further examination of issues raised by their applications and by the evolution of the technologies in question. It should organize appropriate consultations with parties concerned, such as vulnerable groups. It should make recommendations, in accordance with UNESCO's statutory procedures, addressed to the General Conference and give advice concerning the follow-up of this Declaration, in particular regarding the identification of practices that could be contrary to human dignity, such as germ-line interventions."

The implementation includes the following activities:

At the international level, the director-general of UNESCO is invited to prepare a global report on the situation worldwide on the related field with the help of the member states; the IBC should disseminate the principles set out in the Declaration and examine the evolution of the technologies in question, further, an "Intergovernmental Committee" is established to examine the recommendations of the IBC and also process them to the member states. In a joint session of both Committees, the amendment of the Declaration or the adoption of a further Declaration may be considered.

At the national level, states are urged to promote the establishment of independent Ethics Committees and to establish networks among them; states should further take measures to heighten the awareness of individuals that life sciences in

The UN General Assembly's endorsement on 9 December 1998<sup>183</sup> has changed the status of the Human Genome Declaration. Recognizing the importance of international bioethical concerns, the General Assembly adopted the UNESCO version of the Human Genome Declaration on the occasion of the fiftieth anniversary of the Universal Declaration of Human Rights on 23 September 1998. This legally non-binding<sup>184</sup> resolution was drafted and agreed upon by 87 states, including *nota bene* Spain, Costa Rica, and Italy, who were later among the bitterest opponents of the German-French proposal to a partial ban on human reproductive cloning through a UN Convention.

The text was adopted by consensus, without an express vote. The two countries most significantly involved in genetics, the United States and the United Kingdom, did not co-sign the resolution in spite of their strong support of the text of UNESCO the year before.<sup>185</sup> Even more striking is the fact that the new German government clearly sided with the consensus; beforehand, at UNESCO, Germany had been the only UNESCO member state not to vote for the text, on the grounds that it was deemed to be too permissive on eugenics.<sup>186</sup>

# 2. The law in jurisdictions particularly involved in the UN initiative

We may presume that unsettled questions on the international level regarding early life protection with its subcategories of research aiming at human reproductive cloning and cloning for therapeutic

themselves do not guarantee social and human progress; also, states should undertake to promote education and awareness in bioethics and research.

See *UNESCO* (1997a), and, for a detailed report of the IBC on the follow-up of the implementation of the Universal Declaration on the Human Genome and Human Rights", *UNESCO* (1998).

<sup>&</sup>lt;sup>183</sup> See United Nations General Assembly (1998).

<sup>&</sup>lt;sup>184</sup> The UN Charter, in articles 10-14, gives the General Assembly the power to make "recommendataions". According to general international usage, a recommendation describes a legal act which expresses a desire, but which is not binding on the addressees; see *Tomuschat* (1975) at 511. See also in detail *Hailbronner/Klein*, in: Simma (2002) at article 10, margin nos. 43-59.

<sup>&</sup>lt;sup>185</sup> See *Lenoir* (1999) at 575.

<sup>&</sup>lt;sup>186</sup> See UNESCO (1997b) at 4.

purposes originate from diverging national regulation. In focusing on the jurisdiction in six countries, we will try to understand in more detail to what degree there actually is a divergence among the countries. Also, a closer look at the particular protection schemes may reveal that we come across more than two main opposing legal schemes: "Maximalists" with an uncompromising approach to early life protection and "minimalists" which grant virtually no protection to the earliest stages of human life.

In addition, we will address to what extent the issue of cloning has been regulated explicitly by national legal instruments since an explicit regulation might serve as a parameter for the political consciousness within a country regarding the urgency of the matter.<sup>187</sup>

Research on human cloning and a possible use of the somatic cell nuclear transfer "product" for therapeutic purposes always involves the destruction of embryos. In this respect, the more general question of the protection of early human life is involved. Besides an analysis on permissible embryo research in the case of cloned embryos, we may gain a deeper understanding of countries' overall embryo protection schemes by also taking into account other legal issues where the protection of early human life is in question. This is most prominently the case in the abortion debate where a "clash of

<sup>&</sup>lt;sup>187</sup> From such a perspective, it is quite elusive that according to a periodically revised UNESCO research paper, only about 30 countries worldwide have adopted legislation which prohibits human reproductive cloning, see *UNESCO* (2004) at 1. Among these countries are Argentina, Australia, Austria, Belgium, Canada, Denmark, Finland, France, Georgia, Germany, Greece, Iceland, Japan, Korea, Latvia, the Netherlands, New Zealand, Norway, Peru, Slovakia, Spain, Switzerland, the United Kingdom, and Viet Nam. A comprehensive statutory scheme covering both cloning for therapeutic as well as reproductive purposes is currently known in Australia, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Japan, Korea, Netherlands, Slovakia, Spain, Switzerland, the United Kingdom. Moreover, more than ten countries are currently preparing legislation concerning therapeutic cloning and – more general – the creation of embryos for research purposes, among them are Egypt, Italy, Latvia, Lebanon, New Zealand, Norway, Panama, the Philippines, South Africa, Sweden, the United States, and Uruguay.

For a summary of the laws in Europe, see *Beyleveld/Lilie/Mandla*, in: Gethmann (2003) at 111-154.

absolutes", as one prominent author has expressed it,<sup>188</sup> shapes the debate. However, the abortion debate focuses on quite a different conflict, self-determination of women versus the right to life of the unborn, and the aptitude of penal law to protect the unborn against his or her own mother. We shall therefore neglect the abortion debate in the context of human cloning.

More immediately related to the cloning techniques and the conflict of interests involved is the *non-cloning* production of embryos through IVF and the use of supernumerary IVF embryos for stem cell research. In our analysis of national legal instruments we will hence also touch upon this question when deemed relevant. In addition to an analysis of existing law, we will finally try to point out specific aspects of the cultural, political and religious background in the single countries and of the present discussion within these countries.

The countries we will look at are representative for different approaches to human cloning and – equally important – mirror the balance of power at the United Nations in our particular, recent UN negotiations.

*Germany* was one of the initiators of this UN negotiation and can, with its clear-cut domestic legislation at hand, self-conciously steer negotiations. Compared to Germany, the *United Kingdom* stands towards the opposite ends of the spectrum in relation to the restrictiveness of her laws. As a result of this, the European Union lacks a common position in the UN negotiations,<sup>189</sup> while their

<sup>&</sup>lt;sup>188</sup> See *Tribe* (1992) at 12, 16, 28.

<sup>&</sup>lt;sup>189</sup> A common position is also barred due to other states' legislations: Belgium, in April 2003, joined the U.K. and allowed the creation of embryos for research purposes, either through *in vitro* fertilization or somatic cell nuclear transfer. Sweden seems to be moving step-by-step toward a similar policy. On the opposite end of the spectrum, not only Germany, but several European nations prohibit all human embryo research and do not expressly permit research with already-existing human embryonic stem cells. The conservative nations include Austria, Ireland, Italy, Norway, and Poland.

A majority of European nations accept, or are likely to accept, the use of somatic cell nuclear transfer research on supernumerary embryos that are no longer needed

legislations are representative for the two main opposing positions in the UN negotiations (partial ban versus complete ban) that each is supported by a great number of states. Spain, at the United Nations, was, up until the change of government in mid 2004, taking a lead in the group of countries that hold an absolute position aiming at a total ban on both therapeutic and reproductive cloning, and its position assumedly originated from religiously driven convictions, that are also reflected in its domestic legislation. Consequently, Spain attracted the attention of UN member states that have a Catholic majority population, in particular in South America where Spain is often viewed as a forerunner in the codification of laws that entail major ethical implications. Spain's domestic legislation regarding embryo research however is macerating and exemplifies a general trend towards liberalization of embryo research laws around the world – a process that, in the case of Spain, has seemingly not yet reached the ultimate possible.<sup>190</sup>

The *United States* is not only the politically most powerful UN member state, and thus dominates negotiations. More importantly, she does not have domestic Federal legislation on human cloning and stands for the great majority of UN member states which have not yet decided to what extend they should regulate or prohibit human cloning within their state boundaries. The ongoing internal debate and the hesitation to finalize a binding rule well represent a process many states are currently undergoing.

for reproduction. The Czech Republic, Denmark, Finland, Greece, Hungary, the Netherlands, Russia, and Spain have adopted such regulations, either explicitly or *de facto*. France and Switzerland are moving toward the acceptance of such regulations, although human embryonic stem cell research is a contentious issue in both of the nations. In Belgium, Denmark, Germany, Greece, Spain, and the U.K., human embryonic stem cell research policies were liberalized between 2001 and 2003; France and Switzerland have adopted more permissive policies in 2004. For a complete overview in regulations regarding stem cell research and human cloning see the regularly updated world stem cell map at http://mbbnet.umn.edu/ scmap.html; see also *Walter* (2004) at 3-38; *UNESCO* (2004).

<sup>42</sup> 

*China* is the politically strongest representative of the Asian group at the United Nations. China stands for a cultural tradition very different from the European North Atlantic one with less focus on the individual and its uniqueness. Nevertheless, Chinese law of today knows a clear and straightforward prohibition on reproductive cloning.

Similar to Spain, *Costa Rica*, within in the course of over three years of negotiations, had become the strongest advocate favouring a complete ban on all forms of cloning. As politically insignificant as Costa Rica might be at the United Nations and without explicit domestic legislation, the topic of cloning with its religious implications allows Costa Rica, with Catholicism as its State religion, to voice its position strongly and even head a remarkably big group of UN member states.

Common to all six legal systems is that cloning for reproductive purposes is prohibited – be it by express statutory provision as in some countries or by interpretation of more general principles – or, at least, that it is not expressly permitted and subsidized by the government. Considerable divergence, however, exists as to the legality and desirability of cloning for therapeutic purposes. This divergence is found first with respect to the general question of whether or not cloning for therapeutic purposes should be allowed or prohibited. Where it is allowed in general, differences persist as to the extent cloning is admissible and the administrative institutions in charge of the restrictions imposed, as well as to the procedures applicable. Besides these differences in outcome, there are considerable differences in the technique of legal regulations.

Above all this, differences in the extent to which the relevant questions are already settled in the single countries explain why a comparative view on the regulation of cloning is so complex and why we cannot limit our analysis to a mere enumeration of existing statutes.

## a) The United Kingdom

The United Kingdom prohibits reproductive cloning. In principle, it allows therapeutic cloning and hence research on cloning. As for therapeutic research purposes, the United Kingdom for the past fourteen years has had a progressive and well-developed embryonic research licensing and regulatory regime. In 2000, in response to recent scientific advancements in human embryonic stem cell research, the United Kingdom adopted legislation broadening its already existing research regulations to encompass and legitimize additional types of embryonic stem cell experimentation. As a result, the United Kingdom today has one of the most "liberal" stem cell research programs in the world, allowing for the creation and destruction of human embryos for purely scientific purposes.

### aa) The regulatory scheme

The two main sources of law in the United Kingdom are the Human Reproductive Cloning Act 2001<sup>191</sup> regarding reproductive cloning and the Human Fertilization and Embryology Act 1990 (HFEA)<sup>192</sup> regarding therapeutic cloning. Beyond these acts, the United Kingdom is not bound by international law since it has not signed the Council of Europe's Biomedicine Convention and its Additional Protocol.

Creating clones for the purpose of reproduction is without exception prohibited. The sanctioned act is defined as "...plac[ing] in a woman a human embryo which has been created otherwise than by

<sup>&</sup>lt;sup>191</sup> Human Reproductive Cloning Act (2001), enacted 4 December 2001.

<sup>&</sup>lt;sup>192</sup> Human Fertilization and Embryology Act (1990), enacted 1 November, 1999. The preamble of the Act desribes the scope of the Act: To make provisions in connection with human embryos and any subsequent development of such embryos; to prohibit certain practices in connection with embryos and gametes; to establish the Human Fertilisation and Embryology Authority; to make provision(s) about the person(s) who in certain circumstances are to be treated in law as parents of the child; and to amend the Surrogacy Agreements Act 1985.

fertilization...". An offence against this prohibition is penally sanctioned with up to 19 years of imprisonment.<sup>193</sup>

Creating clones for therapeutic purposes, however, is as a matter of principle permitted but subject to strict regulation under the HFEA. According to the Act, an "embryo" is "a live human embryo where fertilisation is complete", "references to an embryo include an egg in the process of fertilisation" and "fertilisation is not complete until the appearance of a two cell zygote."194 The 2001 amendments and a 2003 judgment by the House of Lords<sup>195</sup> made clear that cloned embryos are also "embryos" which had been put into doubt by a judgment of the High Court.<sup>196</sup> Any research project in the United Kingdom involving the creation, keeping or using embryos outside the human body must be licensed by the Human Fertilization and Embryology Authority which was created by the HFEA.<sup>197</sup> Although sources of embryos for research may both be supernumerary embryos produced through *in vitro* fertilization<sup>198</sup> or embryos specifically created for research<sup>199</sup>, the House of Lords Stem Cell Committee (HLSCC) has recommended that embryos should not be created for

<sup>&</sup>lt;sup>193</sup> See paragraph 1(1) and (2) *Human Reproductive Cloning Act* (2001).

<sup>&</sup>lt;sup>194</sup> See paragraph 1(1)(a) and (b). Similar to the definition of "embryo" in the German ESchG, the British definition refers to the living, human embryo *after* fertilization.

<sup>&</sup>lt;sup>195</sup> See R. (Quintavalle) v. Secretary of State for Health [2003] UKHL 13. This judgment of the House of Lords unanimously upheld the decision of the Court of Appeal, see R. (Quintavalle) v. Secretary of State for Health [2002] EWCA Civ 29 at paragraphs 40, 41, 44-48.

<sup>&</sup>lt;sup>196</sup> See R. v. Secretary of State for Health, ex parte Bruno Quintavalle (on behalf of pro-life Alliance) [2001] EWHC Admin 918. Prior to the 2001 amendments of the HFEA and to the rendition of the *Human Reproductive Cloning Act* in 2001, the HFEA contained penal sanctions without expressly mentioning cloning. The principle of *nulla poena sine lege* and the derived principle of narrow interpretation of penal laws might explain why the High Court ruled that cell nucleus replacement (=cloning) did not fall within the reach of the Act. It was thus held that such a broad interpretation of the Act was an "impermissible rewriting and extension of the definition", see paragraph 62 of the judgement.

<sup>&</sup>lt;sup>197</sup> See article 3 and 11(1)(c). Following the HFEA, the Agency was established by Law 115 of 14 November 1991. Besides licensing, the Agency's principal tasks are to monitor clinics that carry out *in vitro* fertilisation (IVF), donor insemination (DI) and human embryo research. The HFEA also regulates the storage of gametes (eggs and sperm) and embryos. See more about the HFEA at http://www.hfea.gov.uk.

<sup>&</sup>lt;sup>198</sup> See the *Human Fertilization and Embryology Authority Code of Practice* (HFEACP 2001), paragraph 6.8b.

<sup>&</sup>lt;sup>199</sup> See *HFEA* (1990), schedule 2, paragraph 3(1).

research unless there is a "demonstrable and exceptional" need that cannot be met by the use of supernumerary IVF embryos.<sup>200</sup> Licences for research projects are granted if the research project falls within one of the five following categories: (i) promoting advances in the treatment of infertility, (ii) increasing knowledge about the causes of congenital disease, (iii) increasing knowledge about the causes of miscarriage. (iv) developing more effective techniques of contraception, or (v) developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation.<sup>201</sup> After intense debate,<sup>202</sup> three more categories have been added in 2001 in order to open the door for new scientific developments, in particular, the prospect of stem cell therapies. These further purposes are: (i) increasing knowledge about the development of embryos, (ii) increasing knowledge about serious disease, and (iii) enabling any such knowledge to be applied in developing treatments for serious disease.<sup>203</sup>

Licenses are granted on a project-specific basis.<sup>204</sup> and subject to independent Ethics Committee approval.<sup>205</sup> Research is permitted up to the appearance of the primitive streak or fourteen days, whichever is earlier.<sup>206</sup> Embryos for research may be stored for a maximum of five years, after which they must be allowed to perish.<sup>207</sup> Embryo research is ultimately dependent on a consent requirement of the "biological parents".<sup>208</sup> For consent to be valid the donors must have

<sup>&</sup>lt;sup>200</sup> Report of the House of Lords Select Committee on Stem Cell Research 13 February 2002, Conclusions and Recommendations ix, see http://www. parliament.the-stationary-office.co.uk/pa/ld200102/ldselect/ldstem/83/ 8301.htm. <sup>201</sup> See *HFEA* (1990), schedule 2, paragraph 3(2).

<sup>&</sup>lt;sup>202</sup> The so-called Human Fertilisation and Embryology (Research Purposes) Regulation debate, see http://www.parliament.gov.uk.

<sup>&</sup>lt;sup>203</sup> See the Human Fertilisation and Embryology (Research Purposes) Regulations 2001, SI 2001, No. 188, at www.gov.uk.org.

<sup>&</sup>lt;sup>204</sup> See *HFEA* (1990), schedule 2, paragraph 4(2)(b).

<sup>&</sup>lt;sup>205</sup> See *HFEACP* (2001), at 11.6.

<sup>&</sup>lt;sup>206</sup> See Medical Research Act 1999, paragraphs 3(3)(a) and (4).

<sup>&</sup>lt;sup>207</sup> See paragraph 14(1)(c).

<sup>&</sup>lt;sup>208</sup> According to schedule 3, paragraph 6(3), an embryo cannot be used for any purpose without the consent of the donors whose gametes led to its creation.

received counselling<sup>209</sup> and have given their written approval<sup>210</sup> for the specific research.

#### bb) The ongoing debate

A milestone in the development of the law of cloning was the parliamentary debate in 2000 which finally led to the 2001 amendments of the HFEA, the extension of the licensing practice of the HFE Authority to therapeutic cloning and to the Human Reproductive Cloning Act 2001.<sup>211</sup> The debate dealt in depth with issues concerning the human embryo in view of possible scientific achievements, but also from an ethical and legal perspective.<sup>212</sup> For instance, the question of when precisely human life could be defined as coming into being was debated. Those in favour of embryo research argued that up to the first 14 days, the embryo remains a cluster of undifferentiated cells. With the development of the 'primitive streak' at 14 days an individual life could be defined as commencing.<sup>213</sup> Those opposed to research on embryos were of the opinion that the embryo prior to 14 days is "not a cluster of cells but a human life, that the living human has its origin in the meeting of the spermatozoon and the egg, at which point an irreversible process of development begins, and human life becomes actual rather than possible."<sup>214</sup> If an embryo can perish, it surely had life to begin with.<sup>215</sup> Also, opposition was largely based on the ethical principle that a life cannot be sacrificed for the benefit of another, or many others.216

<sup>&</sup>lt;sup>209</sup> See schedule 3, paragraph 3(1)(a), (2) and paragraph 4.

<sup>&</sup>lt;sup>210</sup> See schedule 3, paragraph 1.

<sup>&</sup>lt;sup>211</sup> For a compilation of the public and parliamentary discussion leading to the important amendments of 2001 see *House of Lords*, Report from the Select Committee on Stem Cell Research, H.L. Paper No. 83(i) of 2001/2002.

<sup>&</sup>lt;sup>212</sup> See *Bahadur* (2003) at 14.

<sup>&</sup>lt;sup>213</sup> References which follow relate to columns of the debate appearing in Hansard. Here, Audrey Wise, column 92, quoted in *Bahadur* (2003) at fn. 112.

<sup>&</sup>lt;sup>214</sup> Bernard Braine, column 48, quoted in *id*.

<sup>&</sup>lt;sup>215</sup> Bowis, column 116, quoted in *id*.

<sup>&</sup>lt;sup>216</sup> Michael Alison, column 66, quoted in *id*.

The report of this debate concluded that the respect given to the embryo cannot be absolute and must be weighed against the benefits of research.<sup>217</sup> The 14-day embryo acquired significance in the debate as being the point in which human life begins.<sup>218</sup>

Current law in the United Kingdom is liberal, despite the regulatory scrutiny regime.<sup>219</sup> The use of embryos for the benefit of others is permitted, but only under specific purposes (namely the benefits of others), the stage of development of the embryo, and regulatory scrutiny, in addition to parental consent. The ethical position seems to be that the embryo has a proportionate ethical status, which allows weighing the embryo against benefits for others.<sup>220</sup>

The established regulatory system in the United Kingdom seems to have the full confidence of the scientific and medical communities and to have reassured the public that stem cell research is carried out humanely and effectively.<sup>221</sup> It has been the subject of very few legal challenges.<sup>222</sup> Some 48,000 embryos were used in research between August 1991 and March 1998 in the United Kingdom.<sup>223</sup> Most were from spare embryos from IVF clinics; however, 118 embryos were created in the course of research for purely scientific purposes.<sup>224</sup>

<sup>222</sup> See House of Lords (2001) at para 8.1.

<sup>&</sup>lt;sup>217</sup> See *Bahadur* (2003) at 15.

<sup>&</sup>lt;sup>218</sup> For the 14 day-old embryo as a demarcation line for permissible research, see also the legislation in Spain as described below at B.II.2.b) aa) and the guidelines in China, below at B.II.2.e) aa).

<sup>&</sup>lt;sup>219</sup> Disagreeing *Solter* et. al., in: Bethmann (2003) at 123, assuming that it is neither prohibitive nor liberal, but just less restrictive, compared to other EU contries: "It permits the use of embryos for the benefit of others alone, but makes this subject to specified purposes (benefit of others), the stage of development of the embryo, and regulatory scrutiny, in addition to parental consent" - which also characterizes regulation in other EU countries.  $^{220}$  S  $\sim$  5  $^{11}$ 

See Solter et. al., in: Bethmann (2003) at 126, 127.

<sup>&</sup>lt;sup>221</sup> So *Belew* (2004) at 495. Nevertheless, ProLife Party members are infuriated. Prof. Jack Sarisbrick, Chairman of Life, called therapeutic cloning "the manipulation, exploitations, and trivialization of human life of a mist frightening kind. It is perverse that, in the current climate of concern for the protection of animals, the HFEA is allowing experimentation on human beings without even a murmur of public opposition", said the ProLife Party's Julia Millington.

<sup>&</sup>lt;sup>223</sup> See United Kingdom Department of Health (2000) at 32.

Also, the HFE Authority has granted the first one-year licence to create human embryonic stem cells on 11 August 2004. The licence will be held by Newcastle University Institute of Human Genetics to use nuclear transfer to create human clones from which stem cells would be harvested for the production of insulin. The goal is to enable diabetics to receive deposits of histologically compatible cells that could produce the hormone their own bodies cannot make in sufficient amounts – a research project that is estimated to take at least 5 years. This research is preliminary; it is not aimed at specific illnesses, but is the foundation for further development in the treatment of serious disease.<sup>225</sup> The approval by the authority was widely praised as offering hope to patients with diseases in which cells that produce a critical chemical have failed.<sup>226</sup>

All in all, as a result of the widespread confidence in the existing embryonic research laws, the acceptance of somatic cell nuclar transfer "required an extension of the existing framework, rather than the invention of a new one."<sup>227</sup> The Royal Society of the United Kingdom concluded that the legal framework set up by HFEA not only works well, but will continue to be "adequate for the foreseeable future."<sup>228</sup>

The House of Lords Select Committee on Stem Cell Research considered three elements within the English social fabric that foster an atmosphere in which Parliament could sanction experimentation on human embryos to obtain pluripotent stem cells with the acceptance of the English populace.

<sup>&</sup>lt;sup>225</sup> For more information, see HFEA explanation for the decision of granting the licence, including procedure and decision tree at http://www.hfea.gov.uk/ Research/Policy.

<sup>&</sup>lt;sup>226</sup> See *Liebert* (2004) at 565.

<sup>&</sup>lt;sup>227</sup> Hearing of the Senate Committee on Health, Education, Labor, and Pensions examining the scientific and ethical implications of stem cell research and its potential to improve human health, 107<sup>th</sup> Cong. 73 (2001), at http://frwebgate.access.gpo.gov/cgi-bin/useftp.cgi?IPaddress=162.140.64.88&filen ame=75132.pdf&directory=/diskc/wais/data/107\_senate\_hearings.

<sup>&</sup>lt;sup>228</sup> See *The Royal Society* (2001) at 4.

Abortions are currently carried out in England in a significant number of circumstances and have been sanctioned by national legislation for more than thirty years:<sup>229</sup> The British Abortion Act<sup>230</sup> generally criminalizes abortion in Britain.<sup>231</sup> In practice, however, the Act's exception clause swallows the whole Act. The exception clause allows legal abortions for the physical and mental well-being of the mother and in the case of deformed fetuses.<sup>232</sup> By liberally construing this provision, courts, with Parliament's tacit approval, have effectively permitted abortion.<sup>233</sup> The Committee therefore noted, "[i]t would be difficult to justify an absolute prohibition on the destruction of early embryos while permitting abortion in a relatively wide range of circumstances post-implantation – indeed well after the emergence of the primitive streak and into the foetal stage of development."<sup>234</sup>

*In vitro* fertilization had widespread public support,<sup>235</sup> and IVF procedures resulted in the creation of supernumerary embryos, which would eventually be destroyed.

The liberal outlook of several prominent religious leaders toward embryonic research also distinguishes the political culture in the United Kingdom.<sup>236</sup> Although highly regulated, the list of permissive research purposes under the Act is expansive. As a result, the United Kingdom has one of the most liberal stem cell research regimes in the world community.

<sup>&</sup>lt;sup>229</sup> See *House of Lords* (2001) at paragaph 4.20(a).

<sup>&</sup>lt;sup>230</sup> See Abortion Act of 1967, ch. 87.

<sup>&</sup>lt;sup>231</sup> See *Krotoszynski* (1991) at 1408.

<sup>&</sup>lt;sup>232</sup> See Abortion Act, paragraph 1.

<sup>&</sup>lt;sup>233</sup> See *Krotoszynski* (1991) at 1406.

 $<sup>^{234}</sup>$  See *House of Lords* (2001) at para 4.20(a). See the similar debate in Germany as outlined below at B.II.2.c) bb).

<sup>&</sup>lt;sup>235</sup> See *House of Lords* (2001) at para 4.20(b).

<sup>&</sup>lt;sup>236</sup> See *Plomer* (2002) at 137-138, discussing the positions of several high-ranking officials in the Church of England in favour of stem cell research; see also *Solter* et. al., in: Bethmann (2003) at 120, 123-124.

## b) Spain

Spain prohibits reproductive cloning as well as therapeutic cloning. However, embryo research on supernumerary IVF embryos is allowed and has, in late 2004 under the new socialist government, been significantly facilitated. Also, Spain is bound by the Council of Europe's Biomedicine Convention and its Additional Protocol which it ratified in 1999 and 2000.

#### aa) The regulatory scheme

Reproductive cloning, namely the "creation of identical human beings by cloning" is prohibited under the new Spanish Criminal Code of 1995<sup>237</sup>; an offense against this provision is punished with up to five years of imprisonment.<sup>238</sup>

An early interpretation of article 161(2) was that the injury lies in the creation of viable individual beings capable of consistent and relatively autonomous human life *outside* the womb.<sup>239</sup> Therapeutic cloning, namely producing a cloned embryo for research purposes, would thus not be explicitly covered by the Code.

However, a systematic reading of article 161 Criminal Code suggests otherwise. According to article 161(1), "any person who fertilizes human eggs for a purpose other than for human procreation" is punished. It is clear that this article refers to the prohibition of the use of *in vitro* fertilization to produce human embryos for experimentation.<sup>240</sup> If however, the creation of embryos for research purposes through IVF is forbidden, then the prohibition of creating embryos for research purposes must also apply to cloning under

 <sup>&</sup>lt;sup>237</sup> Spanish Criminal Code (1995) of 24 November 1995. For an (unofficial) translation and an introduction to the 1995 amendments of the code that concern genetic manipulation, see *Arzamendi* (1996) at 47-72.
 <sup>238</sup> See article 161.2. The prohibition of cloning corresponds with a prohibition in

<sup>&</sup>lt;sup>238</sup> See article 161.2. The prohibition of cloning corresponds with a prohibition in the ART, article 20(2)(B)(I).

<sup>&</sup>lt;sup>239</sup> See *Arzamendi* (1996) at 66, with further references. The cloning of embryos for the purpose of creating identical human beings would be an 'imperfect realisation' set out in articles 15 and 16 of the Criminal Code.

<sup>&</sup>lt;sup>240</sup> See *Lacadena* (1996) at 199.

article 161(2) - the overall intent being to prohibit the production of human embryos for the mere purpose of experimentation.

Such a reading of the Criminal Code is only stringent in view of the main Spanish law on embryo research, the Assisted Reproduction Techniques Act (ART).<sup>241</sup> The ART was passed into law in November 1988 with Law 35/1988.<sup>242</sup>

In general, assisted reproduction techniques under the ART have as their aim medical action against human infertility to facilitate procreation when other therapeutic methods have been rejected as inadequate or ineffective.<sup>243</sup> The fertilization of human eggs for any purpose other than human procreation is generally prohibited.<sup>244</sup> The techniques may be used in the prevention and treatment of diseases of genetic or hereditary origin, when it is possible to make use of them with adequate diagnostic and therapeutic guarantees, and provided that they are strictly indicated.<sup>245</sup> Thus, in vitro fertilization cannot serve as a primary source to obtain embryos for research.<sup>246</sup>

<sup>&</sup>lt;sup>241</sup> Regulations adopted later are of lesser importance since they did not require parliamentary approval and thus did not arouse much public debate, see Dubouchet/Kloeti, in: Bleiklie et. al. (2004) at 103.

<sup>&</sup>lt;sup>242</sup> See Law 35/1988 of 22 November, Sobre Técnicas de Reproducción Asistida. Boletín Oficial del Estado (BOE, State Gazette) 24 November 1988; No. 282:33373-33378; correction of errors in BOE No. 284 of 26 November 1988. For an English (unofficial) translation of the law by Beatriz de la Gandara, Max Planck Institut für ausländisches und internationals Straftrecht, Freiburg, see Eser et. al. (1990) at 246-263.

 $<sup>^{243}</sup>$  See article 3:" The fertilization of human ovules with any purpose other than that of human procreation is prohibited." <sup>244</sup> See article 20 No. 2 (B): "Very serious infractions are (a) The fertilization of

human ovules with any aim other than that of human procreation."

<sup>&</sup>lt;sup>245</sup> See article 12(1): "All intervention upon the live pre-embryo in vitro with diagnostical purposes may have no other aim than that of evaluating its viability or detecting hereditary illnesses in order to treat them ..." and article 13(1): "All intervention upon the live pre-embryo in vitro for therapeutic purposes shall have no other finality than that of treating an illness or impeding its transmission, with reasonable and confirmed guarantees..."

<sup>&</sup>lt;sup>246</sup> See also the reinforcement of this provision through article 161.1 Criminal Code which punishes "any person who fertilizes human eggs for a purpose other than for human procreation's". It refers to, albeit implicitly, the prohibition of the use of in vitro fertilization to produce human embryos for experimentation, see Lacadena (1996) at 199.

Among the "very serious infractions" of the law are the fertilization of human eggs for any purpose other than human procreation, the performance of ectogenesis or creation of an individual human being in the laboratory and the creation of identical human beings by using cloning techniques or any other procedure. They can be punished with up to 10 Million Pesetas; also, the research facilities used for the infraction could be shut down.<sup>247</sup>

The Spanish legislation does not define the term "embryo". It refers to general practice which regards a "pre-embryo" as the fertilized egg up until 14 days<sup>248</sup> or implantation, and the "embryo" as existing from 14 days to two and a half months.<sup>249</sup>

While the ART decides that supernumerary "pre-embryos" can be frozen only for up to 5 years,<sup>250</sup> it does not decide on their ultimate fate. In that respect, the ART is outdated. The Spanish government in November 2003 undertook a legislative reform, also taking into account recent scientific developments. With Law 45/2003, which is an amendment to Law 35/1988, it allows embryo research to be undertaken.<sup>251</sup> More precisely, the research on pre-embryos left over from *in vitro* fertilization treatments is since then permitted.<sup>252</sup> With the consent of the donors,<sup>253</sup> the pre-embryos that were crypresevered prior to the enactment of the law can be transferred to the newly established "National Center for Transplants and Regenerative Medicine"<sup>254</sup> for research purposes.<sup>255</sup> The research purpose must qualify as a fundamental investigation, i.e. the fundamental

<sup>&</sup>lt;sup>247</sup> See article 20 (B).

<sup>&</sup>lt;sup>248</sup> For the 14 day-old embryo as a demarcation line for permissible research, see also the legislation in the United Kingdom as described above at B.II.2.a) aa) and the guidelines in China, below at B.II.2.e) aa).

<sup>&</sup>lt;sup>249</sup> Paraphrase from the English version of the Official Bulletin of the State No.282, November 1988, Part. II, 5.

<sup>&</sup>lt;sup>250</sup> See article 11 No. 1.

 $<sup>^{251}</sup>$  See Law 45/2003 of 21 November, 2003 that amends Law 35/1988, BOE no. 280 at 41458.

<sup>&</sup>lt;sup>252</sup> See Law 45/2003, first final disposition No. 3.

<sup>&</sup>lt;sup>253</sup> See *id*. No.1.

<sup>&</sup>lt;sup>254</sup> See *id.*, sole additional disposition.

<sup>&</sup>lt;sup>255</sup> See *id.*, final disposition No. 4

improvement of medical knowledge in diagnosis, preventive or therapeutic methods.<sup>256</sup> By means of a Royal Decree, the government should establish and develop procedural and organizational mechanisms to carry out these provisions.<sup>257</sup>

These specific mechanisms for permitting scientists to apply to undertake projects where laid out in October 2004 by a Royal Decree approved by the new Socialist government, which provides a framework for granting authorization for embryo use as well as setting out requirements for corresponding embryo studies.<sup>258</sup>

Under these regulations, embryos created by IVF<sup>259</sup> will only be available for research use if the couple involved explicitly authorizes their use for this purpose.<sup>260</sup> Couples who choose to allow their embryos to be used in this way will sign an informed consent form and grant permission for a specific research project.<sup>261</sup> Applications for research projects will have to mention which embryos are going to be used and will have to confirm that "the same results cannot be obtained through research on animals."<sup>262</sup> Any future cell lines must be registered in a national stem cell bank<sup>263</sup> and made available on a nonprofit basis for other projects.<sup>264</sup>

Embryo research will be coordinated by the Instituto de Salud Carlos III, the research acency of the health ministry, which has already guaranteed €100 million to fund projects.

<sup>&</sup>lt;sup>256</sup> See *id.*, final disposition No. 4.

 $<sup>^{257}</sup>$  See *id.*, final disposition No. 3.

<sup>&</sup>lt;sup>258</sup> Royal Decree no. 2132/2004 of 29 October 2004.

<sup>&</sup>lt;sup>259</sup> This applies only to pre-embryos that were created before the entering into force of the law, see article 1 of Royal Decree no. 2132/2004, BOE no. 262 at 35906.

<sup>&</sup>lt;sup>260</sup> Royal Decree no. 2132/2004 of 29 October 2004, article 2.

<sup>&</sup>lt;sup>261</sup> Royal Decree, article 2, 4 (b).

<sup>&</sup>lt;sup>262</sup> Royal Decree article 4 (i).

<sup>&</sup>lt;sup>263</sup> The creation of the stem cell bank was authorized by Law 45/2003 in sole additional disposition no. 4. With the Royal Decree, the bank was subsequently established, see sole additional disposition.  $^{264}$  See article 4 (j), (k).

Besides the ART, Law 42/1988 of 28 December 1988 on the "Donation and Utilization of Human Embryos and Fetuses, or of their Cells, Tissues or Organs" protects the post-implantation embryo and regulates the donation and use of human embryos and foetuses and the cells, tissues or organs therefrom.<sup>265</sup> It generally prohibits any experiments with living embryos or fetuses.<sup>266</sup> Among the "very serious offences" are the performance of any activity aimed at modifying the nonpathological human genetic patrimony; the creation and maintaining of live embryos or fetuses inside the uterus or outside of it with any purpose than that of procreation; the experimentation with live embryos or fetuses.<sup>267</sup>

## bb) The ongoing debate

The amendment of Law 35/1988 in 2003 introduced the permission of research on supernumerary pre-embryos, including the derivation of stem cells therefrom.<sup>268</sup> This can be considered a serious development towards the liberalization of embryo research in Spain. Although permitting the cloning of embryos for research purposes is currently not seriously debated in Spain, this might be a first step in that direction.

The National Commission of Human Assisted Reproduction (CNRHA) has issued an important report calling for increased use of embryo research. At the same time, the Committee concluded that stem cell research should be focused on adult stem cells.

<sup>&</sup>lt;sup>265</sup> Law 42/1988 de donacion y utilización de embriones y fetos humanos o de sus celulas, tejidos u órganos, BOE No. 314 of 31 December 1988. For an (unofficial) English translation of the law by Beatriz de la Gandara, Max Planck Institut für ausländisches und internationals Straftrecht, Freiburg, see *Eser* et. al. (1990) at 263-269.

<sup>&</sup>lt;sup>266</sup> See article 9 No. 2 (B).

<sup>&</sup>lt;sup>267</sup> See article 9 No. 2 (B).

<sup>&</sup>lt;sup>268</sup> Previously, in Law 35/1988, article 15 No.2, research on viable pre-embryos *in vitro* was only permitted for diagnostic, therapeutic or preventive purposes, meaning that the embryo itself had to benefit from it, see *Casabona* (2001) at 121, 127.

The CNRHA was established by law 35/1988. Although the law provided that the Committee should be constituted within six months following the promulgation of the law, nearly nine years passed until the Committee constituted itself in March 1997. CNRHA consists of 25 independent members appointed by different ministries, scientific societies, and social organizations and it has an advisory role to the health ministry. The Committee is responsible for the update of the law, the evaluation of any project for research on human gametes and embryos, and orientation when conflictive situations occur. It should offer guidance in the use of reproduction techniques, article 21(1), but has no executive powers.

The main issues that were reviewed by the Committee because they were considered to need an urgent ethical and legal revision were research on human embryos and an evaluation of recent scientific achievements in human cloning.

The discussion about these topics and the conclusions reached by the Committee were referred to the government in two different reports. The first report was finished in October 1998 and made public in March 1999.<sup>269</sup> The second report was completed in April 2000 and it was placed in the Government's hands in November 2001. The reports were only recognized by the ministry on 25 July 2003; the most important aspects of both regarding therapeutic and reproductive cloning are as follows:

Regarding *reproductive cloning* which is prohibited by the ART and the Criminal Code, article 161(2) as well as by the Convention on Human Rights and Biomedicine, the CNRHA opinion was that humans should not be considered as a means to an end. The

<sup>&</sup>lt;sup>269</sup> CNRHA (Comisión Nacional de Reproducción Human Asistida), I Informe Anual. Diciembre 1998. Ministerio de Sanidad y Consumo. Madrid, 1999. The report was also published in *Comisión Nacional de Reproducción Human Asistida* (1999) at 246-269.

Committee therefore adhered to the already existing prohibitions on reproductive cloning of human beings.<sup>270</sup>

*Therapeutic cloning* was said to open up a wide range of possibilities to obtain cell lines for transplantation. Concerning the use of human embryos as a source for cell line growth, consensus was not achieved. The Committee considered, however, that if the same type of products can be obtained from adult stem cells, there will be no need to obtain them from embryonic stem cells. Therefore, it recommended the use of non-embryonic stem cells whenever possible.

It is unclear, to what extent the new government will adjust its laws. Already now, the Catholic Church in Spain critizised the new regulations easening embryo research. "The production of human beings in the laboratory is ethically unacceptable. It is seriously illicit and unjustifiable, even with therapeutic goals, to use these embryos to reanimate and then kill them for the obtention of stem cells", says the Episcopal Conference, made up of the top officials of the Spanish Catholic church.<sup>271</sup> This is not surprising as the new law and its Royal Decree make Spain the first Catholic country in Europe to authorize research on human embryos to obtain stem cells.

The strong Catholic tradition in Spain is countered by a medical community, whose expectations with regard to embryo research differ fundamentally from those of the Church. Only shortly after the regulations of embryo research had loosened, Spanish researchers announced the creation of the country's first cell lines from human embryonic stem cells.<sup>272</sup> Possibly, the clashing of two ethically positive concepts, stem cell research versus embryo protection, will not be reconciled.

<sup>&</sup>lt;sup>270</sup> It only proposes to change article 161.2 of the Criminal Code in order to avoid interpretative misunderstandings. <sup>271</sup> Quoted in *Bosch* (2004a). <sup>272</sup> See *Bosch* (2004) at 163.

The government seems to gradually give way to a comprehensive embryo research scheme, thus favouring the views of the medical community much rather than those of the Catholic Church. The health ministry for instance stated recently, it believed that the latest reform is still somewhat constrained by limitations, such as the need to use only embryos frozen for more than 5 years, and the clause in the trial application form that "the same results cannot be obtained through research on animals". Those are, according to the minister of health Salgado, likely to be eliminated. Even more so, Salgado went as far as to state that next year, when the government approves a new Biomedical Research Law, "therapeutic cloning may be included if that is the feeling of society."<sup>273</sup>

### c) Germany

Germany knows a complete ban of human cloning regardless of the ultimate purpose.<sup>274</sup> In the field of embryo research, Germany's laws are highly restricted, reflecting a broad interpretation of the protection of life and of human dignity which is to a large part due to Germany's Nazi past. Not without justification, German law has been referred to as "…the most Draconian law in Europe…"<sup>275</sup> And in line with Germany's tradition of codification, it is certainly one of the most elaborate and detailed one on the question of embryo creation and research including through cloning.

### aa) The regulatory scheme

The main source of German law is the Embryo Protection Act (*Embryonenschutzgesetz*, ESchG) which comprehensively regulates the treatment of human embryos and research on embryos in

<sup>&</sup>lt;sup>273</sup> Quoted in *Bosch* (2004a).

<sup>&</sup>lt;sup>274</sup> For an overview on German cloning law, see *Rosenau*, in: Amelung (2003) at 761-781; *Taupitz* (2002b) at 449-455; critically *Neidert* (2002), 467-471. More specifically on embryonic stem cell research, see *Lilie/Albrecht* (2001) at 2774-2776.

<sup>&</sup>lt;sup>275</sup> See *Bonnicksen* (1994) at 39, 42. See also *Bonnicksen* (2000) at 76; *Kersten* (2004) at 30; *Boshammer* et. al. (1998) at 331; *Riedel* (1997) at 186.

Germany.<sup>276</sup> The ESchG has been supplemented by the Stem Cell Act (Stammzellgesetz, StZG) regulating the importation of stem cells from abroad for research undertaken in Germany.<sup>277</sup>

As to human cloning, the ESchG provides that "...a term of up to five years imprisonment shall be imposed on anyone who artificially causes a human embryo to emerge using genetic information identical to that of a different embryo, a foetus, a human being or a deceased person...<sup>278</sup> For the artificial production of genetically "identical" human beings, two techniques are relevant: embryo splitting and somatic cell nuclear transfer.<sup>279</sup>

With respect to the technique of embryo splitting, the interpretation of section 6, paragraph 1 ESchG is clear as the cells that are split or the split blastocyst are cells from the same human organism and thus are "identical" in the strict sense of the word.<sup>280</sup>

With respect to the technique of somatic cell nuclear transfer, however, doubts have been raised as to such an interpretation based on the terms of "...genetic information identical..." and on the definition of "embryo" in section 8, paragraph 1.281 Somatic cell

<sup>&</sup>lt;sup>276</sup> BGBl. (Federal Law Gazette) I, at 2746 (13 December 1990). In German doctrine, the ESchG is commonly qualified as a criminal law, see Keller/Guenther/Kaiser (1992) at 61, margin no. 1.

<sup>&</sup>lt;sup>277</sup> BGBl. I Nr. 42, at 2277 (28 June 2002). The StZG goes back to an opinion issued by the German National Ethics Council (2001). On its history and functions see http://www.ethikrat.org/ english/about us/function.html. The National Ethics Council is the second advisory body. Another commission was established by the German Parliament already on 24 March 2000 to study "Law and Ethics in Modern Medicine" and to address the question of whether the importation of embryonic stem cells should be permitted. This Commission, in November 2001, declared that the majority of its members opposed the importation of human embryonic stem cells. It had concluded that the importation was "ethically unjustifiable and scientifically not sufficiently well founded", since utilizing imported embryonic stem cell lines was in essence approving the destruction of human embryos, see Enquete-Kommission Deutscher Bundestag (2001) at 95, see http://www.bundestag .de/gremien/medi/2zwischen\_english.pdf.<sup>278</sup> See section 6 paragraph 1 ESchG.

<sup>&</sup>lt;sup>279</sup> See *Keller/Guenther/Kaiser* (1992) at 235, margin no. 2.

<sup>&</sup>lt;sup>280</sup> See above at B.I.2.a). See also Keller/Guenther/Kaiser (1992) at 235, margin no.

<sup>&</sup>lt;sup>281</sup> See Lilie, in: Gethmann (2003) at 139; Schroth (2002) at 170, 172; Gutmann (2001) at 353.

nuclear transfer causes only *almost* identical genetic information; some of the genetic information originates from the mitochondrial material of the carrier egg cell, which altogether leads to a 0,01 to 0,02 % genetic deviation from the donor.<sup>282</sup>

If "identical" is understood to be 100% identical, then the somatic cell nuclear transfer technique does not fall under section 6 ESchG, except for if the egg and the nucleus were stemming from the same donor.<sup>283</sup> If "identical" requires only a relatively broad reading, which is not unproblematic with respect to the principle of narrow interpretation of criminal laws,<sup>284</sup> then section 6 ESchG is applicable for somatic cell nuclear transfer. The latter understanding is, owing to a teleological interpretation, the prevailing view in literature.<sup>285</sup>

As to the definition of "coming into being as an embryo", section 8, paragraph 1 ESchG provides that the embryo is coming into being from the moment of conjugation on.<sup>286</sup> It also applies to every totipotential cell extracted from an embryo which may divide

<sup>&</sup>lt;sup>282</sup> See above at A.I.2.b).

<sup>&</sup>lt;sup>283</sup> So Kersten (2004) at 34, 35.

<sup>&</sup>lt;sup>284</sup> See, specifically with regard to the ESchG, *Schroth* (2002) at 172; *Deutsch* (1991) at 723; *Höfling* (2003) at 109.
<sup>285</sup> See *Eser* et. al. (1997) at 368, 369; *Ipsen*, in: Vöneky/Wolfrum (2004) at 75; v.

<sup>&</sup>lt;sup>285</sup> See *Eser* et. al. (1997) at 368, 369; *Ipsen*, in: Vöneky/Wolfrum (2004) at 75; *v. Buelow* (1997) at A 720; *v. Bülow* (2001) at 147-149; *Rosenau* (2003) at 763, 764; *Keller* (1998) at 485; *Schreiber/Rosenau* (2000) at 396; *Schreiber* (2001) at 902; *Trute* (2001) at 390; *Höfling* (2001) at 278, 288; *Dietlein* (2003) at 65; *Günther* (2003) at 39; *Eser/Koch* (2003) at 26; *Hilgendorf* (2001) at 1160; *Schwarz* (2001) at 187. Suggestions have been made to amend section 6 in such a manner that a punishment shall be imposed on anyone who artificially causes a human embryo to emerge through any other way than the fertilization of a human egg cell through a human sperm, see *Bundesregierung* (1998) at 18, C.3.2 and at 19, C.4.2.

See also how the Council of Europe has dealt with the definition of "identical" in its Additional Protocol. Article 1(2) of the Protocol makes it clear that the technique of somatic cell nuclear transfer is covered by the prohibition through the definition as: "... a human being sharing with another the same nuclear gene set ...", discussed above at B.II.1.b) bb). Another example is the U.S. House Bill 2505 which defines cloning as the production of "... a living organism that is genetically virtually identical to an existing or previously existing human organism...", see below at B.II.2.d) cc).

<sup>&</sup>lt;sup>286</sup> "...The fertilised human egg cell capable of development is regarded as an embryo from the time of conjugation; furthermore, this applies to every totipotential cell extracted from an embryo which may divide and develop into an individual human being once the necessary additional conditions have been met...".

and develop into an individual human being<sup>287</sup> once the necessary additional conditions have been met.<sup>288</sup> In the case of nuclear transfer, however, an embryo does not come into being through fertilization of an egg cell and the subsequent process of conjugation.<sup>289</sup> Further, no totipotent cell is derived from an embryo by somatic cell nuclear transfer. Some therefore reach the conclusion that the use of the somatic cell nuclear transfer technique does not violate section 6 ESchG, since no embryo of the definition of section 8 ESchG is created.<sup>290</sup>

The majority opinion however treats the totipotent cell that was created through somatic cell nuclear transfer as an embryo according to section 8 ESchG.<sup>291</sup> The underlying argument revolves around the word "once" in section 8 ESchG which should be interpreted in the sense of "also". Then, the definition would include every egg cell that

 $<sup>^{287}</sup>$  See *id*. The term "human being" is however not legally defined in the ESchG; it is though, similar to the legal status of the embryo *in vitro*, one of the most controversial questions in constitutional law and also in the law of reproductive medicine, see *Rager* (2000) at 81-84 and, in depth, *Kaminsky* (1998).

<sup>&</sup>lt;sup>288</sup> While this definition of "embryo" also includes every totipotential cell extracted from an embryo, the British HFE Act omits such a fiction: The British prohibition of destructive embryo research commences only with the primitive streak. According to section 3(a) of the HFEA, "a licence cannot authorize keeping or using an embryo after the appearance of the primitive streak..." In addition, section 4 HFEA states that "...the primitive streak is to be taken to have appeared in an embryo no later than at the end of the period of 14 days beginning with the day when the gametes are mixed..." The United Kingdom's permission of destructive embryo research until the 14<sup>th</sup> day stands in strong contrast to the German embryo protection law and serves as an example of divergencies in the level of protection. Such divergencies were recognized for instance in article 18 of the Council of Europe's Biomedicine Convention, which does not prohibit either of the two embryo protection schemes, see above at B.II.1.b) bb).

<sup>&</sup>lt;sup>289</sup> For a detailed discussion and the recommendation to close that gap, see *Bundesregierung* (1998) at 14, C.1.2.3.
<sup>290</sup> So *Kersten* (2004) at 35-38. On the discussion, see *Gutmann* (2001) at 354;

<sup>&</sup>lt;sup>290</sup> So *Kersten* (2004) at 35-38. On the discussion, see *Gutmann* (2001) at 354; *Schroth* (2002) at 172; *Voss* (2001) at 166; *Witteck/Erich* (2003) at 259; *Schulz* (2003) at 363. Undecided *Taupitz* (2001) at 3434. This view interprets "already" in a temporal sense which would bar the application of the ESchG for somatic cell nuclear transfer. Under such an interpretation, the protection granted under the ESchG would only unleash for embryos that came into being through fertilization.

<sup>&</sup>lt;sup>291</sup> See Lilie, in: Bethmann (2003) at 139; Eser et. al. (1997) at 369, 370; v. Buelow (1997) at A 720, 721; Schlegel (1997) at 168; Deutsche Forschungsgemeinschaft (2001) at 21; Bundesregierung (1998) at 14-17; Röger (1999) at 217, 227, 229; Wolfrum (2000) at 237; Enquete-Kommission Deutscher Bundestag (2001) at 23, 24; Wolfrum/Zeller (1999) at 103; Schreiber (2001) at 903; Wolfrum (2001) at 18; Rosenau (2003) at 780; Hillebrand/Lanzerath (2001) at 42.

is able to develop and therefore also the fertilized egg from the moment of conjugation on. Parliament's intent to prohibit cloning comprehensively supports this analysis.<sup>292</sup> Altogether, since the ESchG prohibits cloning and 'genomic copying' is regarded as cloning,<sup>293</sup> it is punishable under section 6 ESchG.

Another discussion revolves around section 6, paragraph 2 ESchG: "Likewise anyone will be punished who transfers into a woman an embryo designated in paragraph 1." In the German debate on cloning for reproductive purposes, the question has sometimes been raised whether section 6, paragraph 2 ESchG provides that cloned embryos that have been implanted in the uterus must be "killed" even if they are short of being born.<sup>294</sup> From a legal point of view, one could consider making a distinction between prohibition and sanction. Section 6 ESchG provides for a prohibition but only under a criminal sanction which by its legal nature does not intend such a kind of restitution (Naturalrestitution). Under current German law, restitution could only be sought by private litigants based on sections 823(2), 249 German Civil Code. However, the only individual, who might be protected by section 6 ESchG – the embryo – and who is thus entitled to the claim, might have a right to sue; and the embryo certainly cannot be supposed to wish being killed. For centuries, there has been a prohibition sanctioned by criminal law on incest. However, once the incest occurred and the woman became pregnant, public law enforcement certainly did not seek abortion or the killing of the "illegal" embryo, foetus or baby. The purported "obligation to kill" should therefore clearly be dismissed.<sup>295</sup>

<sup>&</sup>lt;sup>292</sup> See *Keller/Guenther/Kaiser* (1992) at 235-236, margin no. 7, with further references in Fn. 4; *v. Buelow* (1997) at A 721.

<sup>&</sup>lt;sup>293</sup> See *Lilie*, in: Bethmann (2003) at 139.

<sup>&</sup>lt;sup>294</sup> See *Keller/Guenther/Kaiser* (1992) at 237-238, margin nos. 11-14; *Frommel* (2000) at 67, 74; *Neidert* (2002) at 470; *Gutmann* (2001) at 356, 359; *Hilgendorf* (2001) at 1161. On this alleged "obligation to kill" see also *Lilie*, in: Bethmann (2003) at 139 with further references.

<sup>&</sup>lt;sup>295</sup> Agreeing on this conclusion, *Schroth* (2002) at 172, who dismisses such an interpretation because the ESchG is a protective law; *Kersten* (2004) at 43.

While section 6, paragraph 2 ESchG thus does not force anyone to kill a cloned embryo, the prohibition of an implantation into the womb does however deprive the embryo of the possibility to develop and survive – an interpretation result that can hardly meet the conditions for the protection of the right to life under article 2, paragraph 2 of the German Constitution.<sup>296</sup>

As to German law on the creation and use of embryos in general, sections 1-7 ESchG could be summarized as intending to prevent the misuse of artificial fertilization and of the human embryo *in vitro*, and certain techniques such as germline modification. It regulates the embryo *in vitro* up to its nidation in the uterus of a woman. Offences against any of the provisions are criminally sanctioned with up to three years of imprisonment or a monetary fine.<sup>297</sup> The standard penalty of up to three years' imprisonment has been critizised as an "overall protectionist attitude of the legislature".<sup>298</sup>

German law knows a special set of rules for stem cells won from embryos abroad and imported into Germany for research purposes. These rules are provided in the StZG. Any offence against provisions of the StZG is punished with up to three years' imprisonment.<sup>299</sup> The StZG reinforces the general rule that no embryo may be produced for research purposes and that no existing embryo, i.e. supernumerary

<sup>&</sup>lt;sup>296</sup> See *Kersten* (2004) at 43 and *Bundesregierung* (1998) at 20 who therefore recommend the complete elimination of section 6, paragraph 2 ESchG. See also further references to dissenting opinions in *Kersten* (2004) at 43, footnote 44 and 45.

<sup>45. &</sup>lt;sup>297</sup> E.g. section 1, paragraph 2 ESchG: "By imprisonment of up to three years or by fine will be punished who attempts to artificially impregnate an ovum for another purpose, other than promoting the pregnancy of the woman from whom it came."; section 2, paragraph 1 ESchG: "Any person disposing of a human embryo created outside the body or taken from a woman before completion of its nidation in the uterus or giving away, acquiring or using for purposes other than its maintenance will be punished by up to three years imprisonment or by a monetary fine".

<sup>&</sup>lt;sup>298</sup> See *Lilie*, in: Bethmann (2003) at 134.

<sup>&</sup>lt;sup>299</sup> See section 13 StZG.

embryo, may be used for research purposes so long as research does not directly serve the individual embryo's preservation.<sup>300</sup>

However, embryonic stem cells created abroad may exceptionally be imported into Germany and used in Germany for research purposes.<sup>301</sup> These exceptions are very limited. As a general rule, research projects dealing with embryonic stem cells are only permitted if they "serve high-ranking research objectives in association with the progress of scientific understanding within the framework of basic research or with the extension of medical knowledge when developing diagnostic, prophylactic or therapeutic techniques to be applied on human beings".<sup>302</sup> More precisely, embryonic stem cells may be imported and used for research purposes if (i) they were extracted from supernumerary embryos from in vitro fertilisation in the country of origin before 1 January 2002, (ii) the persons entitled to disposal under the law of the country of origin have properly consented to the extraction of stem cells, (iii) no remuneration or benefit in kind has been granted, (iv) no other regulations, especially those of the ESchG, are violated.<sup>303</sup> Furthermore, research activities may only be carried out if the questions posed have already been provisionally answered as far as possible by using animal cells or animal embryos and if no equivalent results can be expected from research on anything other than embryonic stem cells.<sup>304</sup> The import and use of embryonic stem cells have to be approved by the Robert Koch Institute, section 6, paragraph 1 StZG.<sup>305</sup> Further, the Central Ethics Commission for

<sup>&</sup>lt;sup>300</sup> See section 2, paragraph 1 StZG. On the reach of these prohibitions see *Neidert* (2002), 467, 469.

<sup>&</sup>lt;sup>301</sup> See section 4, paragraph 1 StZG.

<sup>&</sup>lt;sup>302</sup> See section 5, paragraph 1 StZG.

<sup>&</sup>lt;sup>303</sup> See section 4, paragraph 2 StZG.

<sup>&</sup>lt;sup>304</sup> See section 5, paragraph 2 StZG.

<sup>&</sup>lt;sup>305</sup> The *Robert Koch Institute* has been designated under section 7 StZG by the German Federal Ministry of Health as the *competent authority*.

Research on Stem Cells (*Zentrale Ethikkommission*)<sup>306</sup> has to make a statement after consulting the competent authority.

#### bb) The ongoing debate

German law reflects a strong aversion to eugenic policies formerly implemented by the Nazis.<sup>307</sup> In 1945, the Basic Law (the regulations underlying the German Constitution) of the Federal Republic of Germany was written against the omnipresent backdrop of Nazi era crimes: In an effort to demonstrate intolerance for Nazi era policies, the Basic Law included clauses aimed at protecting human dignity,<sup>308</sup> bodily inviolability, and the right to life.<sup>309</sup> These pro-life clauses would serve as defenses against the state, "aimed in particular at preventing state-sponsored interference with life".<sup>310</sup>

It is for its shameful history of eugenics, that Hans Engelhard, then German minister of justice, pointed out, the primary purpose of the Embryo Protection Act was to "exclude even the slighted chance for programmes aimed at so-called improvement of humans" through

<sup>&</sup>lt;sup>306</sup> The composition of the *Ethics Commission* is also stipulated by the StZG. It consists of nine members who are appointed by the Federal government for three years. Four of its members come from the specialized fields of theology and ethics and five come from the fields of biology and medicine, see § 8(1) and (2) StZG.

<sup>&</sup>lt;sup>307</sup> See for instance the laws regarding abortion: In 1871, the newly-formed German state adopted section 218 of its Criminal Code, which declared a penalty of five years imprisonment for abortion. Abortion became a public issue by the late nineteenth century, with feminist groups actively calling for the elimination of section 218, see *Ferree* et. al. (2002) at 26-27. The debate, however, would be temporarily squelched when the Nazis assumed power in 1933. During the Nazi era, eugenics policies demanded the abortion of "unworthy lives", and the Nazis adopted a "eugenic justification" for abortion through changes to the criminal code, see *id.* at 27.

<sup>&</sup>lt;sup>308</sup> See article 1 of the Constitution (Grundgesetz, GG). For the official English translation, see Basic Law for the Federal Republic of Germany 14, Bundestag 2001 at http://www.bundestag.de/htdocs\_e/info/gg.pdf: "Human dignity shall be inviolable. To respect and protect it shall be the duty of all state authority. The German people therefore achnowledge inviolable and inalienable human rights as the basis of every community, of people and justice in the world. The following basic rights shall bind the legislature, the executive, and the judiciary as directly applicable law."

applicable law." <sup>309</sup> See article 2 GG, available at *id*. It provides: "Every person shall have the right to free development of his personality insofar as he does not violate the rights of others or offend against the constitutional order or the moral law. Every person shall have the right to life and physical integrity. Freedom of the person shall be inviolable. These rights may be interfered with only pursuant to law."

<sup>&</sup>lt;sup>310</sup> See *Will* (1996) at 404.

genetic tampering and was in direct response to Germany's history of eugenic experimentation.<sup>311</sup>

So today, Germany promulgates a restrictive embryonic research regime aimed at the protection of embryonic interests. By opting to introduce legislation, Germany, like the United Kingdom, sought to ensure that embryonic research take place within formal, state defined, ethical and legal boundaries. More precisely, the ESchG was unique, marking the first instance where a type of scientific inquiry had been criminally prohibited by the German government.<sup>312</sup> It was adopted in light of the requirements of German Basic Law favouring human life and dignity and was "founded on the principle that embryos *in vitro* are wholly worthy of protection."<sup>313</sup> In essence, it assigns the embryo the same legal rights as fully-developed human beings.

In many ways, the StZG made German stem cell research laws even more restrictive that under the ESchG, by specifically limiting and regulating importation.<sup>314</sup> And yet, the StZG does allow the importation of human embryonic stem cells for scientific research. Support for the legislation came from Chancellor Gerhard Schroeder and others who believed German competitiveness in the biotech industry was a powerful argument supporting importation.

The StZG itself manifests an extreme preoccupation with preventing the destruction of early human life by disallowing derivation within Germany in a manner that not everyone deems consistent with the ideas embodied in German Basic Law.<sup>315</sup>

<sup>&</sup>lt;sup>311</sup> Quoted in *Zell* (1989) at 19.

<sup>&</sup>lt;sup>312</sup> See *Bonnicksen* (1994) at 39, 42.

<sup>&</sup>lt;sup>313</sup> See Enquete-Kommission Deutscher Bundestag (2001) at 29.

<sup>&</sup>lt;sup>314</sup> See *Kim* (2002) at 8.

<sup>&</sup>lt;sup>315</sup> A comparison of the regulations regarding the embryo *in vitro* through the ESchG and the StZG with the protection of the embryo *in vivo* shows the following. While pregnancies may be terminated without stating the reasons after a mandatory consultation without being sanctioned by penal law up to the 12<sup>th</sup> week, paragraph 218 (a) 1 Criminal Code, embryos in a far less developed stage which

Further, the Act attempts to prevent derivation of embryos in other nations to meet German needs by forbidding the importation of lines developed after 1 January 2002. Of course, in placing a restriction on stem cell lines, Germany will face difficulties in obtaining numerous high quality stem cell lines which may eventually hinder Germany's medical progress. Ultimately, it seems Germany is willing to accept the loss of scientific prestige that embryo research promises.

Whether this position is likely to prevail under a long-term perspective is questionable. Rather, an amendment over time may be foreseeable.<sup>316</sup> The ESchG has been in force for thirteen years. As of now, no court decisions applying the ESchG as a criminal law have been published,<sup>317</sup> "and so far, no infringements of its regulations have come to light, neither has there been the least shadow of suspicion that would have warranted investigations."<sup>318</sup> As much as such an obvious adherence can be interpreted as a sign for a suitable, well-placed prohibition,<sup>319</sup> the government's strong stance against research may well be weakening. German minister of justice Brigitte Zypries implied that human embryos might not be protected by Germany's Basic Law and that current prohibitions on stem cell research should be loosened.<sup>320</sup> Zypries stated she believed that an embryo in vitro was not significantly developed enough to have human dignity as protected by the Basic Law.<sup>321</sup>

were not ever meant to produce viable offspring fall under absolute protection of the penal law, see *Lilie*, in: Gethmann (2003) at 140, 141 with further references to Fassbender (2001) at 2753; Dederer (2002) at 24; Schroth (2002) at 173; Mildenberger (2002) at 293. The discrepancy and unequal protection is debated, see Heinemann/Honnefelder (2002) at 540-41, who are pointing out that the ethical rationale behind the abortion legislation is not in conflict with the restrictive position taken on the protection of the embryo *in vitro*. <sup>316</sup> The developments in Spain which are gradually shifting towards a liberalization

of the embryo protection scheme suggest that other countries in the region with strict laws may loosen them over time as well, see for Spain above at B.II.2.b) bb). <sup>317</sup> See *Lilie*, in: Bethmann (2003) at 137.

<sup>&</sup>lt;sup>318</sup> See *id*.

<sup>&</sup>lt;sup>319</sup> See *id*.

<sup>&</sup>lt;sup>320</sup> See *Stafford* (2003); see also Germany hints at a loosening of the stem cell law, Deutsche Welle (2003). <sup>321</sup> See Stafford (2003).

The remarks were widely reported by the German media and renounced by a variety of individuals including church officials, physicians' groups, and politicians. At the same time, the remarks emboldened some scientists who want more flexible research laws.<sup>322</sup> As can be seen, while research laws in Germany have been readily formulated, the debate on possible reforms among special interest groups is ongoing.

# d) The United States

In the United States, one should clearly distinguish between regulation on the Federal and on the state level. On the Federal level, the state of the law is unclear. While Congress has not passed explicit legislation on the topic of human cloning and on the creation and use of embryos in general, the United States Food and Drug Administration has claimed that cloning for reproductive purposes needs its permission and that currently such a permission would not be granted. Although not a prohibition, it is practically of great importance that due to a Presidential Order no Federal funds may be granted for cloning or for research on embryonic stem cells. On the state level, the law differs from one state to another. In some states, cloning is prohibited *per se*, in others it is only permitted for therapeutic purposes and in again others it is even permitted *per se*.

# aa) The regulatory scheme on the Federal level

Although various initiatives have been started in the past years, Congress until now has not passed express legislation on the creation and use of embryos and embryonic stem cells and on cloning in particular.<sup>323</sup> However, after researchers in Massachussetts had announced the successful cloning of human embryos, which later turned out to be a premature announcement,<sup>324</sup> the Federal Food and

<sup>&</sup>lt;sup>322</sup> See *id*.

<sup>&</sup>lt;sup>323</sup> For a discussion of recent legislative attempts see below sub cc).

<sup>&</sup>lt;sup>324</sup> See *Weiss* (2001) at A3. Successful cloning was announced by the company Advanced Cell Technology Inc. based in Worchester, MA in 2001.

Drug Administration (FDA)<sup>325</sup> issued a final rule under which it claimed that "...the clinical research using cloning technology to clone a human being is subject to FDA regulation under the Public Health Service Act (PHSA) and the Food, Drug, and Cosmetic Act (FDCA)<sup>326</sup>. Before such research could begin, the researcher must submit an Investigational New Drug (IND)<sup>327</sup> request to the FDA, which the FDA would review to determine if such research could proceed." At the same time, the FDA announced that without exceptions it would not grant such a permission because until today, the risks of cloning were not clear.<sup>328</sup> However, no complete explanation of the FDA's decision to assert jurisdiction over cloning has yet appeared. According to the claim of the FDA, cloning for reproductive purposes would be prohibited.<sup>329</sup> It could theoretically be sanctioned with up to one year of imprisonment.<sup>330</sup>

<sup>&</sup>lt;sup>325</sup> The FDA has been created as Federal agency under the Federal Food, Drug, and Cosmetic Act (FDCA). Its mission is to protect "...the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health", see the mission statement at http://www.fda.gov/opacom/morechoices/mission.html.

<sup>&</sup>lt;sup>326</sup> See 21 U.S.C. §331 (2002).

<sup>&</sup>lt;sup>327</sup> For a definition, see FDCA §505, 21 U.S.C. §355 (2002).

<sup>&</sup>lt;sup>328</sup> See the letter of the FDA of 28 March 2001 to the research community and the statement of the competent director at the FDA before the House Subcommittee on Oversight and Investigations (Committee on Energy and Commerce) of 28 March 2001, http://www.fda.gov/cber/genetherapy/clone.htm. See the conclusion of the competent director stating that "…because of the unresolved safety questions pertaining to the use of cloning technology to clone a human being, the FDA would not permit any such investigation to proceed at this time."

<sup>&</sup>lt;sup>329</sup> Cloning would probably be a statutory offence under §301 of the FDCA, (a), (d), (p), 21 U.S.C. §331(a), (d), (p), since the manufacture and delivery into interstate commerce of unapproved new drugs is prohibited. However, the FDA is generally reluctant to assert its jurisdiction, see *Merrill* (2002) at 14-17. <sup>330</sup> See §303(a)(1), 21 U.S.C. §333(a)(1) which applies to any misdemeanor

<sup>&</sup>lt;sup>330</sup> See \$303(a)(1), 21 U.S.C. \$333(a)(1) which applies to any misdemeanor violation to a first offence, including in the case of biologics. In general, all violations of the FDCA are subject to civil or criminal enforcement based on the FDA's discretion, see *Adams* et. al. (1997) at 84.

According to its usual practive, the FDA decides on criminal prosecution in cases of gross and life-threatening violations, see *Fine* (1976) at 324. For repeat offenders, 303(a)(2), 21 U.S.C. 333(a)(2) provides for felony prosecution, with a penalty of up to three years imprisonment and up to 10,000 USD in fines.

While the FDA is generally considered to be the most powerful agency in the U.S., the actions of which are only superficially controlled by the courts,<sup>331</sup> it seems to be highly questionable whether the FDA has the jurisdiction it claimed.<sup>332</sup> As a matter of practice, the authority of the FDA has so far been respected, since U.S. scientists have at least not openly been researching on the somatic cell nuclear transfer technique with the goal of cloning a human being on U.S. territory.<sup>333</sup> Also, state legislation has not permitted reproductive cloning. At this point in time, we could therefore conclude that the FDA's invocation of its IND regime had the effect of imposing a theoretical legal moratorium on much domestic human cloning research.<sup>334</sup>

Furthermore, such a restriction in effect is enhanced by the refusal of the current Federal government to subsidize research on embryonic stem cells with Federal funds. Public funding of embryo research is regulated by means of a rider to the Omnibus Consolidated and Emergency Supplemental Appropriations Act for Fiscal Year 1999 – the appropriations bill for the Department of Health and Human Services (DHHS)<sup>335</sup> and by guidelines of the National Institute of

<sup>&</sup>lt;sup>331</sup> See *Lawson* (2004) at 503. Among only few, the most notable Supreme Court case in which the jurisdiction claimed by the FDA for the regulation of tobacco products was denied concerned tobacco products, see Food and Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000). Here, the judgement was not surprising due to tobaccos' unique place in American history and society, and also due to its significant contribution to American economy, see *Rogers* et. al. (2003) at 14.

<sup>(2003)</sup> at 14. <sup>332</sup> See, *Merrill* (2002) at 1-82; *Merrill/Rose* (2001) at 85-148; *Garvish* (2001) at 22; *Rokosz* (2000) at 464-515; *Rothenberg* (1999) at 639-647; *Peterson* (2003) at 226-266.

<sup>&</sup>lt;sup>333</sup> The U.S. researchers Zavos and Antinori, for instance, who publicly promote their effort aiming at successful reproductive cloning, are not researching on U.S. territory, but "in some mediterranean country where authorities have already given their consent to proceed, see *The Ecologist* (2001). Also, there is no evidence that any researcher has so far sought FDA approval for any cloning experiments, which is not to suggest though that no such experiments have been undertaken surreptitiously.

<sup>&</sup>lt;sup>334</sup> See Weiss (1998) at A1; Merrill (2002) at 56.

<sup>&</sup>lt;sup>335</sup> Act of Oct. 21, 1998, Pub. L. No. 105-277, 112 Stat. 2681. This rider has been interpreted as prohibiting the use of funds for embryonic research "…in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury … greater than that allowed for research on fetuses in utero", see *Flannery/Javit* (2000) at D-1, D-6.

Health (NIH) which have been modified on direct intervention of President Bush in 2001 thus limiting research on stem cell lines that have been created before 9 August 2001.<sup>336</sup>

Such a "soft restriction" through the blocking of Federal funds is perhaps the most effective restriction as access to Federal funding is not a trivial matter. Numerous states, universities, charitable foundations, hospitals, and companies within the U.S. proclaim that they are in desparate need of Federal funds to finance embryonic research projects because available private funding is inadequate.<sup>337</sup>

#### bb) The regulatory scheme on the state level

Since cloning and, more generally, the creation and use of embryos and embryonic stem cells for research purposes is not prohibited by Federal law, state legislation sets the legal boundaries for research.<sup>338</sup>

An overview on state law will appear as a patchwork of diverse policies: The law, where the state has enacted legislation at all, differs from state to state. Since Dolly the sheep was born, ten states have passed a law restricting human reproductive cloning<sup>339</sup> and one state

*Iowa*, Iowa Code §707B.1-.4 (formerly IA SB 2046, became IA SB 2118) (2003); Louisiana, La. Rev. Stat. Ann. §1299.36.1-.6 (2003);

<sup>&</sup>lt;sup>336</sup> For the initial guidelines, see National Institutes of Health (2000). For President Bush's intervention see Bush (2001). Currently, there are only 15 stem cell lines available created before 9 August 2001, see National Institutes of Health (2004). Interpretations under the rider alone, according to which the ban on the use of Federal funds for human embryo research does not apply to research on stem cell lines, but only applies to research in which embryos are actually destroyed are hence clearly out of date. For such an interpretation see, e.g. Flannery/Javit (2000) at D-6, explaining that this conclusion resulted from scientific evidence demonstrating that stem cells are not embryos.

<sup>&</sup>lt;sup>337</sup> See *Perez-Pena* (2003) at A 20, stating that "these disparate [private] efforts, significant though they may prove to be, do not approach the sums of money the government woud have devoted to embryonic stem cell research". See also Plomer

<sup>(2002)</sup> at 134. <sup>338</sup> On the various theories of state law preemption, see *Chemerinskiy* (2002) at 374-434. <sup>339</sup> These states are

Arkansas, Ark. Code §20-16-1001 et seq. (formerly AR SB 185) (2003);

California, Cal. Bus. & Prof. §16004, 16105; Cal. Health & Safety §§24185-24187 (formerly CA SB 1230) (2003);

Michigan, Mich. Comp. Laws §§333.26401-06, 333.26274, 16275, 20197, 750.430a (2003);

New Jersey, N.J. SB 1909/AB 2849 (2003-2004):

prohibits only the use of state funds for reproductive cloning.<sup>340</sup> Of these ten states, six also ban therapeutic cloning.<sup>341</sup> Some states also ban shipping, transferring, or receiving for any purpose an embryo produced by human cloning.<sup>342</sup> Also, some states, under the existing reproductive cloning bans, prohibit the purchase or sale of an egg, zygote, embryo, or fetus for the purpose of cloning a human being.<sup>343</sup>

Some states make exceptions for certain types of research. For instance, the ban on reproductive cloning is accompanied by language supporting other types of research or medical practices as in Louisiana and Michigan, where the cloning bans say that they do not prohibit scientific research on a cell-based therapy.<sup>344</sup> Similarly, some states allow the use of nuclear transfer or other cloning techniques to produce molecules, DNA, cells other than human embryos, tissues, organs, plants, or animals other than humans.<sup>345</sup> The Arkansas and Rhode Island laws also specifically allow in vitro fertilization and fertility enhancing drugs, so long as they are not used in the context of human cloning.<sup>346</sup> The Iowa law more broadly allows in vitro fertilization and the use of fertility drugs.<sup>347</sup>

The penalties for the violation of existing cloning bans range widely. In Louisiana and Michigan, for instance, penalties can reach up to ten years imprisonment and fines of \$10 million for an entity such as a

North Dakota, N.D. Cent. Code §§12.1-39-01-02 (formerly ND HB 1424) (2003); Rhode Island, R.I. Gen. Laws §23-16.4-1/.4-4 (2003);

South Dakota, S.D. SB 184 §2 (2004);

Virginia, Va. Code Ann. §32.1-162.21-.22 (2003).

<sup>&</sup>lt;sup>340</sup> *Missouri*, Mo. Rev. Stat. §1.217 (2003).

<sup>&</sup>lt;sup>341</sup> Arkansas, Iowa, Michigan, Virginia, North Dakota, and South Dakota.

<sup>&</sup>lt;sup>342</sup> Ark. Code §20-16-1002 (A)(3); Iowa Code §707B.4(1)(c); ND Cent. Code §§12.1-39-01 to 02; Va. Code Ann. §32.1-162.22(A) (for purposes of implantation).

<sup>&</sup>lt;sup>343</sup> See for instance Cal. Health & Safety Code §§24185(b); La. Rev. Stat. §1299.36.2(B).
 <sup>344</sup> See La. Rev. Stat. Ann. §1299.36.2(c) ; Mich. Comp. Laws §750.430a(2).

<sup>&</sup>lt;sup>345</sup> See, for instance, Ark. Code §20-16-1003(A); Iowa 707B.4(2); R.I. Gen Laws §23-16.4-1. Virginia allows gene therapy, cloning of non-human animals, and cloning molecules, DNA, cells or tissue, see Va. Code Ann. §32.1-162.22(B).

<sup>&</sup>lt;sup>346</sup> Ark. Code §20-16.1003(B); R.I. §23-16.4-2(c)(2)(i).

<sup>&</sup>lt;sup>347</sup> Iowa Code §707B.4(2).

clinic or corporation and \$5 million for an individual.<sup>348</sup> In contrast, in Arkansas, the penalty is a mere \$250,000, but there are also felony criminal penalties.<sup>349</sup> Moreover, in some states, cloning can result in the permanent revocation of a doctor's license<sup>350</sup> and the denial of any other type of license or permit from the state regarding any trade, occupation or profession.<sup>351</sup>

Regarding bans on embryo research, in 19 states, there are no laws specifically addressing research on embryos or fetuses.<sup>352</sup> Twelve states' laws apply to *in vitro* embryos.<sup>353</sup> In New Hampshire, the regulation of research on emryos prior to implantation is minimal.<sup>354</sup> The research must take place before day 14 post-conception,<sup>355</sup> and the subject embryo must not be implanted in a woman.<sup>356</sup> These stipulations could be met by researchers wanting to use IVF embryos as a source of stem cell production.

Nine states ban research on *in vitro* embryos altogether,<sup>357</sup> and two states ban destructive embryo research.<sup>358</sup> In other states, embryo research is banned as part of the broader ban on all research involving live conceptuses. These laws ban embryo stem cell research. The

<sup>&</sup>lt;sup>348</sup> La. Rev. Stat. §1299.36.3; Mich. Comp. Laws §750.430(a)(3). Rhode Island has a penalty of \$250,000 for individuals and \$1 million for entities, see R.I. Gen. Laws §23-16.4-3. <sup>349</sup> Ark. Code §20-16-1002(B) to (D).

<sup>&</sup>lt;sup>350</sup> See, for instance, La. Rev. Stat. §1299.36.4; see also Iowa §707B.4(5).

<sup>&</sup>lt;sup>351</sup> La. Rev. Stat. §1299.36.4; Iowa §707B.4(6).

<sup>&</sup>lt;sup>352</sup> These states are Alabama, Alaska, Colorado, Connecticut, Delaware, Georgia, Hawaii, Kansas, Maryland, Mississippi, Nevaded, North Carolina, Oregon, South Carolina, Texas, Vermont, Washington, West Virginia, Wisconsin, and the District of Columbia, according to a Lexis database search.

<sup>&</sup>lt;sup>353</sup> Fla. Stat. Ann. § 390.0111(6); La. Rev. Stat. Ann. §9:121 et seq., Me. Rev. Stat. Tit. 22 §1593 ; Mass. Ann. Laws. ch. 112 §12J; Mich. Comp. Laws. §§333.2685 to 2692; Minn. Stat. Ann. §145.421; N.D. Cent. Code §§14-02.2-01 to -02; 18 Pa. Cons. Stat. Ann. §3216; R.I. Gen. Laws. §11-54-1.

<sup>&</sup>lt;sup>354</sup> N.H. Rev. Stat. Ann. §168-B:15.

<sup>&</sup>lt;sup>355</sup> *Id.* at I.

<sup>&</sup>lt;sup>356</sup> *Id.* at II.

<sup>&</sup>lt;sup>357</sup> Fla. Stat. Ann. §390.0111(6); La. Rev. Stat. Ann. §9:121 et seq.; Me. Rev. Stat. Tit. 22 § 1593 ; Mass. Ann. Laws. Ch. 112 § 12J; Mich. Comp. Laws. §§333.2685 to 2692; Minn. Stat. Ann. §145.421; N.D. Cent. Code §§14-02.2-01 to -02; 18 Pa. Cons. Stat. Ann. §3216; R.I. Gen. Laws. §11-54-1. <sup>358</sup> S.D. Codified Laws §34-14-16; Iowa Code §707B.1-4.

penalties are high – in some states, the punishment includes imprisonment.<sup>359</sup>

Among all states, California law is the most liberal. It explicitly endorsed stem cell research "involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells from any source including somatic cell nuclear transplantation."<sup>360</sup> California thus permits therapeutic cloning, and so does New Jersey in a similar law.<sup>361</sup> Such research must be reviewed by an approved institutional review board and may not be undertaken without written informed consent of the embryo donor. Interestingly, the law does not say "consent of the donors" in the plural. So it would appear that the female patione of infertility services is the sole source of consent. California also enacted a law urging Congress to ban reproductive cloning, while permitting therapeutic cloning and embryo stem cell research.<sup>362</sup>

Most recently, California's successful "Proposition 71", or "California Stem Cells Research and Cures Initiative"<sup>363</sup> attracted great public attention:<sup>364</sup> It contains a state constitutional amendment to create a "right" under the California Constitution "to conduct" research into stem cells.<sup>365</sup> It raised \$3 billion for stem cell research, explicitly including the use of somatic cell nuclear transfer in California and authorized state bonds to create the California Institute for Regenerative Medicine. The Institute can provide funding for

 $<sup>^{359}</sup>$  The Maine law, for instance, which applies to both research on embryos and research on fetuses, carries a maximum five year prison term. Me. Rev. Stat. tit. 22 §1593. The Massachusetts and Michigan laws also carry with them a potential prison sentence of up to five years. Mass Ann. Laws 112 § 12J(a)(V); Mich. Comp. Laws § 333.2691.

<sup>&</sup>lt;sup>360</sup> See Cal. Health & Safety Code, SB 253 § 125115.

 $<sup>^{361}</sup>$  See N.J. SB 1909/AB 2840 § 2(a) (2002-2003), identical wording with the California Law.

<sup>&</sup>lt;sup>362</sup> California Senate Joint Resolution 38.

<sup>&</sup>lt;sup>363</sup> Official version at http://www.voterguide.ss.ca.gov/propositions/prop71-title. htm.

<sup>&</sup>lt;sup>364</sup> See *Sarewitz* (2004) at B11; *Winickoff* (2004) at E3; *Broder* (2004) at A19, *Gellene* (2004) at B7.

<sup>&</sup>lt;sup>365</sup> See CSCRC, section 4, subsection 1.

California stem cell researchers at universities, medical schools, hospitals and research facilities. The initiative's authors set a tight schedule for implementing Proposition 71, which is a probably a response to Federal restrictions on funding for stem-cell research.<sup>366</sup>

Not all regulations affecting research are however constitutional. Laws restrichting research on conceptuses may be struck down as too vague or as violating the right to privacy to make reproductive decisions.<sup>367</sup> But, in previous cases, the female patient's reproductive freedom was implicated, providing a strong reason to overturn the statute. Stem cell researchers do not have such a potential legal argument. With regard to laws banning reproductive cloning however, there is a slight possibility of a reproductive liberty challenge being raised.

## cc) The ongoing debate on the Federal level

The question remains, how U.S. Federal law will evolve in the next few years. In that respect, the position of the U.S. President and former attempts at drafting Federal legislation are important indications.

After researchers had (falsely) announced the successful cloning of human embryos at Advanced Cell Technology, Inc. in Worchester, Massachusetts, Bush made precise statements on cloning research,

<sup>&</sup>lt;sup>366</sup> State officials must appoint 27 of a 29-member Independent Citizen's Oversight Committee, or ICOC, by 17 December, and hand out the first grants by the end of March. The chair and co-chair will be elected by the ICOC. By mid-January, the ICOC must appoint about 50 members to three Working Groups, who will advise the ICOC on which grant proposals should be funded.

 $<sup>^{367}</sup>$  See for instance Lifchez v. Hartigan, 735 F. Supp. 1361 (N.D. III. 1990), which held that a ban on research on conceptuses was too vague in that it failed to define the terms "experimentation" and "therapeutic", id. at 1364-65. A similar result was reached by a Federal appellate court assessing the constitutionality of a Louisiana law prohibiting nontherapeutic experimentation on fetuses in Margaret S. v. Edwards, 794 F.2d 994 (5<sup>th</sup> Cir. 1986). Here the term "experimentation" was too vague, *id.* at 999. A third case was struck down as vague in the Utah statute that provided that "live unborn children may not be used for experimentation, but when advisable, in the best medical judgement of the physician, may be tested for genetic defects" (Utah Code Ann. § 76-7.3-310), see Jane L. v. Bangerter, 61 F.3d 1493, 1501 (10<sup>th</sup> Cir.).

saying that "[t]he use of embryos to clone is wrong"; society should not "grow life to destroy it."<sup>368</sup>

The President's stance on human cloning corresponds to that of the House of Representatives: Here, the "Human Cloning Prohibition Act of 2001", House Bill 2505, was introduced in early 2001.<sup>369</sup> The legislation proposes a complete ban on somatic cell nuclear transfer to create cloned human embryos – it bans all cloning procedures. Also, it threatens transgressors with criminal punishment and civil fines.

A competing Bill 2172, the "Cloning Prohibition Act of 2001", called for a 10-year moratorium on producing cloned human beings followed by an automatic "sunset." It also required that anyone intending to produce cloned human embryos for research purposes inform the Federal government, and promise not to use them to produce fully formed human clones.

On 31 July 2001, the U.S. House of Representatives passed the Human Cloning Prohibition Act of 2001 (House Bill 2505)<sup>370</sup> by a vote of 265 to 162. It was given strong Presidential support,<sup>371</sup> whilst until today, scientific advisory panels, such as the National Academy of Sciences Advisory Panel, tend to favour a ban that only includes reproductive cloning but not therapeutic cloning.<sup>372</sup>

Although the House proposal failed to win enough support to pass the Senate, the issue is still being debated.<sup>373</sup> Should the Senate follow suit,<sup>374</sup> then all research, private as well as public and regardless of funding sources, involving any form of cloning will be illegal.

<sup>369</sup> On the Human Cloning Prohibition Act, see *Swartz* (2002) at 79; *Forsythe* (1998) at 469; *Peterson* (2003) at 217.

<sup>&</sup>lt;sup>368</sup> See *Bush* (2001).

<sup>&</sup>lt;sup>370</sup> 147 Cong. Rec. H4916, H4945 (daily ed. 31 July 2001).

<sup>&</sup>lt;sup>371</sup> See the press release *The White House* (2001).

<sup>&</sup>lt;sup>372</sup> See Weiss/Connolly (2002) at A01.

<sup>&</sup>lt;sup>373</sup> For a list of debates in Congress see *Swartz* (2002) at 79, 80.

<sup>&</sup>lt;sup>374</sup> Which is not foreseeable at this point in time, see *Dewar* (2004) at A04.

House Bill 2505 is the first human cloning prohibition to pass either chamber of Congress. According to the Bill, human cloning is "asexual reproduction" through transferring a human cell nucleus with a complete set of chromosomes to an enucleated egg "so as to produce a living organism that is genetically virtually identical to an existing or previously existing human organism".<sup>375</sup> "Asexual reproduction" is reproduction not commenced by the confluence of an egg and a sperm.<sup>376</sup>

Persons who clone or try to clone, either for reproductive, therapeutic, or research purposes, will face penalties of up to ten years in prison and, if "pecuniary gain" is involved, a fine of at least one million dollars.<sup>377</sup> Persons, who transport or import embryos and products derived by somatic cell nuclear transfer will be subject to the same penalties.

The Bill allows continued research using somatic cell nuclear transfer so long as the procedures do not create human embryos: "Nothing in this section restricts areas of scientific research not specifically prohibited by this section, including research in the use of nuclear transfer or other cloning techniques to produce molecules, DNA, cells other than human embryos, tissues, organs, plants, or animals other than humans."<sup>378</sup> Here, a problem could be that, while the Bill allows somatic cell nuclear transfer research with non-embryonic human cells, it does not define the term "embryo".<sup>379</sup>

Why is it that the United States, unlike many other Western nations, has not yet been successful in enacting legislation to ban reproductive cloning?

<sup>&</sup>lt;sup>375</sup> H.R. 2505, 107<sup>th</sup> Cong. Section 2 (a) (2001).

<sup>&</sup>lt;sup>376</sup> Id.

 $<sup>^{377}</sup>$  Id. If the gross gain is more than \$500,000 then the civil penalty can be as much as twice the amount of the gross gain. <sup>378</sup> H.R. 2505, 107<sup>th</sup> Cong. Section 2 (a) (2001).

<sup>&</sup>lt;sup>379</sup> Some argue that because the term does not have a fixed meaning in biology, the Bill is vulnerable to a due process challenge for vagueness, see *Swartz* (2002) at 82.

First, the legal status of embryos in the United States is an unsettled area of law.<sup>380</sup> It seems that the main problem in determining it in the U.S. is striking a balance between respect for human life and concerns of procreative choice and bodily integrity.<sup>381</sup> While there are criminal and tort laws that clearly apply to *in utero* fetuses and embryos, application of these laws to preimplantation embryos is not clear.<sup>382</sup> For example, there are three possible designations for preimplantation embryos: persons, property, or entities deserving "special respect".<sup>383</sup>

Also, the United States' difficulty in trying to establish a Federal law regarding human reproductive and therapeutic cloning reflects the issues that a great number of UN member states are dealing with domestically: American society, including the legal, medical, and scientific community, is ethically pluralistic.<sup>384</sup> Thus, developing a consensus within those communities as to a concrete regulation is difficult.

The need for such legislative policy is particularly great in the United States because of the absence of any effective system to license private research laboratories, fertility clinics, or other commercial operations involving human embryos and gametes. The FDA has claimed jurisdiction over human cloning, but is mandated by law to consider only safety and efficacy, and not to consider social, political, or moral issues.<sup>385</sup>

At the Federal level, religious influences play a part in the attempts at drafting legislation. In the United States, religion is a pervasive factor in many of her laws, examples include prohibitions of and limitations on the use of contraceptives, same-sex marriage, and, most

<sup>&</sup>lt;sup>380</sup> See *Perry/Schneider* (1992) at 477-88.

<sup>&</sup>lt;sup>381</sup> See *Robertson* (1990) at 437.

<sup>&</sup>lt;sup>382</sup> See *id.* at 450-52.

<sup>&</sup>lt;sup>383</sup> See *Perry/Schneider* (1992) at 477-88.

<sup>&</sup>lt;sup>384</sup> See *Peterson* (2003) at 263.

<sup>&</sup>lt;sup>385</sup> For an analysis of the FDA's regulation and partial protection, see *id.* at 266-269.

importantly, abortion.<sup>386</sup> President Bush expressly relies on religious beliefs while making important decisions that affect the United States as a whole.<sup>387</sup>

Besides a persistent divisiveness in the U.S. about these issues which affect the attempts at drafting anti-cloning legislation,<sup>388</sup> the strength of her biotech lobby steered the issue of human cloning into its current deadlock.<sup>389</sup> "These two factors were critical in undermining Congressional attempts to pass anti-cloning legislation since 1997, and are obstructing the second wave of such attempts in the present Congress."<sup>390</sup> Both forces, the biotech lobby on the one side and the pro-life/anti-abortion/religious interest groups on the other entered into a trial of strength.<sup>391</sup> As was apparent, for instance, the major feature of the congressional debate on cloning was the divisive politics of therapeutic cloning,<sup>392</sup> which most dominantly touches upon the key question, from what point on cells should be defined as 'human life' and to what extent the earliest stages of human development should be protected. In that respect, President Bush's criteria for Federal funding appear to be a reasonable compromise between two opposing viewpoints.<sup>393</sup> Also, this funding policy and

<sup>&</sup>lt;sup>386</sup> See *Dörflinger* (1999) at 137-40; *Parker* (2001) at 771, 791-808. Both sources provide a discussion of the religious issues pertaining to human embryo research.

<sup>&</sup>lt;sup>387</sup> In an interview with 20/20 concerning his criteria for Federal funding of stem cell research, Bush stated, "I reach out to God every day, I pray every day, I read the Bible every day ... I think this is the kind of decision where it does require prayer"; quoted in Yang et. al. (2001) at ST01. Bush emphasized that his decision to allow for limited Federal funding squared with his ealier asserted opposition to funding research that involved destroying live human embryos, since Federal funds would be used for embryos that have already been destroyed.

<sup>&</sup>lt;sup>388</sup> See *Belew* (2004) at 496-507.

<sup>&</sup>lt;sup>389</sup> See Stenger (1994) at 137.

<sup>&</sup>lt;sup>390</sup> See Center for Genetics and Society, Oakland, California at http://www. genetics-and-society.org/policies/us/cloning.html#3. <sup>391</sup> Intense lobbying campaigns were waged as "both sides ... ferociously pressed

their case", see Connolly (2001) at A1.

<sup>&</sup>lt;sup>392</sup> See *id*. <sup>393</sup> Although critics have pointed out several flaws with his plan, particularly <sup>393</sup> Although critics have pointed out several flaws with his plan, particularly Bush placed much reliance in reaching his decision. The major concern is the therapeutic potential of the existing cell lines, see Yang et al. (2001) at ST01:"There will be concern about the limits the President has proposed on this research, specifically that the existent stem-cell lines could be inadequate to realize its potential lifesacing benefits", quoting U.S. Senator Tom Daschle.

House Bill 2505 possibly delineate a limited precedent for legislative development addressing reproductive and therapeutic cloning.<sup>394</sup>

All in all, the controversy in U.S. domestic politics regarding Federal cloning legislation remains unresolved. The U.S. National Bioethics Advisory Commission, already in 1997, recommended that the United States enact Federal legislation "to prohibit anyone from attempting to create a child through somatic cell nuclear transfer"<sup>395</sup> – that is irrespective of and separate from a policy regarding therapeutic cloning. It further suggested that the U.S. government "cooperate with other nations and international organizations to enforce any common aspects of their respective policies on the cloning of human beings." Both suggestions remained unfulfilled until today. They show however, that a partial ban on reproductive cloning is a possible option for the U.S. domestically, and so is a corresponding cooperation on the international level in view of a similar prohibition.

# e) China

In China, cloning for reproductive purposes is prohibited. However, like the "ordinary" creation of embryos and the use of supernumerary IVF embryos for research purposes, cloning for therapeutic purposes is likewise permitted, but subject to governmental supervision. With a relatively strict regulatory framework evolving about five years ago, China has definitely abandoned its lax policy in embryonic research under which scientists could, e.g., transfer human somatic cell nuclei into animal egg cells<sup>396</sup> or even experiment on

<sup>&</sup>lt;sup>394</sup> For a detailed and descriptive overview of legislative attempts of the U.S. Congress, see *Mariani* (2002) at 397-406.

<sup>&</sup>lt;sup>395</sup> See National Bioethics Advisory Commission (1997) at I.

<sup>&</sup>lt;sup>396</sup> See *Walters* (2004) at 7; *Cohen* (2002); *Weiss* (2002) at A8, reporting the transfer of human cell nuclei into rabit eggs.

reproductive cloning – with the participation of American researchers who could not untertake the same research in the United States.<sup>397</sup>

## aa) The regulatory scheme

As China is not a democracy, the governing Chinese law on embryonic research and cloning results from various regulations and guidelines issued by ministries, primarily by the ministry of health (MOH) and the ministry of science and technology (MOST). The most recent guidelines<sup>398</sup> that comprehensively deal with embryonic research and cloning in particular are the "Ethical Guiding Principles for the Research of Human Embryonic Stem Cells", issued on 14 January 2004 jointly by the MOH and the MOST. Our further discussion will build on these guidelines.<sup>399</sup> For administering and supervising embryonic research in China, the MOH and the MOST have established a new agency, the Chinese Human Genetic Resources Management Office.<sup>400</sup>

<sup>&</sup>lt;sup>397</sup> See *Dennis* (2002); *Zhang* et. al. (2003) reporting that Chinese and American reproductive doctors have performed a medical experiment on a Chinese woman, trying the somatic cell nuclear transfer method – obviously without success. This procedure was not performed in the United States due to considerations of medical risks and ethical concerns, see *Weiss* (2003) at A10. For reports on further hidden experiments aiming at reproductive cloning see *Mann* (2003).

<sup>&</sup>lt;sup>398</sup> Unofficial English translations of the following various official documents can be found in the Eubios Journal of Asian and International Bioethics at http://www.biol.tsukuba.ac.jp/~macer/EJAIB.html.

<sup>&</sup>lt;sup>399</sup>See *Chinese Ministry of Health/Ministry of Science and Technology* (2004), also at http://www.chinalawandpractice.com. These "Guiding Principles" have been preceded since 1998 by various acts, such as MOH's Interim Guidance on Ethical Review of Biomedical Research Involving Human Subject (1998); the MOST's MOH's joint Interim Measures for the Administration of Human Genetic Resources (1998) the State Food and Drug Administration's Drug Clinical Trial Guidelines (2000); the MOH's Regulations on Human Assisted Reproductive Technologies (2001); the MOH's Regulations on Compulsory Labeling on GMO (2002); the MOH's Ethical Principles of Human Assisted Reproductive Technologies (2003) and the MOH's Guidelines on Human Assisted Reproductive Technologies (2003). One of the rare "parliamentary" acts dealing partially with the question is the Law on Practicing Doctors, voted for by the National People's Congress (NPA) in 1999. For an overview on these acts and their background including the bioethicists and other professionals involved, see *Zhai* (2003) at 5-10.

<sup>&</sup>lt;sup>400</sup> See *Döring* (2004) at 39.

Cloning for reproductive purposes is prohibited without exception.<sup>401</sup> This prohibition seems to be enforced through criminal sanctions. China's clear policiy against reproductive cloning is supported by the foreign ministry which proclaimed that human reproductive cloning is a "…tremendous threat to the dignity of mankind and may probably give rise to serious social, ethic, moral, religious and legal problems…" and further, that "…the Chinese government is resolutely opposed to cloning of human beings and will not permit any experiment of cloning human beings…"<sup>402</sup>

As a matter of principle, however, the creation of embryos by way of cloning or otherwise and their use for research purposes is permitted.<sup>403</sup> Under the Guiding Principles 2004, research is restricted to the use of embryos not older than 14 days.<sup>404</sup> Further, it is now clear that no hybrid embryo between human germ cells and germ cells of animals may be created.<sup>405</sup> Prior regulations contain further, more detailed restrictions. These regulations have been adopted pursuant to an advisory group opinion released by the Ethics Committee of the Chinese National Human Genome Center in early 2001 at Shanghai. Among these further, detailed restrictions are the

<sup>&</sup>lt;sup>401</sup> See article 4 Guiding Principles: "Any research for human reproductive cloning shall be prohibited" and article 6(2) Guiding Principles: "...the implantation of the human blastula which has been used for research into human or other animal's reproductive system is prohibited." The prohibition was already expressed in 1998 by the MOH, see *Döring* (2004) at 40.

<sup>&</sup>lt;sup>402</sup> So the foreign ministry of the PRC in a Declaration on 28 October 2003 at the UN negotiations on an international Convention against the reproductive cloning of human beings, available at http://www.fmprc.gov.cn/eng/wjb/zzjg/tyfls/ty fl/2626/2627/t25966.htm.

 $<sup>^{403}</sup>$  See article 5: "The human embryonic stem cell used for research can be derived only by: (1) spared gamete or blastula after IVF; (2) fetal cells after natural or voluntary selective abortion; (3) blastula or monosexual split blastula by somatic cell nuclear transfer technique; and (4) germ cells voluntarily donated".

<sup>&</sup>lt;sup>404</sup> For the 14 day-old embryo as a demarcation line for permissible research, see also the legislation in the UK as described above at B.II.2.a) aa) and in Spain, above at B.II.2.b) aa).

<sup>&</sup>lt;sup>405</sup> See article 6: "The conduct of human embryonic stem cell research must comply with the following norms: (1) when a blastula is obtained by IVF, the somatic cell nuclear transfer technique, the monosexual reproduction technique or genetic modification, the culture period *in vitro* cannot be more than 14 days since fertilization or nuclear transfer;... (3) the hybrid between human germ cells and germ cells of other species is prohibited."

following: The first choice to derive totipotent stem cells for research is from aborted fetal primordial germ cells or supernumerary IVF embryos. Prohibited are the following procedures: Mixing human and animal gametes or embryos to make chimeras; adding any external gene into the embryo, or replacing the nucleus of the embryo with any other human or animal nucleus; coercing or inducing donors to be pregnant and undergo abortion or manipulate the method and time of abortion; selling and buying human gamete, embryo or fetal tissue. Further, ethical review, monitoring, inspection, and ethics training are required.<sup>406</sup>

# bb) The ongoing debate

In its efforts of regulating human cloning and embryo research, China finds itself torn between the necessity to formulate ethical regulations in medicine and aspirations to become a global player in the biomedical sciences.<sup>407</sup> Without any doubts, China is seeking a prominent place in genetics and genomics<sup>408</sup> – a new technological area with enormous economic opportunities in which the race to technological leadership has not been won by the Western countries yet.

What could the future, possibly conservative legislation look like? As of now, the transfer of an embryo into the uterus seems to demarcate

<sup>&</sup>lt;sup>406</sup> The regulations are to be found in an (unofficial) English translation by Zhai, Executive Director, research center for bioethics, Chinese Academy of Medical Sciences & Peking Union Medical College, see *Zhai* (2004) at 5-10.

<sup>&</sup>lt;sup>407</sup> See, e.g., article 1 Guiding Principles 2004: "The present Guiding Principles are formulated for the purpose of keeping the research of human embryonic stem cells in the biomedical field of our country in line with the ethical criterion of life, ensuring the respect to and observance of internationally recognized ethical standards of life and the relevant provisions of our country, as well as promoting the healthy development of the research on human embryonic stem cells."

<sup>&</sup>lt;sup>408</sup> See *Sentker* (2004). See also *Döring* (2003) at 233; *Dennis* (2002) at 334-335. In that context, the government encourages private engagement and joint ventures in establishing biomedical research, see *Normile/Pennisi* (2002) at 32-36; *Swinbanks* (1999) at 178. The tenth Five-Year-Plan (2001-2005) includes app. 600 million USD of direct public investment, and venture capital is invited to share the optimism for growing profits, especially in applied genetics. The authorities have, in fact, given away some of their power, leaving strategic decisions and company policies to the discretion of scientific experts and entrepreneurs outside the political center, see *Böschen/Döring* (2001).

the line between research and medical treatment. Manipulation *in vitro* might be permitted, but implantation into the female system is a taboo. The use of the cloning technology for human reproduction will probably never be endorsed in China, however, the debate in other areas, mainly therapeutic cloning, will continue.

After successful contributions to the Human Genome Project<sup>409</sup> and the Rice Genome Project<sup>410</sup>, China is now on the threshold of openly engaging in a policy-making controversy at the core of biomedical ethics. The common practice of abortion as a means of family planning in China has fuelled a general impression that early human life receives relatively low esteem. Accordingly, China could be expected to promise low ethical standards and huge quantities of biological material for human embryo research. As the China expert Ole Döring put it, "this judgment is certainly premature and unfair, as far as it presupposes a positive decision in favour of killing an embryo or a fetus."<sup>411</sup> At the same time, "confidence in efficient action for the protection of early human life is untimely, too."<sup>412</sup>

For the time being, it may be concluded that in China, the destruction even of an early human life form needs to be justified by high-ranking medical purposes, which are not expected to be achievable otherwise.<sup>413</sup> Such a position to therapeutic cloning may well be interpreted to be pragmatic; a new regulation could possibly follow Western standards, should China decide that it wishes to present itself as a reliable international partner.

What is striking at this point in time is that Chinese scientists themselves seem to push for clear regulations. One particular suggestion of Chinese and French scientists should be highlighted which arose in the context of a recent scientific achievement.

<sup>&</sup>lt;sup>409</sup> See *Cyranoski* (2001) at 10-12.

<sup>&</sup>lt;sup>410</sup> See Normile/Pennisi (2002) at 32-36.

<sup>&</sup>lt;sup>411</sup> See *Döring* (2003) at 237, also referring to *Jing-Bao* (1999).

<sup>&</sup>lt;sup>412</sup> See *Döring* (2003) at 237.

<sup>&</sup>lt;sup>413</sup> See *Qiu*, in: Becker (2000) at 130, 131.

Scientists had transferred the nucleus of a human cell into the somatic cell of a rabbit which led to the creation of "quasi-embryos" (at a success rate of 10-15%).<sup>414</sup> The scientists argued that this construction could not be called "embryo", even if the stem cells derived from those "quasi-embryos" possessed characteristics of embryonic stem cells. The use of the term "embryo", they argued, was restricted to such cells that were able to develop into an adult organism, once placed in the uterus. Any other cells are but "artificial cell constructions". As a result of this new technical procedure, women might practically not have to donate egg cells for the derivation of embryonic stem cells. The ethical stain of using a human embryo only to win stem cells would be removed, since "quasi-embryos" are only artificial cell constructions and not human embryos who possess only some of the characteristics of embryonic stem cells, but especially not those that would be necessary to develop like an embryo until the end – into a normal pregnancy.

The striking result of this new scientific achievement is that somatic cell nuclear transfer can be done from one species to another in order to win stem cells, but without creating an embryo that can develop and eventually result in the birth of a baby.

The challenge of the legislature would then lie not only in formulating a prohibition of human reproductive cloning in the common sense, but to prevent the *implantation* of "quasi-embryos" into the uterus. As can be seen, the challenge wold thus shift from a mere prohibition to a more precise prohibition, namely that of the implantation of embryos.

In its international contributions to biopolitics and bioethics regulations, China has been active in contributing to the setting up of

<sup>&</sup>lt;sup>414</sup> So it was reported by Atlan/Delmas-Marty (2004).

international standards.<sup>415</sup> China has engaged in formulating, and has eventually accepted, the main relevant international declarations and guidelines in bioethics and medical ethics. These include, *inter alia*, UNESCO's Human Genome Declaration; the WHO guidelines on Ethics in Medical Genetics; the endorsement of the World Medical Association Helsinki Declaration on Ethical Principles for Medical Research involving Human Subjects; the UNESCO International Bioethics Committee (IBC) statements on Human Embryo Research and International Solidarity and Cooperation.

These documents form the basis for domestic bio-policy-making and for engaging in the global markets. China seems to attempt to build new regulations based on a universal common ground, yet with Chinese particularities, to honor the special features of China's culture and society.<sup>416</sup>

# f) Costa Rica

As a logical consequence of Costa Rica's general ban on any form of artificial fertilization and consequently also any form of embryo research, Costa Rica knows a total ban of human cloning regardless of its biomedical purpose.

## aa) The regulatory scheme

According to the interpretation of the Costa Rican Supreme Court, the Constitution of Costa Rica requires a prohibition of *in vitro* fertilization. The Supreme Court argued that *in vitro* fertilization violated the right of the unborn to have his life respected, since the *in vitro* fertilization procedures subject the human embryo to a disproportionate risk of death.<sup>417</sup> *A fortiori* the creation of embryos or

<sup>&</sup>lt;sup>415</sup> For instance, China stipulates that biological material can be used only following full informed consent by donors, and reserves claims for all benefits that derive from international biomedical research that uses Chinese sources, see *Dickson* (1998) at 5.

<sup>&</sup>lt;sup>416</sup> See *Döring* (2003) at 233.

<sup>&</sup>lt;sup>417</sup> See Costa Rica Supreme Court, judgment of 15 March 2000 (Res 2000-02306). The case was brought against a regulation which in one of its provisions permitted

the use of embryos for research purposes must be prohibited by statute which in turn automatically embraces cloning.

The Constitution's mandate to protect the embryo is put in place by article 11 of a regulation on assisted reproduction which provides that "...any manipulation or alteration of an embryo's genetic code is prohibited, as well as any kind of experimentation with embryos."<sup>418</sup> One should assume that an offence against this prohibition is criminally sanctioned with imprisonment.

#### bb) The ongoing debate

It is remarkable, that Cost Rica's strict ban on any kind of embryonic research is not strongly disputed within the Latin American scientific community.<sup>419</sup> Within this community, there seems to be a consensus on the point that research on embryos is only acceptable when it is foreseen that the embryos will not be affected as a result of the research. Even if the progenitors authorize research that entails a mortal danger, the right to life of the embryo should take priority and be safeguarded by the medical team.<sup>420</sup>

A characteristic feature of Costa Rican politics is the high prevalence of Catholicism. Religion does have a great impact on reproductive issues.<sup>421</sup> and explains an overall prohibitive policy design.

ordinary in vitro fertilization for reproductive purposes (Decree No. 24029-S of 3 March 1995). Such a strict interpretation of the individual's right to have his life respected also resounds in the Declaration of Human Rights of the American States which states that "... every person has the right to have his life respected. This right shall be protected by law and, in general, from the moment of conception on. No one shall be arbitrarily deprived of his life." This provision has been interpreted by many countries in the region as granting personhood status to the human embryo, and therefore has been used as a guiding source for adopting policies restricting or prohibiting any research or manipulation of the human embryo, see Isasi et. al. (2004) at 11-13. <sup>418</sup> Regulation on Assisted Reproduction, Decree No. 24029-S of 15 March 2000.

<sup>&</sup>lt;sup>419</sup> This community is to a certain degree represented by the Red Latino americana de Reprodicción Asistida, an association of Latin American scientists, constituted in 1994 in Chile. The purpose of the association is to provide guidance to legislators, health authorities, women's organizations and the general public, see Red Latino americana de Reprodicción Asistida (1995).

<sup>&</sup>lt;sup>420</sup> Which individual clinicians supposedly agree to abide by, see *Luna* (2002) at 34. <sup>421</sup> See *id* at 31.

Catholicism being the State religion, strong political pressure and lobbying exist and so does large adherence to the Catholic views on the moral status of the human embryo.<sup>422</sup> As Zegers-Hochshild points out, "in Latin America, legislators have preferred to legislate in literal conformity to principles emanating from moral teachings of the Catholic Church."<sup>423</sup>

This will explain why Costa Rica takes such a strong political stance in the UN negotiations and leads the group of "maximalists" aiming at a complete ban on human cloning. The fact that Costa Rica cannot point to a corresponding explicit domestic law does hardly weaken its political weight at the negotiating table: Costa Rica argues that the complete ban of human cloning is so clearly emanating from the Costa Rican Constitution - all faithful to the covenant of the state with Catholicism - that no explicit formulation of a prohibition in the frame of a basic law was ever necessary. Swinging the sword of the Catholic Church, also in the name of other Latin American countries, gives Costa Rica a position that can hardly be questioned, let alone be ignored.

# 3. Conclusion

The law in the six countries analyzed differs significantly, with the United States having no explicit Federal ban on human therapeutic and reproductive cloning, and only a weak administrative quasi-ban on reproductive cloning; Germany, Spain, and Costa Rica banning all forms of human cloning, and the United Kingdom and China prohibiting reproductive cloning only while permitting therapeutic cloning and stem cell research.

<sup>&</sup>lt;sup>422</sup> See generally *Zegers-Hochschild* (1999) at 21-25. See also the Vaticans Pontifical Academy of Life, February 2004, in which the Vatican condemns all treatments used to create life without sexual intercourse between a married-heterosexual couple and states that the "natural act of conception cannot be replaced by technological intervention." Regarding research on embryos, the Vatican further called the "destruction or loss of embryos in the *in vitro* process a massacre of the innocents in our time", quoted in *id*. at 23.

<sup>&</sup>lt;sup>423</sup> See Zegers-Hochschild (1999) at 23.

Altogether, two observations can be made. There is a joint element in all six states' positions regarding a prohibition of the practice of human reproductive cloning – even in the United States who has not passed Federal legislation yet, the call for a statutory prohibition of reproductive cloning is undisputed.

The point of divergence regards the practice of the production of cloned human embryos for the purpose of isolating embryonic stem cells, i.e. therapeutic cloning. This is, because the degree to which the human embryo is protected in general varies significantly. Spain and the United Kingdom allow for the procurement of human embryonic stem cells from supernumerary IVF embryos by law. Germany prohibits this but allows by law the import and use of (pluripotent) human embryonic stem cell lines under certain conditions. Like Germany, Costa Rica prohibits the procurement of human embryonic stem cells from supernumerary embryos, albeit not explicitly.

As regards the creation of embryos, the United Kingdom and some U.S. states allow by law the creation of human embryos for research purposes; China does so through institutional guidelines. Germany and Spain prohibit the creation of human embryos for research purposes and for the procurement of stem cells, the former by law; the latter also by ratification of the Biomedicine Convention of the Council of Europe. Costa Rica prohibits the same, but through a constitutional court ruling.

The two extreme positions seem to be absolute protection of the embryo *in vitro* (Germany, Costa Rica, and the United States, as expressed at the United Nations by the current U.S. government of President George W. Bush) and relative protection (the United Kingdom, China). Spain should be placed in between these two camps.

It is stringent to assume that even among only six UN member states – and these are among the lead delegations in our particular UN

negotiations - the divergence in national laws is irreconcilable by international law with respect to embryo protection and thus also the whole subject of therapeutic cloning: The divergence in views leads to two political positions which steer the efforts of a UN Convention in different, if not alternative directions.

Naturally, countries whose embryo research scheme is liberal will further a partial ban on reproductive cloning only in order to engage in therapeutic cloning. Conversely, countries who have strict embryo research schemes will aim at a total protection of the embryo. The prohibition they are seeking through a Convention is that of the production (through somatic cell nuclear transfer and other procedures) and the use of embryos for research purposes. This is an entirely different objective.

In that sense, the six countries were later split into two at the UN negotiations, with undecided Spain in between, not because of the scope of a prohibition on reproductive cloning, but because of aiming at a fundamentally different outcome of a Convention: A prohibition of reproductive cloning in an attempt to safeguard human dignity<sup>424</sup> versus a restrictive regulatory scheme governing the production and consumption of embryos.<sup>425</sup> To associate both objectives can be promising only among states that share a common or at least similar view on embryo protection.

As will be seen however, countries such as Germany who are domestically committed to a total ban but wish to pursue a realistic scope for a UN Convention are able to agree to a pragmatic approach. Even Costa Rica, among the strongest advocates of a total ban, has in the past agreed to regulating a partial ban as it has co-adopted UNESCO's Human Genome Declaration. So has Spain, which also

<sup>&</sup>lt;sup>424</sup> This is the group we later call the "minimalists" supporting L.8.

<sup>&</sup>lt;sup>425</sup> This is the group we later call the "maximalists" supporting L.2. Such a regulatory scheme would still address the issue of reproductive cloning by simply prohibiting it, similar to the provision of the Council of Europe's Additional Protocol.

ratified the Council of Europe's Protocol to the Biomedicine Convention.

From the perspective of our country analysis, we may conclude that, despite the differing scope of national legislations on human cloning, a consensual solution is not wholly unthinkable. The prohibition of cloning for reproductive purposes remains a common denomitor - as different as the legal environment that this prohibition is embedded in may be.

Let us also look at the experience with the Council of Europe's Biomedicine Convention and UNESCO's Human Genome Declaration, which might lead us to further conclusions: Although both documents were negotiated successfully, the eventual textual result may overshadow that some issues of biotechnology are, at least to a certain extent, inaccessible to regulation by means of a legally binding Convention.

UNESCO's document is, as was mentioned earlier, not legally binding. One would assume that this would have facilitated the member state's flexibility and commitment on substance: Delegations can agree on issues that they would be unable to accept in the context of a legally binding instrument.<sup>426</sup> And yet, the member states were only able to agree, in article 11 of the Declaration, on naming reproductive cloning as a practice which is contrary to human dignity. An agreement on therapeutic cloning or embryo research could not be reached.<sup>427</sup>

A similar analysis can be drawn from experiences at the Council of Europe, although the member states represent a culturally relatively homogenous group which is also, compared to the United Nations'

 <sup>&</sup>lt;sup>426</sup> On the presumed incentive of states to join legally non-binding texts, see generally *Hathaway* (2004).
 <sup>427</sup> For a detailed (informal) report of negotiations of the Declaration which spells

<sup>&</sup>lt;sup>427</sup> For a detailed (informal) report of negotiations of the Declaration which spells out, *inter alia*, the dynamics in the course of four years of negotiations and the main opposing views see *Lenoir* (1999) at 537-587. See also the Council of Europe's explanatory report in *Council of Europe* (1998a).

191 member states, relatively small. It groups together 45 countries, including 21 countries from Central and Eastern Europe.

In view of the Convention, the goal of the Council of Europe was "to set out common general standards for the protection of the human person in the context of the development of the biomedical sciences", and not even to regulate specific aspects, such as human reproductive or therapeutic cloning. And yet, it took the Council seven years to come to its result. The original proposals were discussed and amended in years of at times painful debates.<sup>428</sup> In contrast, the Additional Protocol to the Convention expressly prohibiting reproductive cloning but preempting therapeutic cloning was established in only one year as there was a consensus on the issue among the member states. But despite the restricted scope of the Protocol, only 14 member states have so far ratified it. Surprisingly, countries such as Germany<sup>429</sup> and the United Kingdom<sup>430</sup> have not yet done so although they could, according to their national legislation, agree to a ban on reproductive cloning. If countries that have corresponding national positions display such hesitation even regarding a narrow scope, how likely will it be that a UN Convention would embrace other countries that have less developed national laws, especially on the issue of therapeutic cloning which is discussed more controversially than reproductive cloning? This seems to suggest that a broader scope than the one focused on by the Council of Europe, including the regulation of human therapeutic cloning, is an unrealistic goal from the very  $outset^{431}$  – at least if countries remain committed to the goal of winning the race against

<sup>&</sup>lt;sup>428</sup> See the elaborate reviews of the process of negotiations in the Council of Europe from *Röspel* (1997) and *Degener* (1998) at 7-33.

<sup>&</sup>lt;sup>429</sup> Germany claims that the Protocol is not strong enough since it does not forbid all research on human embryos, quoted by *Erlanger* (2001) at A4.

 <sup>&</sup>lt;sup>430</sup> The United Kingdom found the Protocol too restrictive, quoted by *Lowrie/Reuters/The Associated Press* (1998).
 <sup>431</sup> See *Simitis*, in: Vöneky/Wolfrum (2004) at 174, 175 who agrees with this

<sup>&</sup>lt;sup>431</sup> See *Simitis*, in: Vöneky/Wolfrum (2004) at 174, 175 who agrees with this analysis. With regard to Declarations, "the participants can agree on points they would never accept in the context of a Convention, unless they never intended to ratify and really apply the Convention and thus never meant for it to be binding."

irresponsible scienctists and prohibiting human reproductive cloning before the first clone is born.

Limiting the scope of a future UN Convention to a prohibition of reproductive cloning even seems promising taking into account those countries whose final goal is to reach a UN Convention on a complete ban of cloning.<sup>432</sup> For it is notable that some of these countries signed the Council of Europe's Protocol and thus agreed to a partial ban on reproductive cloning, namely Spain, Italy, and Portugal. Likewise, these same countries have, as UNESCO member states, agreed to the UNESCO Declaration which also just spells out a partial ban.

Given the overall experience the international community has made with the two documents of UNESCO and of the Council of Europe, prohibiting reproductive cloning only at this point in time in a UN Convention seems preferable and more promising than to negotiate a comprehensive prohibition or regulation of human cloning.

# C. The history and the achievements of the UN negotiations aiming at a Convention against human reproductive cloning

Over a period of almost three years, from February 2002 until November 2004, the member states of the United Nations were negotiating on a possible prohibition of human reproductive cloning through a UN Convention.

The subject of biomedicine is new to international law and human cloning is even newer. The debates on a prohibition in the forum of the UN General Assembly, the Sixth Committee and special Sub-Committees have insofar broached questions, highlighted affinities

<sup>&</sup>lt;sup>432</sup> For a list of such countries, see the list of co-sponsors of a draft Convention against "human cloning" L.2.

and roused controversies that had, until then, at least to a large extent,<sup>433</sup> been left plain by international treaty law.

The first steps of the international community towards the formulation of a prohibition of human reproductive cloning therefore set an important precedent. We may assume that what the General Assembly failed to attain - the agreement on a mandate for negotiations on a Convention against reproductive cloning - will be revisited in other multi-lateral attempts at prohibiting cloning. The forthcoming report and analysis of the history and achievements of the negotiations shall help perceive the relevant issues and their consensual elements, but also the weak points of the German-French initiative as it was initially envisaged.

# I. Introduction: The initiative of Germany and France for an international Convention

It was thanks to the idea of German diplomat Joachim Schemel in May of 2001 that foreign minister Joschka Fischer was sought to initiate negotiations at the United Nations aiming at a prohibition of human reproductive cloning.

# 1. Laying the headstone at the German foreign ministry

In a letter to the minister<sup>434</sup>, it was held that while a comprehensive international Convention regulating human cloning comprehensively was desirable, a first step in that direction would be the prohibition of human reproductive cloning since, on this particular issue, consensus among UN member states was assumed. A comprehensive Convention on the other hand, regulating also therapeutic cloning, was, with regard to the ongoing international debate about ethical questions on embryo research, an unrealistic aim, at least for the time being.

<sup>&</sup>lt;sup>433</sup> See above at B.II.1.

<sup>&</sup>lt;sup>434</sup> The letter, dated 31 May 2001, is at the hands of the author.

The initiative would be in coherence with foregoing UN resolutions on "Human Rights and Bioethics" under the Commission on Human Rights,<sup>435</sup> in particular resolution 2001/71 of the 57<sup>th</sup> Human Rights Commission, in which the UN Secretary-General was invited to "consider establishing a Working Group of independent experts … which would reflect, in particular, on the follow-up to the Universal Declaration on the Human Genome and Human Rights and report to the Secretary General within a period determined by him …" (operative paragraph 4). From among these comprehensive considerations, the German-French initiative against reproductive cloning would choose and consider one particular aspect. The proposed legal instrument would also build upon UN General Assembly resolution 53/152 of 1998 which endorsed that Declaration.

France was considered as a lead partner to advocate the suggested negotiation goal. At the time, Germany and France had similarities in their respective national legislation.<sup>436</sup> Also, a close collaboration of the two European states would send a welcome political signal to the international community of states. And France had, due to its significant contributions to the successful elaboration of UNESCO's Human Genome Declaration, considerable experience on the substance matter.

As for the venue for negotiations, it was argued that the United Nations General Assembly and its Sixth Committee would be the appropriate forum to negotiate such a Convention. The issue at hand was of a multi-disciplinary character and could not be dealt with comprehensively under other specialized UN agencies, such as

<sup>&</sup>lt;sup>435</sup> See UN Commission on Human Rights Resolution 2001/71 on Human Rights and Bioethics, 25 April 2001; Resolution 1999/63 on Human Rights and Bioethics, 28 April 1999; Resolution 1997/71 on Human Rights and Bioethics, 16 April 1997; Resolution 1995/82 on Human Rights and Bioethics, 8 March 1995; Resolution 1993/91 on Human Rights and Bioethics, 10 March 1993.

<sup>&</sup>lt;sup>436</sup> The French Bioethics Law of 1996 prohibited all types of cloning procedures, similar to the German Embryo Protection Act of 1999.

WHO, UNESCO or the Human Rights Commission, who naturally have a limited mandate and competence. Also, to refer this issue back to international agencies that had already "done the possible" in elaborating the respective instruments could be circular – rather, it had to be pushed forward in a new organizational framework.

With respect to the idea of reaching as many states as possible with a Convention, the United Nations had the greater number of member states. The United States, for instance, was not a member state to UNESCO at the time of the decision on the venue<sup>437</sup> and it would not serve the purpose of universality to leave out the politically most powerful state worldwide from this undertaking.

Finally, according to the reasoning of German diplomats, a negotiation result could be accelerated within the context of the General Assembly, much rather than in the context of UNESCO, WHO, or the Human Rights Commission, mainly because the supreme body of the United Nations was the most experienced gathering of states in dealing with cross-cutting issues, and in negotiating treaties.

Minister Fischer agreed to the proposal as it was made and ordered his diplomats in New York to get the move going at the United Nations.

### 2. Negotiations in the context of the UN General Assembly

#### a) Development and codification of international law

According to article 13(1)(a) of the UN Charter, the General Assembly shall initiate studies and make recommendations for the purpose of promoting international cooperation in the political field and encouraging the progressive development of international law

<sup>&</sup>lt;sup>437</sup> The United States had withdrawn from UNESCO in 1984 under President Ronald Reagan. It was only in late 2002 that President George Bush decided to rejoin the organization, see "Fact sheet: United States rejoins UNESCO", 38(4) Weekly Comp. Pres. Doc. 1540 of 12 September 2002.

and its codification. Codification and progressive development of international law have since then become subject of ongoing debate among member states under the auspices of the United Nations: For the purpose of fulfilling the mandate of article 13(1)(a), the General Assembly has established the International Law Commission (ILC), the United Nations Commission on International Trade Law (UNCITRAL) and the Sixth Committee, as well as a variety of Ad Hoc Committees.

The work of codification and progressive development in the institutional framework of the General Assembly is diplomatic in its nature as it aims at ministering to the interests of the member states.<sup>438</sup> In practice, this means that the General Assembly is not entitled to legislate and impose new rules, rights, and obligations upon member states, since the community of states has not conferred such a power upon the General Assembly.<sup>439</sup> Rather, the role of the General Assembly is limited to the deliberation, the drawing up of texts, adopting and recommending them for signature, ratification, and accession. It then lies in the descretion of the member states to make a decision according to their own political will and constitutional transgressions.<sup>440</sup> Accordingly, decisions of the General Assembly are not legally binding and are taken by a simple majority by the states voting.<sup>441</sup>

<sup>&</sup>lt;sup>438</sup> See *Fleischhauer*, in: Simma (2002) at article 13, margin no. 4.

<sup>&</sup>lt;sup>439</sup> See *id*.

<sup>&</sup>lt;sup>440</sup> However, irrespective of the entry into force of individual Conventions, much of the materials produced by the General Assembly and its subsidiary organs in this field will have influence on the evolution of international law as a subsidiary means for determining rules of law similar to those mentioned in article 38(1)(d) of the ICJ Statute.

<sup>&</sup>lt;sup>441</sup> Among the legally binding decisions of the General Assembly are, for instance, the election of the non-permanent members of the Security Council, the elections of the member of ECOSOC, the initiation of new states as UN member states, see *Tomuschat* (1995) at 550. All such decisions need a two-third majority of the member states present.

### b) The power to make recommendations

The General Assembly, under article 10 of the UN Charter, also has the power to make "recommendations". Whether the General Assembly makes use of its power of recommendation is generally at its discretion; in the case of article 13(1), it even has a duty to make recommendations.

In practice, acts of the General Assembly are issued in the form of "resolutions", "declarations" or "decisions". The term "declaration", which is relevant in the context of the cloning treaty<sup>442</sup>, is not contained in the Charter. It is used by the General Assembly for resolutions which "claim to express political or legal principles of particular importance, which sometimes intend to embody general rules of public international law".<sup>443</sup>

As for all recommendations, they are non-binding exhortations describing "a legal act which expresses a desire, but which is not binding on the addressees".<sup>444</sup> Over time, declarations may acquire a binding legal status by way of customary international law, article 38(1)(b) of the ICJ Statute.<sup>445</sup>

# c) The Sixth Committee

The Sixth Committee of the General Assembly consists of representatives of all member states, each with an equal vote. Its

<sup>&</sup>lt;sup>442</sup> See below at C.V.3 and C.VI.

<sup>&</sup>lt;sup>443</sup> See *Hailbronner/Klein*, in: Simma (2002) at article 10, margin no. 41.

<sup>&</sup>lt;sup>444</sup> See *Tomuschat* (1975) at 511. However, in keeping with the UN claim of universality, resolutions passed with a particularly qualified majority can attain a legally binding effect.

<sup>&</sup>lt;sup>445</sup> A prerequisite for the creation of customary international law is a uniform and consistent state practice, coupled with the conviction of the states that their actions satisfy a legal obligation, see North Sea Continental Shelf, ICJ Reports (1969) at 44. Beyond this, some scholars view Declarations of the General Assembly as new sources of public international law when they meet the following criteria: The necessary degree of agreement when the resolution is passed; a wording which confirms the legal nature of the resolution; sufficient conviction of the states as to the legally binding force of the resolution; a degree of enforcement based on subsequent practice of the members over a definite and limited period of time, see *Ellis* (1985) at 692-702. On whether we can already assume the existence of customary international law regarding a prohibition on human reproductive cloning, see below at D.V. with further references.

function in general is to consider and negotiate draft resolutions before they are placed before the General Assembly.<sup>446</sup>

The agenda of the General Assemblys Sixth Committee is limited.<sup>447</sup> allowing it to address each item at great length. Its function is to negotiate the text of treaties and agreements - a time consuming process,<sup>448</sup> especially since the Committee adopts all items by unanimous consent. The consensus principle is however not a procedural rule but a tradition that the Sixth Committee has been following. In that, the Sixth Committee functions different to the Third Committee which adopts many resolutions by vote.

Due to its subject matter, the negotiation of a draft Convention against reproductive cloning could have been negotiated under the auspices of either the Third (Social, Humanitarian and Cultural Committee) or the Sixth Committee (Legal Committee). Despite the procedural obstacle of unanimity, Germany favoured to entrust the elaboration of a Convention upon the Sixth Committee – for practical and substantial considerations.

German diplomats, in the letter to the Minister<sup>449</sup>, reasoned that the envisioned Convention should contain provisions that are universally acceptable. Getting only a majority of votes for its Convention text would be a much weaker starting point for a drive for universal ratification. The Sixth Committee consists of jurists who, in their work, traditionally aim at consensus. As much as the consensus requirement could become an obstacle to reach any outcome, it could also advance the goal of an effective, i.e. worldwide ban on reproductive cloning.

<sup>&</sup>lt;sup>446</sup> For a detailed introduction to the work of the Sixth Committee, see UN website at http://www.un.org/ga/58/ga background.html.

<sup>&</sup>lt;sup>447</sup> In its 59<sup>th</sup> session in 2004, for instance, the Sixth Committee had before it an agenda with only 19 items to be negotiated, see http://www.un.org/law/ cod/sixth/59/sixth59.htm.

<sup>&</sup>lt;sup>448</sup> For example, the Sixth Committee spent 30 years negotiating the definition of aggression, see *Nyiri* (1989). <sup>449</sup> See FN 434.

Also, the drafting of an enforcement instrument in the form of a legally binding Convention requires specific legal expertise, chiefly to be found in the Sixth Committee, whereas the Third Committee usually drafts legally non-binding (human rights) resolutions, which are less a matter of legal drafting than of political horse-trading.

Finally, the Third Committee's work is generally highly politicized due to heightened media and NGO attention, which could have delayed the process of drafting a Convention text.

# *d)* The launching of negotiations: Selection of the topic and the mandate

Member states of the United Nations, pursuant to rule 14 of the Rules of Procedure of the General Assembly, can request for an item to be placed on the agenda of the UN General Assembly.

Before negotiations on the text of a Convention can be launched, the General Assembly has to confer a mandate on the Sixth Committee, defining an assignment of a particular item of deliberation to the Committee. The mandate is conferred through a General Assembly resolution.

Under rule 102 of the Rules of Procedure of the General Assembly, the Sixth Committee, like all other main Committees, has the competence to create its own subsidiary organs. An Ad Hoc Committee or a Working Group of the Sixth Committee can therefore be entrusted with the task of elaborating such a mandate.<sup>450</sup> The Committee or Working Group then proposes the outcome of their work – a draft mandate – to the Sixth Committee which passes it on to the plenary of the General Assembly. Both organs need to agree with the draft mandate consecutively. The final decision of the plenary of General Assembly is generally based on a

<sup>&</sup>lt;sup>450</sup> Delegating the elaboration of legal instruments to "Special Committees" has become a regular method of the Sixth Committee, see *Fleischhauer*, in: Simma (2002) at article 13, margin no. 45.

recommendation of the Sixth Committee, contained in the report of the Committee to the plenary on its work.<sup>451</sup>

The mandate for a negotiation can already lay down the actual outcome or main contents of a Convention. In our particular negotiation, it could for instance decide that a "Convention against human reproductive cloning" should be elaborated. The mandate could also be only a procedural provision and, for instance, state that "the elaboration of a Convention regarding human cloning should be considered".

Once the mandate is decided on, the Working Group of the Sixth Committee or an Ad Hoc Committee starts drafting the specific provisions of the Convention.

# 3. Negotiation strategy: Inductive process of talks

Germany and France had an "inductive" process of negotiation in mind.<sup>452</sup> Instead of presenting the negotiating parties with a ready-formulated draft Convention, the idea was to build up a consensus through a joint learning process. This approach took account of the fact that the codification of bioethical matters was virgin territory for the UN General Assembly and the diplomats could not be expected to possess the necessary specialist knowledge.

Specifically, Germany and France proposed that initially – if possible within one year – the "mandate for negotiation" should be worked out in which the legal issues to be covered by the proposed Convention would be set out. This was to be preceded by hearings involving independent experts from the fields of genetics and bioethics.

<sup>&</sup>lt;sup>451</sup> See rule 65 of the Rules of Procedure of the General Assembly.

<sup>&</sup>lt;sup>452</sup> German diplomats agreed on this inductive approach in informal meetings, the minutes of which are at the hands of the author.

# 4. Getting the move going: The initiation of the UN negotiations

Germany and France launched their initiative without delay or difficulties. Their application submitted on 7 August 2001<sup>453</sup> to the General Assembly for the question of an "International Convention against the reproductive cloning of human beings" to be placed on the agenda of the UN General Assembly's fifty-sixth session (2001) pursuant to rule 14 of the Rules of Procedure of the General Assembly, was accepted by consensus on 19 September 2001.<sup>454</sup> The Sixth Committee was designated to consider the item and to negotiate a draft mandate.

In these initial negotiations<sup>455</sup> in the Sixth Committee in early November 2001, it was noted that the recent announcement by certain laboratories of their intention to proceed with the cloning of human beings raised serious concerns, and justified the taking of urgent measures to prevent such actions. All speakers<sup>456</sup> supported the proposal to establish an Ad Hoc Committee to negotiate a mandate for the future development of such an international agreement.

Finally, on 19 November 2001, the representative of France, also in the name of Germany, introduced a draft resolution to the Sixth Committee<sup>457</sup> which had been negotiated among the UN member states without major difficulties in the two preceeding weeks. At the same meeting, the Committee adopted the draft resolution (which was to be reviewed and agreed upon by the General Assembly) without a vote. Its core elements entailed the need to focus on the prohibition of reproductive cloning; the appointment of an Ad Hoc

<sup>&</sup>lt;sup>453</sup> Letter dated 7 August 2001 with explanatory memorandum and draft resolution, UN Doc. A/56/192.

<sup>&</sup>lt;sup>454</sup> UN Doc. A/56/PV.3 at 7.

<sup>&</sup>lt;sup>455</sup> The author was present at these negotiations. The following report is based on her own observations and minutes.

<sup>&</sup>lt;sup>456</sup> Germany (also on behalf of France), Israel, Japan, the Russian Federation, Malta, Canada, Poland, Grenada, Lithuania, the Libyan Arab Jamahiriya, Venezuela, Uganda, Cuba, Peru, the former Yugoslav Republic of Macedonia, Haiti and Nigeria.

<sup>&</sup>lt;sup>457</sup> UN Doc. A/C.6/56/L.19.

Committee in February 2002 to draw up a mandate for negotiation on the basis of a "list of legal issues to be addressed" and "with regard to relevant international precedents".<sup>458</sup> Also, expert hearings were to take place at the start of the Ad Hoc Committee's activities.<sup>459</sup>

The draft resolution is contained in the report of the Sixth Committee to the General Assembly<sup>460</sup> which recommends to the General Assembly the adoption of the draft resolution. The General Assembly, at its fifty-sixth session (2001) on 12 December 2001 adopted the draft resolution without a vote.<sup>461</sup> With this resolution, the General Assembly decided "to establish an Ad Hoc Committee, open to all States Members of the United Nations or members of specialized agencies or of the International Atomic Agency, for the purpose of considering the elaboration of an international Convention against the reproductive cloning of human beings".<sup>462</sup>

Notable in this paragraph is the formulation "against the *reproductive cloning* of human beings". It should be understood as a provision of substance and thus restricts the mandate of the Ad Hoc Committee to elaborating a prohibition of reproductive cloning without considering therapeutic cloning. Also, the General Assembly decided, in operative paragraph seven, to include in the agenda of its next (fifty seventh) session the item entitled "International Convention against the *reproductive* cloning of human beings".

During the debate in the Sixth Committee, some speakers, most notably the U.S. delegation, had however noted that the resolution was primarily procedural in nature and did not prejudice the final

<sup>&</sup>lt;sup>458</sup> See annex to UN Doc. A/56/599, para. 3. Both the "list of legal issues" and the "list of international precendents" did not exist at the time. Following a common UN practice for such "support documents", the lists were to be provided by the UN Secretariat, in this case in cooperation with the German and French delegations. <sup>459</sup> See annex to UN Doc. A/56/599, para. 3

<sup>&</sup>lt;sup>460</sup> UN Doc. A/56/599.

<sup>&</sup>lt;sup>461</sup> UN Doc. A/56/PV.85 at 13.

<sup>&</sup>lt;sup>462</sup> General Assembly resolution 56/93, operative paragraph 1, UN Doc. A/56/93.

outcome of the Ad Hoc Committee's work.<sup>463</sup> Instead, the Committee had been entrusted with the task of considering the elaboration of the mandate for the proposed Convention. As such, the scope of the Convention could not be considered as having been predetermined by General Assembly resolution 56/93. Further, the resolution says "*considering* the elaboration …". The Ad Hoc Committee could therefore come to the conclusion that the General Assembly should not elaborate on a Convention, but, for instance, refer the issue to another UN agency, such as WHO or UNESCO – an argument that was later made by several delegations.

This debate remained unresolved. It should be noted however that preliminary talks in the preparation of resolution 56/93 made it clear that reproductive cloning was the sole object of talks. Above all, the German-French initiative had a very specific and only goal in mind: It was the counterreaction to announcements of scientists in 2001 to clone human beings.<sup>464</sup> With the referral to article 11 of UNESCOs Human Genome Declaration and the endorsement of the Declaration through the UN General Assembly, this was accentuated even more.<sup>465</sup>

It is remarkable that as many as 47 states identified themselves as "co-submitters" of the German-French initiative, including some that were later to be among its most bitter opponents (e.g. Spain and Costa Rica).<sup>466</sup> Through the adoption of the resolution, the General Assembly condemned human reproductive cloning as being a

<sup>&</sup>lt;sup>463</sup> See summary of the work of the Sixth Committee under agenda item 174 at http://www.un.org/law/cod/sixth/56/summary.htm#174.

<sup>&</sup>lt;sup>464</sup> See *Mueller-Jung* (2001a) at 9; *Mueller-Jung* (2001b) at 49; *Mueller-Jung* (2001c) at 41; *Maak* et. al. (2001) at 44, 45.

<sup>&</sup>lt;sup>465</sup> See preambular paragraph one and two of UN Doc. GA Res. 56/93.

<sup>&</sup>lt;sup>466</sup> Co-submitters to the resolution were Algeria, Andorra, Austria, Azerbaijan, Bangladesh, Belgium, Brazil, Bulgaria, Canada, China, Costa Rica, Croatia, Denmark, Finland, Germany, Greece, Honduras, Hungary, Ireland, Italy, Jordan, Liechtenstein, Lithuania, Luxembourg, Malta, Monaco, Morocco, Netherlands, Norway, Poland, Portugal, Republic of Korea, Romania, Russian Federation, San Marino, Sierra Leone, Slovakia, Slovenia, Spain, Sweden, Tunisia, United Kingdom and Yugoslavia. Uganda, Cuba, Peru, the former Yugoslav Republic of Macedonia, Haiti and Nigeria, see UN Doc. GA Res. 56/93.

practice contrary to human dignity and thus re-emphasized an existing consensus.<sup>467</sup> Also, the General Assembly, in preambular 6, refers to alarming ongoing efforts of scientists aiming at reproductive cloning – these were at the time Severino Antinori, Brigitte Boisselier and Michael Zavos who were announcing the use of the somatic cell nuclear transfer technique on human beings. This means that the General Assembly at least wanted to prohibit this very technique.

### II. A first round of negotiations envisioning a Convention

The first round of negotiations in the Ad Hoc Committee from 25 February to 1 March 2002<sup>468</sup> were, in accordance with paragraph 1 of resolution 56/93, open to all UN member states. In addition, pursuant to paragraph 2, the Secretary-General was requested to invite the specialized agencies that work and have substantial interest in the field of bioethics, including, in particular, UNESCO and WHO, to participate as observers in the work of the Ad Hoc Committee.

The negotiations had three parts, starting with hearings involving independent genetics and bioethics experts appointed by UNESCO and the WHO with an exchange of information and technical assessments. The hearings were followed by a general exchange of views and a discussion of legal issues to be addressed in the anticipated Convention, on the basis of a document, the "list of legal issues", presented by Germany and France.<sup>469</sup>

<sup>&</sup>lt;sup>467</sup> See also article 11 of UNESCO's Human Genome Declaration which prohibits reproductive cloning, see above at B.II.c).

<sup>&</sup>lt;sup>468</sup> An official summary of the course of the negotiations and their results is to be found in the Report of the Ad Hoc Committee on an international Convention against the reproductive cloning fo human beings, 25 February to 1 March 2002, UN Doc. A/57/51.

 $<sup>^{469}</sup>$  "List of issues that may be addressed in the Convention", UN Doc. A/AC.263/2002/DP.1

## 1. Expert presentations on the scientific, ethical and legal aspects of human cloning

The Ad Hoc Committee altogether held three plenary meetings and three meetings in the context of a Working Group of the Whole.<sup>470</sup> After the Ad Hoc Committee had elected its bureau<sup>471</sup>, the five (independent)<sup>472</sup> experts<sup>473</sup> presented their viewpoints.

In their presentations, the experts gave a well-balanced picture of the science of human cloning, its techniques, risks and expected benefits and the moral implications that "experiments" with human cloning bear.<sup>474</sup> The questions raised by delegations to the experts made it

<sup>&</sup>lt;sup>470</sup> The author was present at all meetings of the Ad Hoc Committee. The following report of the meetings is therefore based on her own observations and minutes. Where statements were made available by delegations, they are quoted. In all other cases, the statements are spontaneous interventions the content of which the author gives account of based on her minutes.

<sup>&</sup>lt;sup>471</sup> Ambassador of Slovakia Peter Tomka as chair of the Ad Hoc Committee; delegates from Germany (Mr. Christian Much), Uganda (Mrs. Rosette Nyirinkindi Katungye) and Trinidad and Tobago (Mrs. Gaile A. Ramoutar) as vice chairperson; delegate from Jordan (Mahmoud D. Hmoud) as rapporteur.

<sup>&</sup>lt;sup>472</sup> The process of appointing the experts for the hearing at the Ad Hoc Committee had been long and complicated. Germany, who had sparked the idea of an experts hearing, was arranging the process of nominating experts. Knowing that UNESCO and WHO would feel competent to take an active role in the cloning negotiations but could not do so due to procedural restrictions (UNESCO and WHO have only an observer status), Germany wanted to at least use their expert knowledge when identifying internationally renowned experts and asked both organizations to together list five experts in the field of biomedicine and bioethics who should, if possible, by their country of origin geographically balance the world's regions. After initial brushes between the two organizations, UNESCO presented a list of experts which WHO finally agreed to. The final choice of experts and the "geographical balance" was briefly discussed at the start of the Ad Hoc Committee meeting in the presence of the experts – with the only criticism coming from Syria and Iraq (with an obvious anti-Israeli spearhead).

<sup>&</sup>lt;sup>473</sup> Prof. Arthur Caplan, United States (1993-95: Chairman of the American Association of Bioethics); Prof. Leonardo De Castro, Philippines (Dean of the Faculty of Philosophy at the University of the Philippines, Member of the IBC); Prof. Cesar Nombela, Spain (Professor of Pharmacy at Complutense University, Madrid); Dr. Carmel Shalev, Israel (Professor of Medical Law at the University of Tel Aviv, WHO Consultant on Ethics); Dr. Fernando Zegers-Hochschild, Chile (Lecturer on Medicine at the Catholic University of Chile; Member of various ethical advisory committees).

<sup>&</sup>lt;sup>474</sup> The experts' presentations were not published as UN documents, but only distributed informally among delegations (they are at the hands of the author). Each expert was describing one particular issue related to human cloning.

**Prof. Nombela** presented on "The basic science of cloning". This included the phenomena of twinning and cloning through somatic cell nuclear transfer. He provided the context for human cloning in terms of work that scientists have done in genetic engineering of plants and animals, referring to the experience to date with cloning in different species and considered the relationship of cloning to other

clear they were not well acquainted with the subject matter, especially the scientific procedure.

All experts agreed that the science of cloning is still, relatively speaking, in its infancy. The techniques ("Dolly type techniques") often fail. The risk, at this point in time, was too high, experiments towards human cloning would be "barbaric" and therefore unethical: While the number of species clones is suggestive of a progression toward the cloning of human beings, in fact the failure rate in all species of animals has been very high and reports abound of poor health among liveborn animal clones of every species.

issues such as mapping the genome, genetic engineering, stem cell research and genetic testing.

**Prof. Zegers-Hochschild** lectured on "Human reproductive cloning: teachings from assisted reproductive technology". He focused on reproductive technology and infertility treatment, and here in particular on how human cloning relates to other techniques for creating human beings, in terms of the biology involved, risks, and what is known or not known. He further discussed the demand for infertility services and considered what the demand for human cloning might be for and why. He also described the current state of biology and clinical practice in creating human embryos.

**Prof. Caplan** talked about "The rights and wrongs of human cloning". He gave a basic description of the interface between the science of cloning and the ethical and social questions raised, including such key questions as what constitutes cloning, what is the moral status of an embryo, is there a right to reproduce, can non-therapeutic research ever ethically be conducted on a human embryo or human clone, who should consent to human cloning if it is to be done, are existing regulations governing human experimentation relevant to human cloning, and who owns and controls the technology involved? The presentation also offered comments on some current policy responses to human cloning in different nations and from different professional and consumer groups.

**Prof. De Castro** presented on the topic "Reproductive cloning: A survey of ethical issues and concerns". He covered the various considerations that govern the thinking about the right to reproduce or create human beings or human embryos in law, philosophy and theology around the world. He commented on questions, such as what sorts of considerations should be brought to bear in thinking about human cloning as a form of human experimentation given the uncertainties that surround the safety of cloning?; what existing forms of regulation and law govern any attempt to clone humans?; what frameworks do we have available for thinking about the moral status of human reproduction including the status of cloned human embryos, parthogenesis, animal-human clone constructs, transformed adult stem cells etc?

**Dr. Shalev** talked about "Reproductive cloning – A Human Rights Framework". She focused on the broader social and ethical significance of thinking about cloning, how cloning relates to our moral views about reproduction, the role of sexual reproduction and the family in human life, the priority which we should give to allowing or encouraging research on human cloning relative to other demands to address important human needs and medical requirements. Her presentation offered a human rights framework and referred to relevant international human rights instruments.

Comparison to the cloning of animals with cloning humans was made: Cloning cannot do what pet owners fantasize. It cannot bring back their dead animals. A cloned animal is not going to have the same mind, behavior or personality as its parent. Clones are genetic copies but genes are not destiny. The reasons for which someone would like to duplicate himself or a dead relative are therefore either in themselves questionable (self-duplication) or unattainable (duplication of a relative, since main characteristics of a person are not determined by a gene set alone but also through education and environmental and social influences).

It was further pointed to that, on biological grounds alone, the human embryo is a living human organism. Structurally, the embryo is genetically complete. What is necessary for continued growth is suitable nurture and environment. Metabolically, at every cell division the embryo copies the complete human genome with nearly perfect fidelity and, in transcribing his or her genetic code, has begun the journey toward actualization of all the functional capacities that uniquely typify a being of the species *homo sapiens*. However, as some scientists argue, "human worth" develops gradually as the nervous system reaches a stage of maturation when certain functional capacities are demonstrable. Insofar, there is a disagreement at what point *human life* starts. A partial ban against reproductive cloning would not truly be a ban against cloning but against the implantation - and hence the survival - of human clones.

Also, it was reiterated that, on biological grounds alone, both forms of cloning cannot be separated: Regardless of their legality, therapeutic and reproductive cloning are technologies that lie within the realm of reproduction. To speak of a distinction between "reproductive" cloning and "therapeutic" cloning is to neglect the important commonality between both: It can be said that both methods of human cloning are reproductive in that they give rise to new individual human lives. Further, existing international instruments were quoted which were said to reflect a popular sentiment that is deeply averse to human reproductive cloning. Also, the declaration that the cloning of human being is "contrary to human dignity" was specified in the sense that the "cloning" rather than the "clone" is contrary to human dignity. The process of cloning is objectionable. Concerns about "the instrumentalization of human beings through the deliberate creation of genetically identical individuals" (European Protocol) were expressed: What jarred moral sensibility was the intention to treat a human being as a means to the ends of others. However, the experts drew attention also to the impairment of rights that a ban on human cloning would entail, in particular the restriction on the freedom of science and reproductive autonomy.

Finally, it was said that while therapeutic cloning provokes an ethical dilemma – killing an embryo in order to potentially save other lives – this is not true for reproductive cloning where the ethical 'bad' would not be compensated by an equivalent 'good'.

#### 2. First exchanges of viewpoints in the plenary

The experts' deliberations served as a common ground of understanding for delegations to enter into a debate on human cloning.<sup>475</sup> During a general exchange of views, the UN delegates participated in the Committee sessions with tangible interest, earnestness and engagement. It was a high point, not only for the German-French initiative but also for the United Nations as a whole. With its largely spontaneous exchange of opinions, this Committee was very different from some of the other sessions, where there was a tendency to present a ritualized series of monologues.

The main direct result of the discussion was that the fundamental scientific facts and ethical issues were more clearly understood. In

<sup>&</sup>lt;sup>475</sup> The following summary of this first debate is based on observations of the author who participated in the session. Since almost all statements made by delegations were spontaneous interventions, they are not available in writing.

particular, the experts helped the Committee members to appreciate that a cloned human being is a person with the same rights as any other person and is not a "monster"; rather, what is monstrous is the *procedure* itself, its *motives*, the incalculable *psychological effects* on the cloned person and the equally incalculable *social consequences*.

Very serious misgivings regarding the cloning *procedure* arose from the prospect that, through cloning and genetic manipulation, the human species might bring about changes in itself with unforeseeable consequences; or, in religious terms, that man would be interfering in Creation. Equally serious misgivings were expressed in view of the extreme risk of deformities - which in itself would suffice to identify cloning as cruel and unethical - as well as in view of the risk of creating a market for donated eggs, which would threaten women in the Third World, in particular, with new forms of material and medical exploitation. Several delegations warned that acceptance of therapeutic cloning would remove the barriers against reproductive cloning. They added that research on embryonic stem cells is superfluous since research could be done equally well, perhaps even better, using adult stem cells. Finally, a number of delegations described it as reprehensible that embryos should be destroyed in the course of therapeutic cloning, whereas others - led by Singapore argued that it is a moral obligation to do everything possible to develop new treatments.

Regarding the *motives* for reproductive cloning (desire to have a child, production of customized human beings or 'designer babies', self-immortalization), it was generally agreed that these motives can either be satisfied by other means (the desire for a child) or are unacceptable because of the flagrant imbalance between selfish expectations and the burden placed on the cloned person.

It was in the *psychological effects* of being cloned that some saw the real violation of human dignity. The cloned person would be able to

see, by observing the (necessarily older) "original", what genetically determined circumstances (diseases, life expectancy) are likely to affect his life and thus, to a certain extent, he would be able to look into his own future. He would therefore be forced into a predeterminist pattern of life which would be difficult to deal with psychologically and which would considerably restrict his freedom to make decisions, which is largely dependent on not knowing what the future will bring. Therefore, the situation of a clone is different from that of identical twins, who are biologically "natural clones" but who live at the same time and not in succession. Also, he might have diminished self-esteem and sense of identity since he knows that he is not unique. He might even feel shame for coming into being through an "unnatural procedure", namely through asexual reproduction.

As regards the *social consequences*, delegates pointed especially to possible forms of discrimination against the cloned person (owing to the stigma attached to his origin), against people left in their "natural state" who diverge from the "ideal" (which?) owing to their skin color, a disability or other characteristics, or against people from developing countries as regards access to possible therapeutic applications of genetic technology. Some delegations considered it unacceptable that the family, as the traditional reproductive community, should be called into question by new forms of reproduction based neither on a mixed-gender partnership nor other traditional family relationships.

Also, reproductive cloning could represent an enormous step in the direction of transforming human procreation into human manufacture. In natural procreation, two individuals come together to give life to a new individual as a consequence of their own being and their own connection with one another, rather than merely of their will. They do not design the final product, they give rise to the child of their embodied selves, and they therefore do not exert control over the process or the resulting child. It was pointed out that even present

forms of partially artificial reproduction, including *in vitro* fertilization, essentially imitate this natural process as they cannot claim to control the final outcome as an artisan might shape his artifact.

Several delegations, mainly those that did not have national legislation on human cloning, indicated that their views were only of a preliminary character as they were still in the process of formulating their positions on the proposed Convention, and therefore more time for deliberation would be needed.

Also, the view was expressed that consideration should be given to the fact that developing countries were particularly susceptible to the threat posed by new biotechnologies and that the social, cultural and ethical aspects of cloning should be examined, as well as the role of women.

### 3. Introduction of a list of legal issues that may be addressed in the Convention

The "list of legal issues that may be addressed in the Convention"<sup>476</sup> was only touched upon briefly. France and Germany who had submitted the list, noted that it should not be understood as taking a position on the issues listed or on the final wording of the future Convention. It aimed at "offering a general framework for the reflexion of the Committee with a view to elaborating a mandate without any intent of defining the orientation that might be given to each of these rubricas".

The proposed list<sup>477</sup> included thoughts on a "Preamble" and "Considerations and Purposes", in which the Committee could lay down some of the considerations that have been elaborated by experts

<sup>&</sup>lt;sup>476</sup> The list was issued under UN Doc. A/AC.263/2002/DP.1.

<sup>&</sup>lt;sup>477</sup> The following explanations on some terms and issue of the list reflect the informal meetings of the delegations of Germany and France in which they discussed the scope of the future UN document and drafted the list together; the author was present at the meetings. Some of the ideas are also reflected in the list as issued, see UN Doc. A/AC.263/2002/DP.1.

and specify the purpose of the future Convention.<sup>478</sup> Further, according to usual practice, "definitions" of technical terms may be given to the extent that they are useful for the clarification of the articles of the Convention. It was made clear however, that definitions should not aim too far and, for instance, define human life and, in particular, when it comes into being.<sup>479</sup> Then, the specification of a "prohibition of human reproductive cloning" could follow, as well as a provision on "national implementation", which could deal with the translation of the Convention into the national sphere, including possible "sanctions"<sup>480</sup> for violations of the prohibition, and mechanism" "reporting and monitoring for national а implementation.<sup>481</sup> Also, the question of "material gains" derived

<sup>&</sup>lt;sup>478</sup> The French and the German delegations considered that, whatever may be the divergences expressed during the general debate, all delegations agree to say that the birth of a child should result exclusively of a sexual reproduction process involving the meeting of a male and a female gamete. Also, since the purpose of the Convention would be to prohibit exclusively the reproductive cloning of human beings, following the terms stated in GA Res. 56/93, the Ad Hoc Committee might state the possibility for State Parties to adopt stricter national measures, consisting, for instance, in the prohibition of other uses of cloning techniques.

<sup>&</sup>lt;sup>479</sup> Regarding a definition of "human being" or "human life", it was clear to the German delegation, that it should be avoided at all costs in the Convention; not only would member states fail to agree, it was also unnecessary, as preceding national and international instruments could prohibit reproductive without such a definition.

<sup>&</sup>lt;sup>480</sup> The general term "sanctions" has been chosen in order to cover a whole range of measures of a different nature (civil, criminal, administrative, disciplinary) as the States parties may wish to take. That general formula could, according to Germany, include, for instance, the question of criminalization of the attempt or complicity of the main offence considering the gravity of the facts, the question of the legal nature of the persons (physical or juridical) as foreseen in certain Conventions for the repression of terrorism which have been worked out in the framework of the Sixth Committee; the question of proportionality of penalties applicable in respect of the gravity of the offences considered: a number of Conventions adopted in the framework of the Sixth Committee impose to State parties the obligation to take the necessary measures to criminalize certain actions and to punish these offences with appropriate penalties, taking into account their gravity (inter alia the Conventions against Terrorism and the recent Convention against Organized Crime); the question of the judicial competence of State parties (Germany did not believe that it is appropriate to entrust this competence to an international jurisdiction). Besides, let alone the possibility of creating a case of international competence, the Ad Hoc Committee might envisage to create cases of particular competence similar to those created by some Conventions (for instance, if the infraction takes place on board of a ship or aircraft); the question of the institution of information, and administrative, police, and judicial cooperation procedures.

<sup>&</sup>lt;sup>481</sup> This kind of mechanism was included in the Universal Declaration on the Human Genome and Human Rights in article 24, as adopted by UNESCO and endorsed by the General Assembly.

from the reproductive cloning of human beings should be discussed<sup>482</sup>, as well as whether and how states parties should take "preventive measures"<sup>483</sup>.

"Freedom of research" and whether it should be restricted with regard to research in reproductive cloning of human beings could be addressed.

Finally, "assistance for implementation and reporting" and "final clauses" which are usually included in internationally binding instruments should be discussed. They would cover the necessary procedures for the entry into force of the respective text (signature, ratification and accession), the nomination of the depositary and finally the possible question of reservations.

Delegates expressed that this list of legal issues should serve as a basis for future negotiations once the member states had agreed on the scope of the future Convention.

#### 4. The scope of the Convention

Then, the plenary sought to address the question which should become the Achilles' Heel of the entire exercise, the scope of a future Convention, i.e. the substantive issues that should be covered by it.

#### a) A broad versus a narrow scope

The only delegations that, at this early point in time, positioned themselves regarding the scope of the Convention were Spain, the United States, and the Holy See: The scope envisaged by France and Germany was too narrow, negotiations should aim at banning all forms of human cloning, independent of the ultimate purpose being

<sup>&</sup>lt;sup>482</sup> France and Germany considered that this question is about the prevention of incitement to reproductive cloning and would specify the financial aspects of the applicable penalties, for instance confiscation of the profits, but could be also extended to other aspects.

<sup>&</sup>lt;sup>483</sup> France and Germany suggested that under this question, it should also be considered whether these preventive measures must include, and to what extent, the field of scientific research, see UN Doc. A/AC.263/2002/DP.1.

reproduction, therapy or research. The United States, in her statement on 26 February, said:

"First, a ban that prohibited only "reproductive" cloning, but left "therapeutic" or "experimental" cloning unaddressed, would essentially authorize the creation and destruction of human embryos explicitly and solely for research and experimentation [...]. Second, to ban "reproductive" cloning effectively, all human cloning must be banned. Under a partial ban that permitted the creation of cloned embryos for research, human embryos would be widely cloned in laboratories and assisted-reproduction facilities. Once cloned embryos are available, it would be virtually impossible to control what was done with them [...]. Third, a ban that permits embryonic clones to be created and forbids them to be implanted in utero legally requires the destruction of nascent human life and criminalizes efforts to preserve and protect it once created, a morally abhorrent prospect. *Fourth*, there may be other routes to developing new treatment therapies using stem cells and to solving the transplant rejection problems that may result from the use of non-identical tissue transplants. A legal ban on "therapeutic" cloning would allow time for the investigation of promising and less problematic research alternatives such as adult stem cell research [...]."<sup>484</sup>

Spain supported the United States in that it aimed at the elaboration of an international Convention that prohibits reproductive and therapeutic cloning, "because all human cloning, no matter what the final objective, is against the dignity of the human being; and an international Convention should seek the maximum protection of human dignity".<sup>485</sup>

<sup>&</sup>lt;sup>484</sup> See statement by Carolyn Willson, Legal Adviser, U.S. Mission to the United Nations, available at http://www.usunnewyork.usmission.gov/02\_025.htm.

<sup>&</sup>lt;sup>485</sup> See statement by the Director General of the Spanish Institute of Health "Carlos III" Mr. Antonio Campos at the UN General Assembly Ad Hoc Committee on an international Convention against the reproductive cloning of human beings, New York, 26 February 2002 (which is at the hands of the author).

The Holy See<sup>486</sup> also supported this approach: "Every process involving human cloning is in itself a reproductive process in that it generates human beings at the very beginning of his or her development, i.e. a human embryo. As previously mentioned, the Holy See regards the distinction between reproductive and therapeutic cloning to be unacceptable. This false distinction masks the reality of the creation of a human being for the purpose of destroying him or her to produce embryonic stem cell lines or to conduct other experimentation. Therefore human cloning should be prohibited in all cases regardless of the aims that are pursued." Costa Rica argued similarly in a spontaneous intervention.

France and Germany were taken by surprise when they heard the U.S. delegate in her address to the Sixth Committee. Until then, the U.S. had seemed to be in favour of not elaborating any Convention until she had finalized her own Federal laws. Now, she argued in favour of a Convention, but only if it took a holistic approach and addressed all forms of human cloning.<sup>487</sup>

# b) A suggested "pragmatic approach" to reaching an agreement on the scope

However, the great majority of delegations that took the floor favoured what France and Germany promulgated as a "pragmatic approach" when determining the scope, and with it the mandate of the Convention.

France and Germany, in their first and for the future course of negotiations decisive statement, said: "We are aware that reproductive cloning is only one aspect within the broad range of new

<sup>&</sup>lt;sup>486</sup> See statement by H.E. Archbishop Renato R. Martino, head of the Holy See delegation before the Ad Hoc Committee on an international Convention against the reproductive cloning of human beings, New York, on 25 February 2002 (which is at the hands of the author).

<sup>&</sup>lt;sup>487</sup> As a member of the state department explained in an informal meeting, in which the author was present, the debate in the United States regarding a prohibition of human cloning had thematically become broader since the beginnings of the German-French initiative at the UN. The initiative had given the incentive for the U.S. to define her position regarding an international prohibition of human cloning.

human genetic technologies. We therefore fully support the initiative taken by UNESCO in its resolution 22 entitled "Bioethics programme: Priorities and prospects" of the 31<sup>st</sup> session of the General Conference to elaborate universal norms on bioethics. The French-German initiative, however, follows a more focused approach by heading for a universal ban on cloning of human beings for reproductive purposes. This should not be taken as a lack of sensitivity towards other bioethical concerns. But only a focused approach will enable us to reach, within the urgency imposed by events, an international agreement to face successfully the challenge that lies ahead." <sup>488</sup>

Therefore, the Committee should view the issue with a sense of urgency since it was conceivable that the first successful cloning of a human being could take place soon. The proposed pragmatic approach would mean that the Committee would first focus on the area where general agreement seemed to exist among delegations, namely a ban on reproductive cloning of human beings. It was pointed out that widening the scope of the potential Convention to include issues for which no consensus existed could threaten the entire exercise, leaving the international community without a coordinated legal response. It was also noted that it was important that the treaty should enjoy universal acceptance so as to prevent the establishment of "cloning havens" where such activities were not prohibited.

This position however was taken without the intention of drawing a distinction between different ethical priorities. Instead, the real distinction was between what was realistically achievable and what was not. Therefore, France and Germany, at this early stage, suggested different possibilities, including covering other forms of

<sup>&</sup>lt;sup>488</sup> See statement by Christian Much, head of the German delegation, also on behalf of the French delegation, before the Ad Hoc Committee on an international Convention against the reproductive cloning of human beings, New York, 26 February 2002 (which is at the hands of the author).

cloning by alternative mechanisms, but without preventing the adoption of an international instrument banning the reproductive cloning of human beings. For example, it was suggested that a stepby-step approach could be adopted, beginning with a Convention on banning the reproductive cloning of human beings which would in no way limit the ability of states to regulate other forms of cloning by means of national legislation.

# *c)* The gradual formation of two incompatible positions regarding the scope

The United States' delegate however disagreed. The main goal that the United States was pursuing was to grant absolute protection to the embryo, which, she argued, could only be secured by prohibiting all forms of human cloning in a single Convention. The underlying argument was a biological one, namely that the procedure of somatic cell nuclear transfer was one and the same, regardless of the later purpose.<sup>489</sup> Therefore, any means that the procedure could serve should be addressed at once and together. Spain, in support of the U.S. position, reiterated that human life is sacred and that man should not interfere in God's creation.

This position was a break that was to have serious consequences. It not only called into question the goal set by Germany and France of drawing up with due swiftness a universally binding legal instrument,<sup>490</sup> it actually steered away from this goal. Since there was no worldwide consensus for a comprehensive ban including the prohibition of therapeutic cloning, the demand for a total ban meant there would be either a long tug-of-war trying to find a universally acceptable basis for negotiation, possibly ending in deadlock, or there

<sup>&</sup>lt;sup>489</sup> See above under B.I.3. and B.I.4.

<sup>&</sup>lt;sup>490</sup> An international ban would not, *per se*, prevent reproductive cloning (any more than a law against a criminal offense can completely prevent such an offense being committed). However, a Convention, like a penal provision, can be an effective deterrent (by removing any instances where the limits to freedom of research are unclear; by integrating the provisions of the Convention into national law and the domestic range of sanctions) and could cause the morass of usually private funding for cloning experiments to dry up.

would be short-term negotiations, but only among the advocates of a total ban, i.e. omitting important states that are already engaged in research (such as the United Kingdom, China, Japan, India and Brazil) – a situation that has been likened to negotiating a ban on nuclear weapons without the participation of the nuclear powers.

Some delegates assumed that the U.S. was mainly interested in deferring any decision at the United Nations on substance until she had finalized her own Federal laws. In that, the U.S. were thought to pursue a fundamentally different goal than her main sponsor, Spain, which took its position for substantive and not for tactical reasons, in line with its then existing domestic laws and apparently under the influence from the Catholic Church.

In truth, the U.S.' position was probably more than a question of mere tactics; it was a fundamental change in the U.S.' negotiating goal. Unlike the initiative proposed by Germany and France, which aimed to find the "highest common denominator" and quickly implement it in the form of a Convention, the U.S. aimed to modify that denominator in the course of a longer-term campaign of persuasion.

### d) Aiming at a compromise through a revised German-French proposal

Germany and France persisted in their conviction that a consensual solution must be found and made a new negotiating proposal.<sup>491</sup>

It took account of the misgivings regarding therapeutic cloning and proposed a two-phase process of negotiation ("step by step approach").<sup>492</sup> The first phase would, ideally within one year, deal with the issues on which consensus existed and which could therefore

<sup>&</sup>lt;sup>491</sup> For the text of this proposal, which was further modified in the course of the negotiations, see the first version in UN Doc. A/C.6/57/WG.1/CRP.1/Rev.1 and the final version in UN Doc. A/C.6/57/L.8.

<sup>&</sup>lt;sup>492</sup> The strategy of a two-phase negotiation was adopted from previous negotiating experiences, most recently the negotiations on the terrorism resolution.

be resolved in a timely manner (reproductive cloning). The second phase, which would follow on immediately, would deal with the more controversial issues (therapeutic cloning).<sup>493</sup>

This proposal was supplemented with elements that would be significant especially in the transitional phase between the first and the second Convention, i.e. an appeal to all states to prohibit what they regard as unethical forms of cloning immediately through their national laws, and to expressly exclude the *e contrario* argument, i.e. that a ban that is initially restricted to reproductive cloning does not mean that therapeutic cloning is permitted.

The proposal was rejected by the U.S. delegation and left the meeting of the Ad Hoc Committee without an agreement regarding the mandate for the negotiation of a future Convention against human cloning. However, many other delegations expressly supported a focused approach, in particular the United Kingdom, the Nordic states in a joint statement,<sup>494</sup> China,<sup>495</sup> Japan,<sup>496</sup> Malaysia,<sup>497</sup> and

<sup>&</sup>lt;sup>493</sup> In an informal meeting, at which the author was present, two alternatives for a step-by-step approach were identified:

*First*, in connection with the Convention against reproductive cloning (in the preamble or in the General Assembly resolution with which the Convention is tabled for signature), parties to the Convention could commit themselves to further negotiating other questions of genetic engineering, including therapeutic cloning, immediately following the first Convention. The result of such a process could be a second Convention or an Additional Protocol to the Convention against reproductive cloning.

*Second*, the first Convention regarding reproductive cloning could foresee that after x years an assembly of states would decide on the prohibition of therapeutic cloning. Up to that date, member states would have x years of time to prepare and work towards the agreement without hindering the first Convention prohibiting reproductive cloning to take full force. Exemplary for this second approach is the ICC. Here, the seemingly unsolvable problem of defining 'war of aggression' was deferred to a conference of states that was to meet six years later. <sup>494</sup> See statement by Dr. Harriet Wallberg-Henriksson on behalf of Denmark,

<sup>&</sup>lt;sup>494</sup> See statement by Dr. Harriet Wallberg-Henriksson on behalf of Denmark, Finland, Iceland, Norway, and Sweden, New York, 26 February 2002 (which is at the hands of the author).

<sup>&</sup>lt;sup>495</sup> The statement was not submitted in writing.

<sup>&</sup>lt;sup>496</sup> See statement by H.E. Ambassador Yoshiyuki Motomura, Permanent Representative of Japan at the Ad Hoc Committee on the Convention against the reproductive cloning of human beings, New York, 26 February 2002 (which is at the hands of the author).

<sup>&</sup>lt;sup>497</sup> See statement by H.E. Ambassador Hasmy Agam, Permanent Representative of Malaysia at the first Ad Hoc Committee meeting on the international Convention

Israel<sup>498</sup> (which would have probably accepted even "less" since it domestically put a five-year moratorium on human cloning). Among the group of Islamic states, no state took an ethical position regarding therapeutic cloning.<sup>499</sup> With but few exceptions,<sup>500</sup> the delegations from the group of African states remained silent.

Besides the United States, Spain (which thus broke the once existing consensus among EU member states<sup>501</sup>) and Costa Rica supported a broad mandate for negotiations of a future Convention. South Africa joined that group und so did Italy but with an additional declaration that Italy did not wish to block negotiations and would therefore be flexible for the sake of compromise.

#### 5. Analysis of the first round of negotiations

After this initial brief round of negotiations, it became clear that the task at hand pressuring the Sixth Committee was going to be more twisted than the usual challenge of UN delegates when negotiating treaties.

The substance that was to be regulated required knowledge and understanding of biology and reproductive medicine. The delegates to

against the reproductive cloning of human beings, New York, 26 February 2002 (which is at the hands of the author).

<sup>&</sup>lt;sup>498</sup> See statement by Mr. Tal Becker, Representative of Israel to the Ad Hoc Committee on an international Convention against the reproductive cloning of human beings, New York, 26 February 2002 (which is at the hands of the author).

<sup>&</sup>lt;sup>499</sup> The reason was twofold: 1) At this early stage of negotiations, the group of Islamic states had not finalized their stand on therapeutic cloning and therefore did not want to take the floor. 2) In any case, the Islamic viewpoint regarding therapeutic cloning would not be as absolute as the Catholic's conviction: According to the prevailing interpretation of the Qur'an, the human embryo will be bestowed with a soul (and thus become a human being) only weeks after procreation.

procreation. <sup>500</sup> Most notably Uganda which shifted within two days from a support of the German-French approach to the U.S. approach, see statement by Rossette Nyirinkindi, representative of the Ugandan delegation to the Ad Hoc Committee on an international Convention against the reproductive cloning of human beings, New York 26 February 2002 (which is at the hands of the author). Similarly so South Africa and Ethiopia.

<sup>&</sup>lt;sup>501</sup> All EU member states had been co-sponsors to the German-French General Assembly resolution 56/93 in late 2001.

the Sixth Committee however were lawyers and mostly lacked substantive knowledge of the issue.

This became particularly evident when the accuracy of the terminology was questioned, mainly with regard to "therapeutic" cloning.<sup>502</sup> While it was created to describe the hypothesized procedure, named both for the intention of the researchers and for what it might make possible in the future, it was also meant to separate the creation of embryonic clones for research from the identical procedure of creating embryonic clones for reproduction. However, some believed the term could misguide: They insisted that the term "cloning" was inaccurate because the researchers have no intention of creating a cloned live-born human being. What they were really doing was one (or all) of the following: "somatic cell nuclear transfer" (the procedure used to create embryonic clones); "nuclear transplantation" (which presumably describes both the transplantation of DNA used to create embryonic clones and the hoped-for transplantation of stem cells to future patients); or "cell replacement by nuclear transfer" (again, putting the emphasis on the procedure that creates embryonic clones and the future hoped-for medical benefits).

Others, most notably the U.S. delegate, argued that the term was inaccurate for very different reasons. "Therapeutic" cloning *was* cloning, because the nature of the act does not turn on the intention: The product of the procedure (namely, cloned embryos) does not differ from the cloned embryos created for the purpose of initiating a pregnancy. The intended uses may be different, but the cloned embryos are not.

Further, some had difficulty especially with the label "therapeutic". They argued that to refer to the procedure as "therapeutic" cloning

 $<sup>^{502}</sup>$  For a definition of how the terms reproductive and therapeutic cloning are used here, see above at B.I.3.a) and b).

suggests that the procedure itself was therapeutic – that is, that the act of "therapeutic" cloning serves or heals an existing patient. But there is no patient as yet, only future and hoped-for patients. In reality, they argued, "therapeutic" cloning was simply a euphemistic way of describing experimental research on cloned human embryos, thereby obscuring the fact that the embryos would be destroyed in the process of deriving stem cells from them. A more accurate term, they argued, would be "experimental" cloning or "research" cloning.

Turning to science in search of answers on what should be prohibited and what could be regulated would not necessarily facilitate the diplomats' work: Reproductive medicine is in a continuous process of development and scientists are unable or hesitant to give clear-cut answers on the risks and opportunities that are inherent in their research. One finds differing opinions, based on personal interests of scientists (including financial gains), state interests that scientists feel obliged to further, or even personal convictions and beliefs. Also, any prohibitions or regulations that the United Nations adopts would necessarily be based on a prognosis that science makes at this particular moment in time. Some delegations may take this uncertainty as the grounds for prohibiting everything, others for allowing everything until more evidence is given.

Also, human cloning has moral and religious implications – "human dignity" is at stake. The member states were pressured to reach a result that sends an adequate *political* signal of utmost respect for human dignity and human life. More than on other subject matters, unanimity is therefore indispensable.

The great time pressure would not necessarily facilitate the reaching of an agreement. Ideally, a universal agreement should be reached before science presents its first success. It seemed however, that, merely for the sake of swiftness, delegations would not want to be rushed into a binding agreemtent. The mandate will prejudge the outcome of the negotiation. It is thus particularly difficult to start negotiations on substance when the mandate of the negotiation is the core of the issue.

Only relatively few of the 191 UN member states had passed legislation on reproductive and therapeutic cloning; mainly industrial states that had reached a scientific and technical level that obliged them to establish national rules and regulations governing their research. The great majority of member states could not take a specific stand on the question of the mandate as they had, at that point in time, not received instructions from their capitals. Also, the few existing national laws regarding the prohibition of cloning differed from country to country. The limited international consensus was not only reflected in having just two international instruments, but also in the paucity of international guidelines.<sup>503</sup>

However, the difficulties could not overshadow that delegations attached great importance to a possible international Convention against reproductive cloning and displayed a commitment to the successful elaboration of a legal text. The statements made during the meeting of the Ad Hoc Committee display the following barometer of opinion: States in favour of including human therapeutic cloning in the negotiations of an international Convention were the U.S., the Holy See, Spain, Costa Rica, South Africa, Italy (but with a constructive approach). States supporting the German-French proposal to restrict the mandate of negotiations to reproductive cloning were Sweden, Denmark, Finland, Norway, Island, Uganda, Jordan, Venezuela, Mexico (still awaiting instructions from capital), Cuba (same), Thailand, Brazil, Israel (suggested a moratorium as an alternative), Austria, Hungary. The states pointing out possible scientific gains from therapeutic cloning were China, Japan, South

<sup>&</sup>lt;sup>503</sup> See above B.II.1.a), b), and c). See also the overview of national, regional and international instruments that the UN Secretariat has provided for delegations UN Doc. A/AC.263/2002/INF/1/Rev.1.

Korea, Malaysia, the United Kingdom. The states in favour of continuing along the lines of the German-French proposal with a reservation to a later change of course were Iran, Kenia, Saudi-Arabia, Russia.

The Ad Hoc Committee produced a report in which the differing positions were described.<sup>504</sup> As the original General Assembly resolution A/56/93 had foreseen in operative paragraph 3, the issue of a future Convention against human reproductive cloning was decided to be further discussed from 23 to 27 September 2002, within the framework of a Working Group of the Sixth Committee.

# III. A second round of negotiations with a focus on the mandate

The Working Group of the Sixth Committee which had a similar composition as the Ad Hoc Committee – delegates to the Sixth Committee and, in some cases, legal advisors and experts from their capitals - met from 23 to 27 September 2002.<sup>505</sup>

Since it had become evident during the Ad Hoc Committee meeting that many of the UN member states had not taken a final stand on the question of the mandate for an international Convention, Germany and France sought to accelerate the shaping of states' opinion. They instructed their diplomatic representations throughout the world in the summer of 2002 to carry out demarches in favour of the German-French proposals.<sup>506</sup>

The countries' response to the demarche showed that the new proposal met with general approval, including however some hesitation from states which were in the process of developing national laws on cloning and stem cell research. However, it was also

<sup>&</sup>lt;sup>504</sup> UN Doc. A/57/51.

<sup>&</sup>lt;sup>505</sup> See the Final Report in UN Doc. A/C.6/57/L.4.

<sup>&</sup>lt;sup>506</sup> The text of the demarche and the countries' responses are at the hands of the author. Due to the non-disclosure policy of the German Foreign Ministry, the responses cannot be published in this paper.

evident that those states which had strong reservations concerning negotiations on therapeutic cloning (including the United Kingdom, China, Japan and Sweden) had reached the pain barrier. The reaction of the U.S. and Spain remained open until the end of the Working Group of the Sixth Committee in September 2002.

### 1. The development of the German-French draft resolution

The Working Group held seven meetings<sup>507</sup> and decided to hear statements made by representatives of UNESCO, WHO<sup>508</sup>, the Office of the United Nations High Commissioner for Human Rights<sup>509</sup> and

<sup>&</sup>lt;sup>507</sup> The author was present at all meetings. The following report is based on her own minutes and observations.

<sup>&</sup>lt;sup>508</sup> See Statement of the WHO representative at the Working Group on an International Convention against the reproductive cloning of human beings, New York, 23 September 2002 (which is at the hands of the author). Notable in the statement was that WHO agreed on attempts to ban reproductive cloning and referred to WHO resolutions WHA50.37 and WHA51.10. With regard to therapeutic cloning, he said: "As an extension of existing research with stem cells derived from existing embryos and fetal tissue, biomedical scientists in some countries are pursuing the potential use of stem cells derived from cloned human embryos for research and therapeutic purposes. In its own deliberations on cloning, the World Health Assembly has recognized the need "to respect the freedom of ethically acceptable scientific activity and to ensure access to the benefits of its applications". France and Germany understood this statement as being in favour of their initiative of banning reproductive cloning only.

<sup>&</sup>lt;sup>509</sup> The representative of the Office of the High Commissioner for Human Rights distributed a document, the "Conclusions of the Expert Group of the UN High Commissioner for Human Rights on Human Rights and Biotechnology" (Geneva 24-25 January 2002), available at http://www.unhchr.ch/biotech/conclusions.htm. In his statement in the Working Group on 23 September 2002 (which is at the hands of the author), he referred to it. In the paper, the "Expert Group" recommended that a human rights-based approach to the issue be integrated into the discussions of the Sixth Committee. This would involve the viewing of a particular issue from the perspective of the rights and obligations imposed by international human rights norms. More particularly, a rights-based approach would: "1. place emphasis on participation of individuals in decision-making; 2. introduce accountability for actions and decisions, which cal allow individuals to complain about decisions affecting themselves adversely; 3. seek non-discrimination of all individuals through the equal application of rights and obligations to all individuals; 4. empower individuals by allowing them to use rights as leverage for action and legitimizing their 'voice' in decision-making; and 5. link decision making at every level to the agreed human rights norms at the international level as set out in the various human rights covenants and treaties." These more general remarks were followed by concrete suggestions regarding the text of a future Convention which were made by a group of experts on Human Rights and Biotechnology: "1. In negotiating a treaty ban, extreme care should be taken in drafting the definition of the proscribed activity. The prime concerns in this respect are: (a) that too broad a definition could result in the proscription of therapeutic techniques that appear to be essentially beneficial to humankind and are supportive of an individual's right to health and life; and (b) that a definition which is specific

the Council of Europe. Discussions were subsequently held both in the Working Group and in informal consultations.

The Working Group mainly considered the question of the elaboration of a mandate for the negotiation of an international Convention.

Some states submitted individual proposals which remained more or less unnoticed. Mexico suggested a temporary moratorium on all human cloning techniques, which would be in effect while the adoption of an international binding instrument was pending.<sup>510</sup> The Netherlands proposed a "balanced approach", which meant that the Convention could spell out a permanent ban on reproductive cloning and a temporary ban of maximum five years on therapeutic cloning so that the United Nations could follow scientific developments with time.<sup>511</sup>

Malaysia and the Republic of Korea, albeit separately, made similar suggestions. Malasyia spoke of a "fast track-approach" for a ban on reproductive cloning and a "slower track-approach" for therapeutic cloning.<sup>512</sup> The Republic of Korea called it a "two-tier approach" with a "focus on the reproductive cloning of human beings, and …

to current scientific techniques risks being unable to be applied to future, as yet unknown techniques. 2. In negotiating a treaty ban, attention must also be focused on implementation and monitoring of the obligations parties assume under the treaty, so that no more is prohibited than can be effectively implemented. In this regard, the danger of driving the proscribed activity into unregulated environments must be addressed." Most important for delegations was suggestion (a) which made it clear the Expert Group of the High Commissioner was against a ban on therapeutic cloning.

<sup>&</sup>lt;sup>510</sup> See UN Doc. A/C.6/57/WG.1/CRP.3.

<sup>&</sup>lt;sup>511</sup> See statement by Bart Wijnberg, representative of the Kingdom of Netherlands to the United Nations, New York, 24 Sept. 2002 (which is at the hands of the author).

<sup>&</sup>lt;sup>512</sup> See statement by Mr. Hasmy Agam, representative of the Government of Malaysia to the United Nations, New York, 25 Sept. 2002 (which is at the hands of the author).

provisions on other human cloning activities ... that Contracting Parties would be able to opt in or opt out of ...<sup>513</sup>

France and Germany, in a spirit of compromise, tried to integrate the comments that delegations had made during the meeting of the Ad Hoc Committee in spring of 2002 and presented, on 23 September 2002, to the Working Group a revised draft resolution – in the form of a *non-paper*<sup>514</sup> - which now had more concrete provisions:

"The General Assembly,

*Recalling* the Universal Declaration on the Human Genome and Human Rights, adopted by the General Conference of the United Nations Educational, Scientific and Cultural Organization on 11 November 1997, and in particular article 11 thereof, which states that practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted,

*Recalling also* its resolution 53/152 of 9 December 1998, by which it endorsed the Universal Declaration on the Human Genome and Human Rights,

*Bearing in mind* Commission on Human Rights resolution 2001/71 of 25 April 2001, entitled "Human rights and bioethics", adopted at the fifty seventh session of the Commission,

*Aware* that the rapid development of the life sciences opens up tremendous prospects for the improvement of the health of individuals and mankind as a whole, but also that certain

<sup>&</sup>lt;sup>513</sup> See statement by Mr. Hahn Myung-jae, representative of the Permanent Mission of the Republic of Korea to the United Nations, New York, 24 Sept. 2002 (which is at the hands of the author).

<sup>&</sup>lt;sup>514</sup> See UN Doc. A/C.6/57/WG.1/CRP.1. A non-paper submitted by delegations is not recognized as a UN document officially submitted to the UN Secretariat. The procedural consequence of distributing a non-paper is that it does not receive a UN document number.

practices pose potential dangers to the integrity and dignity of the individual,

*Concerned* by the seriousness of problems posed by the development of techniques of reproductive cloning of human beings applied to mankind which may have consequences for respect for human dignity,

*Particularly concerned*, in the context of practices which are contrary to human dignity, at recently disclosed information on research into and attempts at the reproductive cloning of human beings,

*Determined* to prevent, as a matter of urgency, such an attack on the human dignity of the individual,

*Recalling* its resolution 56/93 of 12 December 2001, by which it decided to establish an Ad Hoc Committee, open to all States Members of the United Nations or members of specialized agencies or of the International Atomic Energy Agency, for the purpose of considering the elaboration of an international Convention against the reproductive cloning of human beings,

*Bearing in mind* that this purpose does not preclude the possibility of States Parties adopting stricter national regulations,

1. *Welcomes* the report of the Ad Hoc Committee on an international Convention against the reproductive cloning of human beings on its work from 25/2/02 to 1/03/02 (Doc. A/57/51);

2. *Requests* the Ad Hoc Committee to prepare, as a matter of urgency, a draft text of an international Convention against the reproductive cloning of human beings;

3. *Requests* the Ad Hoc Committee, in developing the draft Convention,

a) to consider, inter alia, the following indicative elements:

i. scope (as mentioned in para. 2 above)

ii. definitions;

iii. prohibition of reproductive cloning of human beings;

iv. national implementation, including penalties;

v. preventive measures;

vi. jurisdiction;

vii. promotion and strengthening of international cooperation, technical assistance;

viii. collection, exchange and analysis of information; and

ix. mechanisms for monitoring implementation;

b) to specify that the prohibition of reproductive cloning of human beings does not prejudge the question of whether other human cloning activities are licit or illicit;

c) to ensure that States Parties shall not be prevented from adopting or maintaining stricter regulations on the prohibition of reproductive cloning of human beings that those contained in the draft Convention;

4. *Requests* the Ad Hoc Committee to take into consideration the relevant existing international instruments;

5. *Requests* the Secretary-General to provide the Ad Hoc Committee with the necessary facilities for the performance

of its work, to be conducted in two sessions from ... February 2003 and ... September 2003;

6. *Invites* the Ad Hoc Committee to take into consideration the contributions of UN subsidiary bodies, and to closely involve the UNESCO and the WHO in the process of negotiations;

7. *Requests* the Ad Hoc Committee to report on its work to the General Assembly at its fifty-eighth session;

8. *Decides* to include in the provisional agenda of its fiftyeighth session the item entitled "International Convention against the reproductive cloning of human beings".

In its introductory remarks to the draft resolution<sup>515</sup>, the head of the German delegation reiterated the new "step-by-step approach" as it had been developed at the end of the Ad Hoc Committee in spring of 2002. He drew attention to three fundamental ideas: First, "diplomats have a moral obligation to act now". Second, "to ban reproductive cloning now does not mean allowing other forms of cloning". Third, "we have to proceed step-by-step" and explained in detail how these three fundamental ideas were reflected in the proposed draft resolution.

The draft resolution was met with broad approval. In the course of two days, like-minded delegations made several suggestions on how to improve the draft resolution in order to win support from as many delegations as possible.<sup>516</sup> The following changes were made in a revised (informal) version, distributed among delegates on 25 September 2002:

<sup>&</sup>lt;sup>515</sup> See statement by Mr. Christian Much on behalf of the German delegation, New York, 24 September 2002 (which is at the hands of the author).

<sup>&</sup>lt;sup>516</sup> The author was present at these informal talks, the following summary of proposals is based on her own minutes and "non-papers" delegations distributed (which are at the hands of the author).

*Mexico* suggested adding a new preambular paragraph four: "Mindful of the importance of the development of the life sciences for the benefit of mankind with full respect of the integrity and dignity of the human being" thus stressing the indissoluble link between developments of science with human dignity.

*France and Germany* changed preambular paragraph ten "Bearing in mind that this purpose could lead to a step-by-step approach to **Resolved to addressing** issues related to other forms of human cloning through a step-by-step approach..."<sup>517</sup> Thus the commitment to further steps beyond the first step of a Convention against reproductive cloning was manifested.

*Mexico* added a new preambular paragraph twelve: "Determined to adopt provisional measures at the national level to prevent potential dangers on the human dignity of the individual pending the adoption and entry into force of an international Convention against the reproductive cloning of human beings and any other instrument in the field of cloning of human beings". This was to encourage member states to, independently of a possible international instrument, act on a national level.

*France and Germany* added to operative paragraph two the following: "The General Assembly requests the Ad Hoc Committee to prepare, as a matter of urgency **and if possible by the end of 2003**, a draft text of an international Convention against the reproductive cloning of human beings" thus setting a foreseeable timeframe which also stresses the urgency.

*Uganda* changed former operative paragraph three b) "The General Assembly requests the Ad Hoc Committee, in developing the draft Convention, to specify that the prohibition of reproductive cloning of

<sup>&</sup>lt;sup>517</sup> To best reflect the diplomats' work in progress, we will, in the following use their re-drafting style when describing the discussions on the amendment of individual paragraphs.

human beings does not prejudge the question of whether other human eloning activities are licit or illicit imply the authorization of other forms of cloning of human beings" which was to strengthen the original statement by making it more precise. The intention was to take into consideration the reservation of the "maximalists" who interpreted a partial ban of reproductive cloning as an implicit approval of other forms of cloning.

*Canada,* formulating the results of the open debate among delegates added a new paragraph four bis:

"The General Assembly

a) Decides that it will favourably consider any proposal to launch negotiations on a further legal instrument on other forms of cloning of human beings as soon as negotiations on a draft international Convention prohibiting reproductive cloning of human beings have been concluded;

b) Requests WHO and UNESCO to start elaborating without delay a joint preparatory document for these negotiations, outlining from a scientific and ethical perspective the issues to be considered, and to submit this document no later than by the end of 2003;"

*Germany and the United Kingdom* together developed a new paragraph four ter: "The General Assembly calls upon States, pending the entry into force of an international Convention against the reproductive cloning of human beings, to adopt at the national level a prohibition of reproductive cloning of human beings and to control other forms of cloning of human beings through regulations, moratoria or prohibition."

One day later, on 26 September 2002, another revised (informal) version was distributed among delegates, taking into consideration

amendments and suggestions that delegations had made on the version from the previous day. These were:

*The United Kingdom* suggested for preambular paragraph ten: "Resolved to address issues related to other forms of human cloning, through a step by step approach, including through the **possibility of the** elaboration of a separate an appropriate international instrument as soon as negotiations on a Convention against reproductive cloning of human beings have been concluded." The United Kingdom wanted to emphasize that an international instrument on other forms of cloning could be elaborated, but only as an option. This position tried to better reflect United Kingdom law because of which the United Kingdom would prefer not to elaborate a Convention regulating therapeutic cloning.

*The United Kingdom* also suggested in operative paragraph two: "Requests the Ad Hoc Committee to prepare, as a matter of urgency and if possible by the end of 2003, a draft text of an-international Convention against the reproductive cloning of human beings" for stylistic reasons.

*Finland and Sweden* suggested in operative paragraph three a) (iv): "Requests the Ad Hoc Committee, in developing the draft Convention, to consider national implementation, including <del>penalties</del> **sanctions and preventive measures**". They argued that the word "sanctions" was the appropriate UN-language covering what was meant by the drafters.

*China, supported by Sweden and Sierra Leone* suggested in operative paragraph three b): "Requests the Ad Hoc Committee, in developing the draft Convention, to specify that the prohibition of reproductive cloning of human beings does not imply the <del>authorization</del> **endorsement** [China, supported by Sweden] of **any** [Sierra Leone] other forms of cloning of human beings **for any purpose** [Sierra Leone]." The first amendment was made for stylistic reasons, the other two in order to strengthen the language and thus the provision as such. The ultimate goal was to meet the fears of the "minimalists" who argued that a prohibition of reproductive cloning only would entail the silent approval of other forms human cloning for other purposes

*Ecuador* suggested in operative paragraph three c): "Requests the Ad Hoc Committee, in developing the draft Convention, to ensure that State Parties shall not be prevented from adopting or maintaining stricter regulations on the prohibition of reproductive cloning of human beings than those contained in the draft Convention", again making the possible range of regulations in the prohibition of all forms of cloning as wide as possible.

*Brazil* suggested in operative paragraph four: "Requests the Ad Hoc Committee to take into consideration the relevant existing international instruments and requests an appropriate subsidiary body of the United Nations to prepare an in-depth study addressing inter alia:

a) the current state of the art of the human cloning technologies;

b) the possible dual use of the existing non-human cloning techniques

Thus, the necessary technical medical and biological knowledge would be provided to delegations which they could use as a basis for arguments in favour or against the reproductive, but mainly the therapeutic cloning of human beings. "Existing non-human cloning" refers to the possible use of adult stem cells instead of embryonic stem cells for the purpose of curing diseases.

*The United Kingdom* suggested in operative paragraph four bis a): "Decides that it will favourably carefully consider, as a priority, proposals for the most appropriate international approach of other forms of cloning of human beings, including by the elaboration of any proposal to launch negotiations on a further legal instrument on other forms of cloning of human beings as soon as negotiations on a draft international Convention prohibiting reproductive cloning of human beings have been concluded." This formulation again displays the United Kingdom's hesitance towards any international legal instrument which goes beyond reproductive cloning due to its national laws which do not prohibit therapeutic cloning.

*The United Kingdom* further suggested in operative paragraph four bis: "The General Assembly, **to this end**, requests WHO and UNESCO to start elaborating without delay a joint preparatory document for these negotiations **to inform those considerations**, outlining from a scientific and ethical perspective the **relevant** issues to be considered and to submit this document no later than by the end of 2003." These are stylistic changes.

Russia and Mexico suggested in operative paragraph four ter: "The General Assembly calls upon those States which have not yet done so [Russia], pending the entry into force of an international Convention against the reproductive cloning of human beings, to adopt at the national level a prohibition of reproductive cloning of human beings and to control other forms of cloning of human beings that are contrary to human dignity through regulations [Mexico], moratoria or prohibition." The Russian amendment is merely stating the obvious. The Mexican amendment conveys the idea that if a State deems that a certain form of cloning is contrary to human dignity, regulating that practice was no option, but only a prohibition or a moratorium would be the adequate response. The Mexican amendment also wants to refer to natural twins which, they argued, are biologically speaking clones, but whose "natural" creation is not contrary to human dignity. This amendment was however considered as a possible loophole by several delegations: If countries decide to permit certain practices, they could argue that the practice in question is not contrary to human dignity. This ambiguity was, of course,

precisely what Mexico had in mind: To wrap an "agreement to disagree" in an ambiguous formulation. But those countries that were determined to achieve a total ban on cloning were not amenable to this type of compromises.

*Brazil* suggested in operative paragraph six: "The General Assembly invited the Ad Hoc Committee to take into consideration the contributions of UN subsidiary bodies, and to closely involve the UNESCO, and the WHO, UNCTAD and ECOSOC in the process of negotiations."

Once more, a great number of delegations took the floor to voice their support for the revised German-French proposal. Its current version<sup>518</sup> was printed in the report of the Working Group which was discussed on 27 September 2002.<sup>519</sup> It reads:

"The General Assembly,

*Recalling* the Universal Declaration on the Human Genome and Human Rights, adopted by the General Conference of the United Nations Educational, Scientific and Cultural Organization on 11 November 1997, and in particular article 11 thereof, which states that practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted,

*Recalling also* its resolution 53/152 of 9 December 1998, by which it endorsed the Universal Declaration on the Human Genome and Human Rights,

<sup>&</sup>lt;sup>518</sup> See UN Doc. A/C.6/57/WG.1/CRP.1/Rev.1

<sup>&</sup>lt;sup>519</sup> See UN Doc. A/C.6/57/L.4. The minor changes in the text were made by the UN Secretariat's Treaty and Codification division in order to meet the formal standards, including terms and numbering of UN documents. Also, the submitters of the draft resolution decided to keep the original numbers of the paragraphs in order for delegations to understand the changes made in the course of the week.

*Bearing in mind* Commission on Human Rights resolution 2001/71 of 25 April 2001, entitled "Human rights and bioethics", adopted at the fifty seventh session of the Commission,

*Mindful* of the importance of the development of the life sciences for the benefit of mankind with full respect for the integrity and dignity of the human being,

*Aware* that the rapid development of the life sciences opens up tremendous prospects for the improvement of the health of individuals and mankind as a whole, but also that certain practices pose potential dangers to the integrity and dignity of the individual,

*Concerned* by the seriousness of problems posed by the development of techniques of reproductive cloning of human beings applied to mankind which may have consequences for respect for human dignity,

*Particularly concerned*, in the context of practices which are contrary to human dignity, at recently disclosed information on research into and attempts at the reproductive cloning of human beings,

*Determined* to prevent, as a matter of urgency, such an attack on the human dignity of the individual,

*Recalling* its resolution 56/93 of 12 December 2001, by which it decided to establish an Ad Hoc Committee, open to all States Members of the United Nations or members of specialized agencies or of the International Atomic Energy Agency, for the purpose of considering the elaboration of an international Convention against the reproductive cloning of human beings, *Bearing in mind* that this purpose does not preclude the possibility of States Parties adopting stricter national regulations,

*Resolved* to address issues related to other forms of human cloning through a step-by-step approach, including through the elaboration of a separate international instrument, as soon as negotiations on a Convention against reproductive cloning of human beings have been concluded,

*Bearing in mind* that this purpose does not preclude the possibility of States parties adopting stricter national regulations,

*Determined* to adopt provisional measures at the national level to prevent potential dangers to the human dignity of the individual pending the adoption and entry into force of an international Convention against the reproductive cloning of human beings and any other instrument in the field of cloning of human beings,

1. *Welcomes* the report of the Ad Hoc Committee on an international Convention against the reproductive cloning of human beings on its work from 25/2/02 to 1/03/02 (Doc. A/57/51);

2. *Requests* the Ad Hoc Committee to prepare, as a matter of urgency and if possible by the end of 2003, a draft text of an international Convention against the reproductive cloning of human beings;

3. *Requests* the Ad Hoc Committee, in developing the draft Convention,

a) to consider, inter alia, the following indicative elements:

i. Scope (as mentioned in paragraph 2 above)

ii. Definitions;

iii. Prohibition of reproductive cloning of human beings;

iv. National implementation, including penalties;

v. Preventive measures;

vi. Jurisdiction;

vii. Promotion and strengthening of international cooperation, technical assistance;

viii. Collection, exchange and analysis of information; and

ix. Mechanisms for monitoring implementation;

b) To specify that the prohibition of reproductive cloning of human beings does not imply the authorization of other forms of cloning of human beings;

c) To ensure that States Parties shall not be prevented from adopting or maintaining stricter regulations on the prohibition of reproductive cloning of human beings that those contained in the draft Convention;

4. *Further requests* the Ad Hoc Committee to take into consideration the relevant existing international instruments;

4 bis. a) *Decides* that it will favourably consider any proposal to launch negotiations on a further legal instrument on other forms of cloning of human beings as soon as negotiations on a draft international Convention prohibiting the reproductive cloning of human beings have been concluded;

b) *Requests* the World Health Organization and the United Nations Educational, Scientific and Cultural Organization to start elaborating without delay a joint preparatory document for these negotiations, outlining from a scientific and ethical perspective the issue to be considered, and to submit this document no later than by the end of 2003;

4 ter. *Calls upon* States, pending the entry into force of an international Convention against the reproductive cloning of human beings, to adopt at the national level a prohibition of the reproductive cloning of human beings and to control other forms of cloning of human beings through regulations, moratoria or prohibition;

5. *Requests* the Secretary-General to provide the Ad Hoc Committee with the necessary facilities for the performance of its work, to be conducted in two sessions from ... February 2003 and ... September 2003;

6. *Invites* the Ad Hoc Committee to take into consideration the contributions of UN subsidiary bodies, and to closely involve the United Nations Educational, Scientific and Cultural Organization and the World Health Organization in the process of negotiations;

7. *Requests* the Ad Hoc Committee to report on its work to the General Assembly at its fifty-eighth session;

8. *Decides* to include in the provisional agenda of its fiftyeighth session the item entitled "International Convention against the reproductive cloning of human beings".

In an aide-memoire<sup>520</sup> relating to the proposal submitted by Germany and France, the head of the German delegation discussed, once more,

<sup>&</sup>lt;sup>520</sup> The aide-memoire is at the hands of the author.

the concerns of the "maximalists". Also, he said that Germany and France do not believe that a prohibition which does not cover cloning for research and therapeutic purposes would necessarily be inefficient, as some delegations asserted during discussions in the Ad Hoc Committee in February 2002. The efficiency of the proposed Convention would be ensured by the obligation on States parties to take appropriate measures to prohibit the reproductive cloning of human beings. Moreover, he said, it would also be possible for states parties to adopt complementary preventive measures.

Co-sponsors to the draft resolution, which up to this point, Germany and France had not officially submitted to the UN Secretariat but distributed over the course of the week as a working paper, were: Belarus, Belgium, Brazil, Canada, China, Cuba, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Japan, Latvia, Liechtenstein, Lithuania, Luxembourg, Norway, Slovenia, and Switzerland.<sup>521</sup>

Other like-minded delegations or "friends of the German-French proposal" were<sup>522</sup>: Australia, Burkina Faso, Croatia, Guatemala, Israel, Madagascar, Mexico, New Zealand, Portugal, Russia, Singapore, South Africa, Sweden, Uganda, the United Kingdom, Venezuela, Vietnam, and Yugoslavia.

## 2. The introduction of a rivalling draft resolution by the United States, Spain, and the Philippines

However, as much as the multi-revised German-French proposal was trying to integrate the demands of the "maximalists", the U.S., Spain, the Philippines and a few other delegations intransigently rejected it. In retrospect, the efforts of the "minimalists" were doomed since they were focusing on the details of a resolution which left the key question of the scope of the Convention untouched. According to the

<sup>&</sup>lt;sup>521</sup> See UN Doc. A/C.6/57/L.4.

 $<sup>^{522}</sup>$  The following list of states is based on the personal minutes of the author.

"maximalists", not only reproductive cloning, but also creating and destroying human embryos for experimentation purposes, including for "therapeutic" cloning, was contrary to human dignity. The advantages of adult stem cell research were instead pointed to. The draft resolution proposing the narrow "partial" approach was also criticized for failing to properly ensure that all forms of cloning would be addressed as a follow-up to a treaty on reproductive cloning.

Compromises suggested in the plenary by the German side – parallel (rather than consecutive) negotiations on two Conventions; negotiations on a single Convention with 'opt in' and 'opt out' clauses – were rejected outright by the United States.

Thus, it seemed that the negotiations would hardly succeed in producing a swift result, especially since the U.S., Spain and the Philippines, to the great surprise of delegations, submitted, without prior informal announcement, their own, rival draft resolution<sup>523</sup> on 27 September 2002 calling for negotiations on a Convention banning all forms of cloning. It reads:

"The General Assembly,

*Recalling* the Universal Declaration on the Human Genome and Human Rights, adopted by the General Conference of the United Nations Educational, Scientific and Cultural Organization on 11 November 1997, and in particular article 11 thereof, which states that practices which are contrary to human dignity, such as the reproductive cloning of human beings, shall not be permitted,

*Recalling also* its resolution 53/152 of 9 December 1998, by which it endorsed the Universal Declaration on the Human Genome and Human Rights,

<sup>&</sup>lt;sup>523</sup> See UN Doc. A/C.6/57/L.3.

*Bearing in mind* Commission on Human Rights resolution 2001/71 of 25 April 2001, entitled "Human rights and bioethics", adopted at the fifty-seventh session of the Commission,

*Mindful* of the importance of the development of the life sciences for the benefit of mankind with full respect for the integrity and dignity of the human being,

*Mindful also* that certain practices pose potential dangers to the integrity and dignity of the individual,

*Concerned* at recently disclosed information on research into and attempts at the creation of human beings through cloning processes,

*Determined* to prevent as a matter of urgency such an attack on the human dignity of the individual,

*Conscious* of widespread preoccupations that the human body and its parts should not, as such, give rise to financial gain,

*Recalling* its resolution 56/93 of 12 December 2001, by which it decided to establish an Ad Hoc Committee, open to all States Members of the Untied Nations or members of specialized agencies or of the International Atomic Energy Agency, for the purpose of considering the elaboration of an international Convention against the reproductive cloning of human beings,

*Determined* to adopt permanent and provisional measures, as appropriate, to prevent potential dangers to the human dignity of the individual, 1. *Welcomes* the report of the Ad Hoc Committee on an international Convention against the reproductive cloning of human beings on its work from 25 February to 1 March 2002;

2. *Requests* the Ad Hoc Committee to prepare, as a matter of urgency, the draft text of an international Convention against human cloning, bearing in mind that it does not prohibit the use of nuclear transfer or other cloning techniques to produce DNA molecules, organs, plants, tissues, cells other than human embryos or animals other than humans;

3. *Also requests* the Ad Hoc Committee, in developing the draft Convention, to consider, inter alia, the following indicative elements;

- (a) Scope;
- (b) Definitionns;
- (c) The objective;
- (d) Implementation;
- (e) Preventive measures;
- (f) Jurisdiction;

(g) Promotion and strengthening of international cooperation;

(h) Exchange of information;

(i) Mechanisms for monitoring implementation;

4. *Solemnly declares* that, pending the adoption of an international Convention against human cloning, States shall not permit any research, experiment, development or

application in their territories or areas under their jurisdiction or control of any techniques aimed at human cloning;

5. *Calls upon* States to adopt such measures as may be necessary to prohibit those techniques of genetic engineering that may have adverse consequences on the respect for human dignity;

6. *Requests* the Secretary-General to provide the Ad Hoc Committee with the necessary facilities for the performance of its work;

7. *Invites* the Ad Hoc Committee to take into consideration the contributions of United Nations agencies and competent international organizations, as well as other relevant bodies of international opinion in the process of negotiations;

8. *Requests* the Ad Hoc Committee to report on its work to the General Assembly at its fifty-eight session;

9. *Decides* to include in the provisional agenda of its fiftyeight session an item entitled "International Convention against human cloning".

Co-sponsors were Antigua and Barbuda, Argentina, Costa Rica, Dominica, Dominican Republic, El Salvador, Eritrea, Ethiopia, Fiji, Georgia, Grenada, Honduras, Italy, Kazakhstan, Kenya, Kyrgyzstan, Lesotho, Marshall Islands, Micronesia, Nicaragua, Nigeria, Panama, Paraguay, Philippines, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Spain, Suriname, Tajikistan, Timor-Leste, Tonga, Turkmenistan, Tuvalu, the U.S., Uzbekistan and Vanuatu.<sup>524</sup>

<sup>&</sup>lt;sup>524</sup> See UN Doc. A/C.6/57/L.3/Rev.1/Corr.1.

#### 3. Analysis of the Working Group meeting

At the end of the Working Group meeting, the alternatives were thus clearly staked out: The opposing groups were willing to fight for a majority and could not agree on a mandate in consensus. The report of the Working Group<sup>525</sup> could therefore only summarize its proceedings and attach the amendments and proposals submitted by delegations. As for the most important part of the report, the recommendations and conclusions drawn from the negotiations, the Working Group decided to refer the report as it was to the Sixth Committee for its consideration and recommended that the Sixth Committee continue the consideration of the elaboration of a negotiation mandate during the current session of 2002, taking into account the discussions in the Working Group, including the proposals contained in the annex of the report.

The second round of negotiations had so far achieved but one thing: It staked out the two different approaches to a prohibition on human cloning more clearly. Also, more member states had in the meantime received instructions from their capital and could thus voice their support for either of the two proposals. The plenary was divided into two regarding the scope of a Convention and attempts at finding common ground were fruitless.

Again, it became clear that the great majority of delegations who took the floor favoured the German-French proposal for a mandate,<sup>526</sup> among them even former "maximalists", for instance St. Vincent and Grenada and Sierra Leone – trying to find a balance between serious moral reservations against all forms of cloning on the one hand and the necessity to further a possible focused, but timely prohibition on

<sup>&</sup>lt;sup>525</sup> See UN Doc. A/C.6/57/L.4.

<sup>&</sup>lt;sup>526</sup> These countries were, according to the minutes of the author, besides the cosponsors of the proposed draft resolution Brazil, Portugal, Sweden, Finland, the Czech Republic, the United Kingdom, Norway, Greece, South Africa, Israel, Guatemala, China, Japan, Singapore, Hungary, the Netherlands, Russia, Mexico, Cuba, Denmark, Belarus, TSR, Vietnam, Madagascar, Venezuela, Canada, New Zealand, Luxembourg, Belgium, Austria, Uganda, Australia, Jordan, Ecuador.

the other hand, for instance Guatemala and Uganda. However, such former countries with a "maximalist" approach that showed a tendency to change lanes were probably pressured politically by the "maximalists".

The group of "minimalists" embraced countries who favoured the German-French proposal for different reasons, be it a generally low interest in the Convention as such (many African states who argued that they were dealing with far more pressing issues), be it a commitment to elaborating a prohibition of reproductive cloning quickly (Germany and France) or an interest in therapeutic cloning (United Kingdom, China, Japan, Korea, Singapore).<sup>527</sup>

# 4. Informal attempts made by the "minimalists" aiming at a compromise

Germany and France continued their work on their draft resolution, together with their co-sponsors in an informal setting after the Working Group meeting.<sup>528</sup> Further amendments were made until 30 September.

*The Netherlands* suggested in preambular paragraph ten: "Resolved to address issues related to other forms of human cloning, including through the possibility of the elaboration of an appropriate **separate** international instrument, as soon as negotiations on a Convention against reproductive cloning of human beings have been concluded." The paragraph was thus changed back to its original version since the "possibility of the elaboration" [United Kingdom proposal] was considered to be too weak a formulation. The previous proposal of adding the word "appropriate" [United Kingdom] was kept, but only in addition to the word "separate", emphasizing that human

<sup>&</sup>lt;sup>527</sup> Interestingly, the United States, at least her state California at the time, could have been said to have similar interests according to their law of 22 September 2002 which prohibited reproductive cloning only, see above at B.II.2.d) aa).

<sup>&</sup>lt;sup>528</sup> The author was present at these informal meetings. The amendments described below are based on her own minutes.

reproductive cloning should be dealt with in an international legal instrument separate from other forms of human cloning.

The United Kingdom, the Netherlands, Switzerland and Germany together drafted a new operative paragraph five:

a) "The General Assembly decides that it will favourably consider any proposals to launch negotiations on a further legal instrument on other forms of cloning of human beings as soon as negotiations on a draft international Convention prohibiting reproductive cloning of human beings have been concluded." Here, the former United Kingdom proposal was replaced by Germany's original proposal (former operative paragraph four bis a)), mainly because it was found to be more precise in putting emphasis on "a further legal instrument" rather than on an "appropriate international approach" which could mean instruments other than legally binding ones.

b) "To this end, requests WHO and UNESCO to start elaborating without delay in close cooperation with the appropriate UN bodies a joint preparatory document for these negotiations, outlining from a scientific and ethical perspective the relevant issues to be considered, such as the current state of the art of the human cloning technologies and the possible dual use of the existing non-human cloning techniques, among others, and to submit this document no later than by the end of 2003." This paragraph is a merger of former paragraph four a) and four bis b), for stylistic matters.

The United Kingdom drafted a new operative paragraph six which reads: "The General Assembly calls upon States which have not yet done so, pending the entry into force of an international Convention against the reproductive cloning of human beings **and their becoming Party thereto,** to adopt at the national level a prohibition of reproductive cloning of human beings". This was former operative paragraph four ter with a slight addition which makes the meaning more precise. The addition "and other forms of cloning of human beings that are contrary to human dignity" was put into a new operative paragraph seven:

New operative paragraph seven reads: "The General Assembly also calls upon States which have not yet done so, to adopt at the national level a moratorium on, or a prohibition of other forms of cloning of human beings that are contrary to human dignity" which was a part of the former operative paragraph four ter [Mexico].

Finally, the new operative paragraph nine [former operative paragraph six] now reads: "The General Assembly invites the Ad Hoc Committee to take into consideration the contributions of UN subsidiary bodies, and to closely involve the UNESCO, WHO, ECOSOC and UNCTAD." ECOSOC was crossed from the list of UN bodies because the issue of cloning was thematically closer to the other three agencies and it was considered that the co-operation of too many agencies could possibly delay a timely outcome.

### 5. Discussion in the framework of the Sixth Committee

The Sixth Committee took up the issue in October 2002.<sup>529</sup>

### a) Introduction of the draft resolution by Germany and France

On 17 October, 2002, the representative of Germany introduced draft resolution A/C.6/57/L.8 (and Corr.1) entitled "International Convention against the reproductive cloning of human beings". Its final version reads:

"The General Assembly,

*Recalling* the Universal Declaration on the Human Genome and Human Rights, adopted by the General Conference of the United Nations Educational, Scientific and Cultural

<sup>&</sup>lt;sup>529</sup> The author was present at the meetings documented in the following, her report is based on her own minutes.

Organization on 11 November 1997, and in particular article 11 thereof, which states that practices which are contrary to human dignity, such as the reproductive cloning of human beings, shall not be permitted,

*Recalling also* its resolution 53/152 of 9 December 1998, by which it endorsed the Universal Declaration on the Human Genome and Human Rights,

*Bearing in mind* Commission on Human Rights resolution 2001/71 of 25 April 2001, entitled "Human rights and bioethics", adopted at the fifty-seventh session of the Commission,

*Mindful* of the importance of the development of the life sciences for the benefit of mankind with full respect for the integrity and dignity of the human being,

Aware that the rapid development if the life sciences opens up tremendous prospects for the improvement of the health and the restoration of human dignity of individuals and mankind as a whole, but also that certain practices pose potential dangers to the integrity and dignity of the individual,

*Concerned* by the seriousness of problems posed by the development of techniques of reproductive cloning of human beings applied to mankind, which may have consequences for respect for human dignity,

*Particularly concerned*, in the context of practices that are contrary to human dignity, at recently disclosed information on research into and attempts at the reproductive cloning of human beings, *Determined* to prevent as a matter of urgency such an attack on the human dignity of the individual,

*Recalling* its resolution 56/93 of 12 December 2001, by which it decided to establish an Ad Hoc Committee, open to all States Members of the United Nations or members of specialized agencies or of the International Atomic Energy Agency, for the purpose of considering the elaboration of an international Convention against the reproductive cloning of human beings,

*Resolved* to address issues related to other forms of human cloning, including through the elaboration of an appropriate separate international instrument, as soon as negotiations on a Convention against the reproductive cloning of human beings have been concluded,

*Bearing in mind* that this purpose does not preclude the possibility of States parties adopting stricter national regulations,

*Determined* to adopt provisional measures at the national level to prevent potential dangers to the human dignity of the individual pending the adoption and entry into force of an international Convention against the reproductive cloning of human beings and any other instrument in the field of cloning of human beings,

1. *Welcomes* the report of the Ad Hoc Committee on an international Convention against the reproductive cloning of human beings on its work from 25 February to 1 March 2002;

2. *Decides* that the Ad Hoc Committee shall be reconvened from \_\_\_\_\_ to \_\_\_\_ February and from \_\_\_\_\_ to \_\_\_\_ September 2003

in order to prepare, as a matter of urgency and if possible by the end of 2003, a draft international Convention against the reproductive cloning of human beings;

3. *Requests* the Ad Hoc Committee, in developing the draft Convention:

a) To consider, inter alia, the following indicative elements: scope, definitions, prohibition of reproductive cloning of human beings, national implementation, including penalties and preventive measures, jurisdiction, promotion and strengthening of international cooperation and technical assistance, collection, exchange and analysis of information and mechanisms for monitoring implementation;

b) To specify that the prohibition of reproductive cloning of human beings does not imply the endorsement of any other form of cloning of human beings for any purpose;

c) To ensure that States parties shall not be prevented from adopting or maintaining stricter regulations on the prohibition of cloning of human beings than those contained in the draft Convention;

4. *Requests* the Ad Hoc Committee to take into consideration the relevant existing international instruments;

5. *Decides* that it will consider, as a priority, proposals to address issues related to other forms of cloning of human beings, including one or more appropriate separate international instruments, as soon as negotiations on a draft international Convention prohibiting the reproductive cloning of human beings have been concluded;

6. *Invites*, to that end, the World Health Organization and the United Nations Educational, Scientific and Cultural

Organization to start elaborating, without delay, in close cooperation with the appropriate United Nations bodies, a joint preparatory document, outlining from a scientific and ethical perspective the relevant issues to be considered, inter alia, the current state of the art of the human cloning techniques, and to submit this document no later than the end of 2003;

7. *Calls upon* those States which have not yet done so, pending the entry into force of an international Convention against the reproductive cloning of human beings and their becoming party thereto, to adopt at the national level a prohibition of reproductive cloning of human beings;

8. *Also calls upon* those States which have not yet done so to adopt at the national level a moratorium on or a prohibition of, other forms of cloning of human beings that are contrary to human dignity;

9. *Requests* the Secretary-General to provide the Ad Hoc Committee with the necessary facilities for the performance of its work;

10. *Invites* the Ad Hoc Committee to take into consideration the contributions of United Nations bodies and to closely involve the United Nations Educational, Scientific and Cultural Organization, the World Health Organization and the United Nations Conference on Trade and Development in the process of negotiations;

11. *Requests* the Ad Hoc Committee to report on its work to the General Assembly at its fifty-eight session;

12. *Decides* to include in the provisional agenda of its fiftyeight session an item entitled "International Convention against the reproductive cloning of human beings".

In his speech, the representative of Germany, also on behalf of France, drew an analogy taken from the Sixth Committee's negotiations on anti-terrorist Conventions: "Do you think that those who are now trying to lead us into inaction, or into false action, would buy the argument that we cannot deal with, let's say, bombing terrorism unless we agree on the related issue of financing terrorism? Did we accept a blockade on sectored negotiations because we believed that the only valid solution would be a comprehensive Convention?"<sup>530</sup> This statement displays a determination to convince the plenary but also a disappointment that other delegations decided not to follow their reasoning. The representative further urged delegations to act now and accept the German-French proposal by appealing to the responsibility of the Sixth Committee and the wrong signal that would be sent to the international community if it decided not to elaborate a Convention against reproductive cloning now: "What will it say about the Sixth Committee, which after all is the Legal Committee, if we would spend considerable amounts of energy legislating such issues as electronic signatures and receivables in international trade, but lost our sense of urgency in the face of legislating the issue of reproductive cloning – an issue that all of us, in UNESCO, have identified as a severe violation of human dignity?"531

### b) Introduction of the draft resolution by the United States, Spain, and the Philippines

Then, the representative of Spain introduced draft resolution A/C.6/57/L.3 (and Rev.1 and Corr.1), entitled "International

 <sup>&</sup>lt;sup>530</sup> See statement by Christian Much, head of the German delegation, also on behalf of the French delegation, before the Sixth Committee, New York, on 17 October 2002 (which is at the hands of the author).
 <sup>531</sup> Ibid

Convention against human cloning", arguing along the lines of previous statements made by the "maximalists".<sup>532</sup> Its final version reads:

"The General Assembly,

*Recalling* the Universal Declaration on the Human Genome and Human Rights, adopted by the General Conference of the United Nations Educational, Scientific and Cultural Organization on 11 November 1997, and in particular article 11 thereof, which states that practices which are contrary to human dignity, such as the reproductive cloning of human beings, shall not be permitted,

*Recalling also* its resolution 53/152 of 9 December 1998, by which it endorsed the Universal Declaration on the Human Genome and Human Rights,

*Bearing in mind* Commission on Human Rights resolution 2001/71 of 25 April 2001, entitled "Human rights and bioethics", adopted at the fifty-seventh session of the Commission,

*Mindful* of the importance of the development of the life sciences for the benefit of mankind with full respect for the integrity and dignity of the human being,

*Mindful also* that certain practices pose potential dangers to the integrity and dignity of the individual,

*Concerned* at recently disclosed information on research into and attempts at the creation of human beings through cloning processes,

<sup>&</sup>lt;sup>532</sup> See statement by the delegation of Spain on the draft resolution entitled "International Convention against human cloning" before the Sixth Committee, New York, on 17 October 2002 (which is at the hands of the author).

*Determined* to prevent as a matter of urgency such an attack on the human dignity of the individual,

*Conscious* of widespread preoccupations that the human body and its parts should not, as such, give rise to financial gain,

*Recalling* its resolution 56/93 of 12 December 2001, by which it decided to establish an Ad Hoc Committee, open to all States Members of the Untied Nations or members of specialized agencies or of the International Atomic Energy Agency, for the purpose of considering the elaboration of an international Convention against the reproductive cloning of human beings,

*Determined* to adopt permanent and provisional measures, as appropriate, to prevent potential dangers to the human dignity of the individual,

1. *Welcomes* the report of the Ad Hoc Committee on an international Convention against the reproductive cloning of human beings on its work from 25 February to 1 March 2002;

2. *Requests* the Ad Hoc Committee to be reconvened from 24 March to 4 April 2003 and prepare, as a matter of urgency, the draft text of an international Convention against human cloning, bearing in mind that it will not prohibit the use of nuclear transfer or other cloning techniques to produce DNA molecules, organs, plants, tissues, cells other than human embryos or animals other than humans, and recommends that the work continue during the fifty-eighth session of the General Assembly from 29 September to 3 October 2003 within the framework of a Working Group of the Sixth Committee;

3. *Also requests* the Ad Hoc Committee, in developing the draft Convention, to consider, inter alia, the following indicative elements;

(a) Scope;

(b) Definitions;

(c) The objective;

(d) Implementation;

(e) Preventive measures;

(f) Jurisdiction;

(g) Promotion and strengthening of international cooperation;

(h) Exchange of information;

(i) Mechanisms for monitoring implementation;

4. *Solemnly declares* that, pending the adoption of an international Convention against human cloning, States shall not permit any research, experiment, development or application in their territories or areas under their jurisdiction or control of any techniques aimed at human cloning;

5. *Calls upon* States to adopt such measures as may be necessary to prohibit those techniques of genetic engineering that may have adverse consequences on the respect for human dignity;

6. *Requests* the Secretary-General to provide the Ad Hoc Committee with the necessary facilities for the performance of its work;

7. *Invites* the Ad Hoc Committee to take into consideration the contributions of United Nations agencies and competent international organizations, as well as other relevant bodies of international opinion in the process of negotiations;

8. *Requests* the Ad Hoc Committee to report on its work to the General Assembly at its fifty-eight session;

9. *Decides* to include in the provisional agenda of its fiftyeight session an item entitled "International Convention against human cloning".

# c) Further development of the German-French draft resolution

Discussion on content practically ground to a halt. Hopes that the Holy See would step in as a last-minute mediator were disappointed in New York.<sup>533</sup> The supporters of the rival draft resolutions now tried to establish a majority for their respective proposals.

The United States and Spain were lobbying extensively both through communications among ambassadors and through discussions among delegates. As a consequence, many states in favour of a focused approach for a Convention hinted to the "minimalists" that it might be difficult for them to uphold their position due to political pressure.

France and Germany launched a second worldwide demarche to Capitals in order to win support from UN member states. So did the United States, together with Spain and Costa Rica.

# *d) A meeting of the "friends" of the German-French draft resolution*

The group of about 45 states who at that point had a final negotiating position that was in favour of the German-French initiative met again

<sup>&</sup>lt;sup>533</sup> A representative of the Holy See had indicated that, from the Holy See's perspective, the worst possible result of the ongoing UN negotiations would be to have no result whatsoever. But eventually the Holy See seems to have preferred to uphold its principles, rather than working towards a compromise.

in early November 2002 in New York to discuss how to proceed.<sup>534</sup> The meeting followed a previous meeting on the level of ambassadors from the protagonists of both opposing groups. In this meeting, the U.S. ambassador made it clear that he was planning to use all necessary means to win a vote.<sup>535</sup>

The friends of the German-French initiative asked themselves: Should the vote that the U.S. wished to move towards be accepted? A point in favour of doing so was that the vote could be won (albeit not very impressively); and, above all, another point in favour was that there was no time to lose in the race against irresponsible scientists. Points against the holding of a vote were that it did not seem worthwhile trying to establish a Convention that was concerned with human rights - and hence, by definition, sought to be universally valid – by negotiating among a UN membership that was so deeply divided. Only Japan and Hungary pressed for a decision at any price, even through a vote.

The United Kingdom, China, Singapore and France insisted that the current formulation of the title of the Convention be kept. Once the group agreed that the issue should be kept at the United Nations not least because public opinion would judge a referral to another UN agency as a clear defeat, the next question was, when the Working Group as a whole should reconvene.

The friends of the German-French proposal eventually recommended almost unanimously, albeit with a heavy heart, to propose that the initiative be adjourned, in order to preserve the chance of reaching consensus and hence of winning universal acceptance for the future legal instrument.

<sup>&</sup>lt;sup>534</sup> The author was present at these meetings.

<sup>&</sup>lt;sup>535</sup> So it was reported by the German delegation back to Berlin headquarters, the report is at the hands of the author.

## *e)* The decision following an informal meeting of the two sides

On the basis of this discussion among the friends of the German-French draft Convention, informal negotiations with the protagonists of both opposing groups, France and Germany on the one side, the U.S., Spain, and the Philippines on the other, were launched in New York on 1 and 2 November 2002.<sup>536</sup> All options on how to proceed were discussed. They ranged from referring the negotiations to UNESCO or WHO, from pausing at the United Nations for one or more years, to agreeing at the spot on one of the two draft resolutions. The atmosphere was tense, at times even hostile and several times in the course of negotiations close to being adjourned.

The group agreed insofar as that a vote on the rivalling draft resolutions should be avoided as it would factually break with a tradition of the Sixth Committee that was in itself considered valuable. Also, and more importantly in this particular negotiation, the past days had shown that the great majority of Sixth Committee delegates had been strongly opposed to being forced to vote, most as a matter of principle (consensus tradition should be upheld at all costs), others as a matter of substance (a matter that has implications for human dignity and human life must be unanimous and not "won" by a vote). Many would have abstained. Also, neither of the two groups wished to take the blame for calling on a vote, although the U.S. reiterated several times in the debate that she would not fear to call for a vote and that she was confident to win it.

Of particular concern to France and Germany was the fact that, since the U.S., Spain and the Philippines had submitted their draft resolution to the UN Secretariat first, it would have been voted on first. Many states would hesitate to vote against a U.S. proposal. The voting procedure was thus in favour of the "maximalists" – and had

<sup>&</sup>lt;sup>536</sup> The author was present at this meeting, the following report is based on her own minutes.

most probably been taken into consideration when they so hastily and without prior announcement submitted their proposal to the UN Secretariat.

The two main problems that were discussed in the informal meeting were: France and Germany aimed at continuing the pace of previous negotiations and wanted a meeting of the Ad Hoc Committee in spring of 2003 and a meeting of the Working Group of the Sixth Committee in fall of 2003. The U.S., Spain and the Philippines on the other hand wanted a deferral for a whole year so that only in fall of 2003, the Sixth Committee would take up the issue again in its 58<sup>th</sup> session.

Also, France wanted to keep the current formulation of the title of the Convention with a focus on reproductive cloning, whereas the U.S., Spain and the Philippines aimed at a broadening of the scope so as to include all forms of human cloning, avoiding any reference to former differing textual, thematic decisions of the Sixth Committee.

The result of the lengthy, emotional and at times tensed and strained negotiations was that both groups should suggest the following nonnegotiable package to their capitals:

A concession to U.S. and Spain would be made that no Ad Hoc Committee meeting in spring of 2003 would take place. The next round of negotiations would be deferred to the Sixth Committee meeting in fall of 2003. A concession to France and Germany would be made that the current formulation of the title of the Convention would be kept, with reference to existing UN documents and the negotiation history.

These informal negotiations proved once more to the diplomats in charge that the U.S. might have held no result whatsoever for the best result. Germany and France, as they said in informal discussions, considered it a great success to have kept the original formulation for the title of the Convention since, thus reiterating that the title was a matter of substance.

The capitals of both groups agreed last minute to the package as it had been elaborated. A decision, analogous to the agreement of the protagonists, was subsequently made in the Sixth Committee in consensus on 7 November 2002.<sup>537</sup>

France and Germany did not hide their disappointment on the decision of a deferral just adopted by the Committee. The delegates expressed that the compromise remained behind everybody's expectations and should therefore be no more than an intermediate result.

The United States expressed a similar disappointment and blamed the "minimalists". Costa Rica insisted that this procedural decision of a deferral would in no way prejudge the outcome of future debates on substance. With this statement, Costa Rica was referring to the operative paragraph (c) of the recommendations of the Sixth Committee to the General Assembly, contained in the report<sup>538</sup>: "The General Assembly decides also to include in the provisional agenda of its fifty-eighth session the item entitled International Convention against the reproductive cloning of human beings." Costa Rica thus reiterated the argument that the title – and with it the scope - of a future Convention was up until this point not decided on. Spain assured the Sixth Committee of their cooperation in future negotiations but insisted on its "maximalist" position regarding the scope.

The decision was then passed to the General Assembly which decided to adjourn the matter for a year, i.e. until fall 2003.<sup>539</sup> Thus, the General Assembly drew the logical conclusion from the fact that

<sup>&</sup>lt;sup>537</sup> See UN Doc. A/C.6/57/L.24.

<sup>&</sup>lt;sup>538</sup> See UN Doc. A/57/569 at 7.

<sup>&</sup>lt;sup>539</sup> See GA decision in UN Doc. A/57/49 (vol. II) of 19 November 2002.

the negotiating positions had become entrenched, in particular in the course of the past weeks: Immediate fruitful negotiations on a future Convention which aimed at universality could hardly be imagined. In that respect, whichever delegation had won a vote on its draft resolution could have claimed but a Pyrrhic-victory.

# 6. Analysis of the second round of negotiations: Options for moving on

Following this setback, Germany and France envisioned several options to work the negotiations out of their current deadlock.<sup>540</sup>

They reached the conclusion that improving on their initial position might be the most viable approach. It would show a consistent attitude towards the international community. Germany and France understood however, that the conditions for a swift result had, since the beginnings of the negotiations, worsened – for instance, George Bush had just won the 2002 Congressional elections, was holding a personal position against therapeutic cloning and was supported by the majority of Republicans in the U.S. Congress; also, no meeting of an Ad Hoc Committee was scheduled for spring of 2003 which meant a great loss of time.

Therefore, a new framework had to be elaborated that the "maximalists" could agree to. The most realistic *new* framework seemed to be to agree on a broader mandate aiming at *one* Convention prohibiting or at least regulating all forms of cloning. Germany and France could argue that it was its third attempt at reaching a consensus on the mandate and this new option was trying to integrate the demands of the "maximalists" more than ever before.

Germany however had to be prudent. While it had been blaming the United States of pursuing domestic policy in disguise, Germany itself

<sup>&</sup>lt;sup>540</sup> The following report is based on oral discussions among German and French diplomats and reports of the German delegation back to Berlin headquarters (which are at the hands of the author).

was under a similar suspicion<sup>541</sup>, namely that the foreign ministry was trying to implement a prohibition of reproductive cloning only to then be able to soften its own laws according to the protection level that existed in international law.<sup>542</sup> This accusation was particularly delicate since the German Parliament (Bundestag) had explicitly called for a legally-binding instrument, prohibiting human cloning *to the furthest possible extent*.<sup>543</sup> Insofar, from the viewpoint of some vociferous members of the German Parliament, the only consistent political stance of the German delegation at the UN would have been to side with the "maximalists", the group that aimed at a complete ban on all human cloning.

This conclusion would however have been premature. Germany occupied a lead role in these *consensus-driven* negotiations while having the most restrictive domestic legislation at hand which could never be copied comprehensively into international law. Because the German delegation had the task of reaching at least some tangible results, it was not pressing for a Convention that would merely redraft the German laws - an unrealistic aspiration that would be unsuccessful altogether.<sup>544</sup> In order to fulfill the mandate of the Parliament, the German delegation had to realistically take into consideration the point of view of states with a "minimalist" position to lead the whole exercise to a success. Insofar, the German

<sup>&</sup>lt;sup>541</sup> See Kersten (2004) at 293, 294; Schwägerl (2002a) at 43.

<sup>&</sup>lt;sup>542</sup> See *Kersten* (2004) at 294. Already in 2001, the German government was said to pursue a policy which would leave all possible options for amending German domestic law open, see *Schröder* (2001) at 56, 57.

 <sup>&</sup>lt;sup>543</sup> See SPD, CDU/CSU and Buendnis 90/Die Gruenen in the German Bundestag (2003) at 1, 2. See also Böhmer et. al. (2003).
 <sup>544</sup> Other states such as Costa Rica and the United States were trying to do so and

<sup>&</sup>lt;sup>544</sup> Other states such as Costa Rica and the United States were trying to do so and failed later on – negotiations ended without any legally-binding implications, see particularly the end of UN negotiations when the General Assembly resorted last minute to the drafting of a political Declaration instead of a legally-binding Convention, below at C.V. and C.VI.

delegation was in its careful strategy very well following the Parliament's call to draft a prohibition to the extent possible.<sup>545</sup>

#### IV. A third round of negotiations leading to a deadlock

The third session of the Working Group (29 September – 3 October 2003) was, as many diplomats had feared, largely a déjà-vu experience.<sup>547</sup>

Discussions were held both in the Working Group and in informal consultations. The issue remained the same: the search for a mandate of the future Convention. Many speakers, in spontaneous interventions, reiterated their support for the continued consideration of the topic. However, it was noted with concern that, despite two years of discussing the topic in the General Assembly, limited progress had been made. Nevertheless, strong support was expressed for retaining the item in the agenda of the General Assembly.<sup>548</sup>

The Working Group's attention was drawn to recent announcements of the birth of cloned humans, which, although not confirmed, had highlighted the urgent need for an international ban of reproductive cloning. It was stated that a lack of universally binding regulations dealing with any type of cloning of human beings constituted an open invitation for certain scientists to undertake the kind of research

<sup>&</sup>lt;sup>545</sup> The reproaches on the German delegation were particularly unjustified insofar as they were targeting at the head of the German delegation, Mr. Christian Much, who was a mastermind behind the negotiations as a whole. In substance, the reproaches took their origin in a campaign by some fundamentalist nongovernmental organizations who misrepresented comments that Mr. Much had made in the course of the negotiations. Disagreeing in a comprehensive discussion *Kersten* (2004) at 293-296. See also the ongoing critique of *Schwägerl* (2002a) at 43; *id.* (2002b) at 4; *id.* (2003a) at 12. But so much is true: Only when the domestic law would be amended, i.e. loosened with regard to the protection of early life, Germany would be able to take its foreign policy position that aims at a consensus with regard to a prohibition on reproductive cloning *only* in a manner that will appear less contradictory. On the whole discussion, see further *Sahm* (2001) at 43; *Schwägerl* (2003b) at 2; *Schwägerl* (2003c) at 2, reporting on the critique coming from the German Ethics Council.

<sup>540</sup> 

 <sup>&</sup>lt;sup>547</sup> The author was present at all meetings of the Working Group. Her report is based on her own observations and minutes taken during the meeting.
 <sup>548</sup> See Final Report: UN Doc. A/C.6/58/L.9.

which was considered by all to be morally repugnant and contrary to human dignity.

A new aspect was that those states that were seeking a mandate for a negotiation that was open as to its results – specifically, a combination of a ban on reproductive cloning and a regulation of therapeutic cloning – now articulated their position under Belgian leadership and on the basis of their own draft resolution<sup>549</sup> which rivaled the proposal again put forward by the U.S. and Costa Rica.<sup>550</sup> Germany and France had withdrawn from the lead positions as the proposal that was being developed was too far from their initial intent and, more so, the German Parliament's objective and the latest developments in French law which was liberalized with regard to embryo research.<sup>551</sup> Spain disappeared likewise as a lead partner of the "maximalists", mainly due to a change in the Spanish government which would have an effect on Spain's foreign policy.<sup>552</sup>

### 1. The new proposal under Belgian leadership

Key provisions of the draft resolution submitted by Belgium – which leaned on the concept Germany and France had previously elaborated - were:

The title of the future Convention was "International Convention against the reproductive cloning of human beings". Operative paragraph two of the draft resolution read: "The General Assembly decides that the Ad Hoc Committee shall be reconvened from ... to ... September 2004 in order to prepare, as a matter of urgency and if possible by the end of 2004, a draft international Convention against

<sup>&</sup>lt;sup>549</sup> See UN Doc. A/C.6/58/L.8.

<sup>&</sup>lt;sup>550</sup> See UN Doc. A/C.6/58/L.2.

<sup>&</sup>lt;sup>551</sup> In July 2004, the French parliament adopted a bioethics law banning human cloning as a "crime against the human species" but making embryonic stem cell research legal in France, after the result of three years of haggling. The new law updates a bioethics law of 1994 to make living human embryos available for research. French researcher may now derive stem cells from donated IVF embryos beginning in the spring of 2005, see Sénat No. 92 (2004).

<sup>&</sup>lt;sup>552</sup> See the analysis of Spain's domestic laws and the ongoing political debate at B.II.2.b) aa) and bb).

the reproductive cloning of human beings." Most important was its operative paragraph three: "The General Assembly requests the Ad Hoc Committee, in developing the draft Convention, to include the following elements: (a) An obligation on all contracting parties to ban reproductive cloning of human beings with no possibility of making any reservations; (b) An obligation on all contracting parties to take action to control other forms of human cloning by adopting a ban or imposing a moratorium or regulating them by means of national legislation."<sup>553</sup>

The operative part of the draft resolution thus contains a mandate for a Convention with two elements: A total interdiction of reproductive cloning with no possibility of making any reservations and an obligation on contracting parties to take action on a national level regarding therapeutic cloning in keeping with their own beliefs by either banning it altogether, or imposing a moratorium while waiting for a definite stance, or else by regulating it strictly in order to prevent misuses.

In his address to the delegations<sup>554</sup>, the Belgian representative spoke along the lines of previous German and French ideas. He said that his proposal took into account the fact that different views existed concerning therapeutic cloning. The proposal would respect these differences and not express any judgment on this issue. This option would not oblige any state to renounce its own philosophical beliefs. Rather, it would allow the states willing to ban all forms of human cloning to do so. It would also allow states to keep open the possibility of research for therapeutic purposes, if they so wish, under strict controls.

<sup>&</sup>lt;sup>553</sup> See UN Doc. A/C.6/58/L.8.

<sup>&</sup>lt;sup>554</sup> Which was not submitted in writing.

Under such a mandate for negotiations, therapeutic cloning would only be regulated or prohibited under national law but not at an international level.

Problematic about this approach was however that the provisions in operative paragraph three (b) regarding "other forms of human cloning" were put into the context of a Convention against – reproductive – cloning. Either, it was argued by France and Germany, the United Nations would elaborate a Convention on reproductive cloning only or one that regulates all forms of human cloning in one Convention.

Co-sponsors to this draft resolution were Belarus, Brazil, China, Czech Republic, Denmark, Estonia, Finland, Greece, Iceland, Japan, Latvia, Liechtenstein, Lithuania, Slovenia, Singapore, South Africa, Sweden, Switzerland, Republic of Korea, Turkey and the United Kingdom.<sup>555</sup>

### 2. The proposal made by the United States and Costa Rica

Key provisions of the draft resolution submitted by the United States and Costa Rica remained as they had been drafted one year ago.

The title should be "International Convention against human cloning". The Ad Hoc Committee should be reconvened in fall 2004.<sup>556</sup> Also, "pending the adoption of an international Convention

 <sup>&</sup>lt;sup>555</sup> See UN Doc. A/C.6/58/L.8. The list of "friends" to the new Belgium proposal was in truth much longer. Many delegations refrained from acting as co-sponsors to this draft resolution in order not to infuriate the U.S. delegation. They did however signal their support in informal consultations.
 <sup>556</sup> See draft operative paragraph one of the draft resolution contained in UN Doc.

<sup>&</sup>lt;sup>556</sup> See draft operative paragraph one of the draft resolution contained in UN Doc. A/C.6/58/L.2: "The General Assembly requests the Ad Hoc Committee to be reconvened from ... to ... 2004 in order to prepare, as a matter of urgency, the draft text of an international Convention against human cloning, bearing in mind that it will not prohibit the use of nuclear transfer or other cloning techniques to produce DNA molecules, organs, plants, tissues, cells other than human embryos or animals other than humans, and recommends that the work continue during the fifty-ninth session of the General Assembly from ... to ... 2004 within the framework of a Working Group of the Sixth Committee." In that respect, draft operative paragraph one expressly states that the Convention will only ban cloning when it creates human embryos.

against human cloning, States shall prohibit any research, experiment, development or application in their territories or areas under their jurisdiction or control of any technique aimed at human cloning.<sup>557</sup>

The list of co-sponsors to this draft resolution had in the meantime grown. They were Albania, Angola, Antigua and Barbuda, Benin, Burundi, Chile, Costa Rica, Cote d'Ivoire, Democratic Republic of Congo, Dominica, Dominican Republic, Ecuador, Equatorial Guinea, El Salvador, Eritrea, Ethiopia, Fiji, Gambia, Georgia, Grenada, Haiti, Honduras, Italy, Kazakhstan, Kenya, Kyrgyzstan, Lesotho, Madagascar, Marshall Islands, Micronesia, Nauru, Nicaragua, Nigeria, Palau, Panama, Paraguay, Philippines, Portugal, Rwanda, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, San Marino, Sierra Leone, Spain, Suriname, Tajikistan, Timor-Leste, Turkmenistan, Tuvalu, Uganda, United Republic of Tanzania, United States of America, Uzbekistan, Vanatu and Zambia.<sup>558</sup>

As can be seen, the United States and Costa Rica were able to gather much more political support for their draft resolution. However, this did not remove the problem in itself as many delegations did not want to be forced to vote and still aimed at a consensual solution.

#### 3. Another German-French proposal

Germany took the floor, also on behalf of France, after the introduction of these two competing draft resolutions.<sup>559</sup> The delegate drew attention to the fact that two years ago, when Germany and France introduced the issue of a possible Convention into the General Assembly, countries who are now co-sponsoring either of the two draft resolutions had then enlisted themselves as co-sponsors to a

 $<sup>^{557}</sup>$  See draft operative paragraph three of the draft resolution contained in UN Doc. A/C.6/58/L.2 which thus declares a global moratorium of human cloning until the Convention is adopted.

<sup>&</sup>lt;sup>558</sup> See UN Doc. A/C.6/58/L.2.

<sup>&</sup>lt;sup>559</sup> See statement by Christian Much, head of the German delegation, also on behalf of the French delegation, before the Sixth Committee, New York, on 2 October 2003 (which is at the hands of the author).

consensual approach. He reiterated that France and Germany had, since the beginnings of their initiative, modified their approach twice in an attempt to accommodate other delegations. The goal (which delegations were acknowledging) was to find a reasonable compromise.

In the same speech, Germany and France, once more, offered one, namely negotiations on a single Convention possibly containing a ban on reproductive cloning and strict limitations on therapeutic cloning. It was thus, regarding "reproductive cloning", phrased as an obligation on all contracting parties to ban reproductive cloning with no possibility to make any reservations; regarding "other types of cloning" as an obligation on all contracting parties to ban or impose a moratorium on other types of cloning or otherwise regulate them by means of national legislation.

This was another attempt to accommodate the maximalists' interests of launching negotiations on one Convention addressing all forms of cloning.

In submitting this proposal, Germany was also implementing the beforementioned instruction issued by the *Bundestag* on 20 February 2003<sup>560</sup> to continue the initiative, along with France, on the basis of a further revised negotiating proposal, with the aim of achieving "as far as possible a comprehensive ban" that "as many countries as possible" could agree to. The repeated use of the expression "as .... as possible" reflected the realistic assessment that it was still not possible to achieve complete consensus for a ban on cloning.

### 4. Developments in the Working Group and decision

After the discussion on the rivalling draft resolutions, the German-French compromise quickly started to develop along the usual antagonistic lines.

<sup>&</sup>lt;sup>560</sup> See above at C.III.6. and the Bundestag Report 15/464 "Launching a New Initiative for an International Ban on the Cloning of Human Embryos".

The "maximalists" were unwilling to work on any compromise solution. The "minimalists", in their speeches, defined more clearly that the ethical "worth" of pre-embryonic life and its level of protection underlies different regional and cultural convictions, traditions and beliefs, none of which could therefore be lifted to a worldwide standard. For instance, the delegate of Liechtenstein said: "The questions on the table are far from being purely legal. And the answers to these questions can vary considerably, depending on the criteria applied – be they moral, ethical, philosophical, religious, or scientific. My delegation respects these views of other countries on these issues, knowing that none of them has taken these views easily."<sup>561</sup>

Of particular interests to the plenary was that Iran, in the name of 57 member states of the Organization of the Islamic Conference (OIC)<sup>562</sup> declared that the OIC could not agree to a mandate for the negotiation of a future Convention which would, once and for all, close the door to therapeutic cloning.<sup>563</sup> Only OIC members Senegal and Uganda, in oral interventions, distanced themselves from the speech.

The inflexibility of the "maximalists" was overshadowing that informal negotiations among interested delegations under the chairmanship of the head of the Dutch delegation, Professor Bart Wijnberg, had shown some small possibilities on proceeding in

<sup>&</sup>lt;sup>561</sup> See statement by Mr. Stefan Barriga, Permanent Mission of the Principality of Liechtenstein to the United Nations, New York, 2 October 2003 (which is at the hands of the author).

<sup>&</sup>lt;sup>562</sup> The Organization of the Islamic Conference, set up by the Kings and Heads of State and Government of Islamic States, in 1969, was the concrete expression of the necessity to establish an Organization embodying its aspirations and capable of "carrying out its just struggle against the various dangers which threatened it and still persist" (OIC mission statement). The OIC is an inter-governmental organization grouping fifty-seven States. These States decided to pool their resources together, combine their efforts and speak with one voice to safeguard the interest and ensure the progress and well-being of their peoples and those of other Muslims in the world. For the list of OIC members, see http://www.bernama.com/e vents/oicsummit/oicbasic/country.php?cat=BI.

<sup>&</sup>lt;sup>563</sup> See statement of the delegation of Iran on behalf of the states members of the Organization of the Islamic Conference before the Working Group of the Sixth Committee on an international Convention against the reproductive cloning of human beings, New York, 2 October 2003 (which is at the hands of the author).

consensus. These were (a) a procedural solution, namely holding on to the consensus and universality principle and (b) a substantial solution, namely negotiating *one* Convention that prohibits reproductive cloning and regulates therapeutic cloning, including mechanisms for sanctions and controls and a conference of states that would evaluate and review the success of these mechanisms.

Despite all efforts in these informal negotiations, the Working Group as a whole could not agree on any proposals made. Nevertheless, no delegation called for a vote on the rivalling draft resolutions. The Working Group therefore decided, in response to a proposal made by Iran on behalf of the states members of the Organisation of Islamic Conference, that the matter should be adjourned for a further two years. The Working Group received an insubstantial report to the Sixth Committee, drafted by the UN Secretariat in which it proposed this deferral to the Committee.<sup>564</sup>

In the discussions on the draft report, the "maximalists" made it clear that even in the future there would no room for compromise. The United States and Costa Rica prevented the UN Secretariat from including any formulation regarding future procedural or substantive steps. For instance, the results of the important informal consultations which were held among the protagonists of both sides were not to be included in the report. Also, they tried to hinder the chairman of the Working Group from attaching his own personal assessment of negotiations – a procedure that is common at the United Nations, in particular in the case of controversial negotiations.

### 5. Analysis of the Working Group meeting

The Working Group had not made any progress. On the contrary, positions had become entrenched. The ethical pivot for all delegations was the attempt to safeguard human dignity. However,

<sup>&</sup>lt;sup>564</sup> See UN Doc. A/C.6/58/L.9.

delegations were still unable to find common ground on the question of when human dignity is touched upon.

The one group of states, the "maximalists", believed that it could uphold human dignity only through a total ban of all forms of cloning since any experiments which involve human life is unethical. As the representative of the United States put it, "the killing of a human being can never be justified for research ends... Such experimental cloning would exploit tiny human lives, treating them as a mere resource to be mined and exploited, eroding theirs, and indeed, all human dignity in the process."565 Only few states besides Germany, which had very strict national laws banning all forms of cloning and were generally in favour of a "maximalist" approach, could be as flexible as the representative of Austria put it in his address: "Austria's national legislation prohibits all forms of human cloning. We therefore fully support the efforts to achieve a worldwide comprehensive ban. There are however different views on how to achieve this goal. Austria is flexible in this regard. We could immediately start negotiating a comprehensive ban. Or we could first negotiate a ban on reproductive cloning and subsequently negotiate a total ban. But we will have to bear in mind that an international Convention will only constitute a positive result, if it is signed, ratified and implemented by as many states as possible. A Convention, comprehensive or limited, will not constitute added value, if only those states become parties to it that already have the respective domestic legislation in place."566

Most countries that had national laws banning human cloning comprehensively saw it as their ethical duty to enforce such a ban on

<sup>&</sup>lt;sup>565</sup> See United States Statement – 58<sup>th</sup> UNGA Sixth Committee, Agenda Item 158: International Convention against the Reproductive Cloning of Human beings, 30 September 2003, New York (which is at the hands of the author).

<sup>&</sup>lt;sup>566</sup> See statement by Alexander Marschik, Representative of Austria on Agenda Item 162, International Convention against the Reproductive Cloning of Human Beings, 29 September 2003, New York (which is at the hands of the author).

an international level and could not be flexible in choosing a pragmatic process that would lead to that goal.

The other group, the "minimalists", including states who took a "middle" position, defined research cloning as an ethical duty through which all forms of potential therapeutic good would be explored. As the representative of the United Kingdom said, "we believe that all types of stem cell research, including therapeutic cloning should be encouraged. Indeed we believe that it would be indefensible to stop this research and deny millions of people – and their families – the chance of new treatments which could save their lives."<sup>567</sup>

Insofar, two ethically positive concepts were at that point in time standing against each other. A consensus seemed out of reach. Rather, a vote in the upcoming Sixth Committee meeting, scheduled for October 20 and 21, 2003 was very likely.

The following distribution of potential voters was noted at the end of the Working Group meeting<sup>568</sup>: The group of "maximalists", if counted by their co-sponsorship of the draft resolution, counted 56 in number. This number does not include a great number of states, particularly from Africa, who would (have to) show sympathy for the draft resolution in case of a vote. On the other hand, some Latin-American "maximalists", who had been on the list of co-sponsors in

<sup>&</sup>lt;sup>567</sup> See statement by Elizabeth Woodeson, Department of Health, Delegation of the United Kingdom of Great Britain and Northern Ireland, 20 October 2003, New York (which is at the hands of the author). In the same speech, the representative of the United Kingdom made another crucial point: "We believe that it would be totally unjustifiable to attempt to impose a ban on therapeutic cloning in those countries which have reached a national consensus in favour of this research; which have nationally agreed regulatory systems for embryo research; and which are working to deliver new treatments for serious and life threatening diseases." Such countries would, *de facto* and *de jure*, not be able to agree to an international Convention against therapeutic cloning. Delegations aiming at a comprehensive Convention would thus willingly exclude such countries and compromise on then goal of universality for the sake of principle.

<sup>&</sup>lt;sup>568</sup> The following potential voters' list is based on the authors own observations, informal talks and minutes.

the previous year (for instance Argentina, Ecuador and Peru) were not on the list anymore.

The group of "minimalists", if counted by their co-sponsorship of the draft resolution, counted 22 in number. According to their speeches in the Working Group meetings, India and Australia also counted in.

The group of states that were holding a "middle position" counted about 60 states in number. Among these, the countries that would substantially thrift towards a "maximalist" approach, due to their national legislation, but with a willingness to compromise for a consensual solution were France, Germany, Austria, Canada, Norway and Morocco.

Countries that substantially drifted towards a "minimalist" approach were Korea, New Zealand, Cuba, Russia, the Netherlands and Iran (speaking for the OIC, and supported expressly by Jordan, India and Sudan, while Senegal and Uganda expressly dissociated themselves); Eastern Europeans and the majority of Asian countries (some of which though were "minimalists", such as China and Singapore).

A special case was Mexico which tended to a "maximalist" approach, but expressly supported a consensual solution, most probably because the chairman of the Working Group was Mexican.

This distribution of positions suggests that three main groups had formed: 70 "maximalists", 25 "minimalists" and 60 consensusoriented countries.

However, in case of a vote on the U.S./Costa Rican draft resolution, some countries could potentially abstain on the principle that the Sixth Committee should not adopt a decision by vote but by consensus. On the other hand, some of the "middle ground" countries could vote in favour of that draft resolution (for instance Mexico and some OIC members). Also, in case of a vote on the Belgian proposal, the majority of "middle ground" countries would probably vote in favour, some however could potentially abstain, again either out of the principle of no-vote or because they do not want to harm the "maximalists" (especially Latin American countries out of regional loyalty with Costa Rica, or under pressure from the United States).

Altogether, the result of a vote was difficult to foresee. Many countries could potentially decide for other than substantive reasons, for instance, in order not to expose themselves to either of the two sides, to show political loyalty to a country from their region, to give way to political pressure, or to simply show their annoyance with the whole process.

## 6. Sixth Committee meeting reviewing the report of the Working Group

The Sixth Committee took up the issue on 20 and 21 October 2003.

### a) Developments since the end of the Working Group

Since the end of the Working Group meeting, some developments had taken place, following informal negotiations.<sup>569</sup>

Some "maximalists" argued within their group that they could agree to the formulation proposed by France and Germany (middle position): "to convene an Ad Hoc Committee to elaborate a Convention addressing all forms of cloning of human beings". The majority of "maximalists" however rejected this option. Procedurally, the United States and Costa Rica seemed to push the development towards a vote, maybe to get the great number of states that were unwilling to vote on the rivalling resolutions to agree to a deferral of the issue for another two years. At least among the "maximalists", the majority seemed ready to agree on a deferral.

<sup>&</sup>lt;sup>569</sup> The author was present in New York during this time, observing developments on behalf of the German delegation. The following report is based on her minutes.

The "minimalists" agreed that they would not be able to win a vote in favour of their draft resolution. They identified two options, one, to call for a no-motion action should the U.S. call for a vote; two, to agree to a two year deferral. The majority of "minimalists" favoured a deferral since otherwise the no-motion action would lead to the end of the anti-cloning initiative at the United Nations

Also, the (Philippine) chairman of the Sixth Committee let both groups know that he would favour a deferral over a vote. Altogether, a deferral of the decision on the mandate of a future Convention seemed very likely.

#### b) Decision of the Sixth Committee

In the Sixth Committee meeting<sup>570</sup>, the U.S./Costa Rica and Belgium introduced their respective draft resolutions once more and a general debate was held which only reiterated the well-known positions of delegations.

On 20 October 2003, the representative of Costa Rica, on behalf of the group of sponsors, introduced draft resolution A/C.6/58/L.2. In its address to the Sixth Committee<sup>571</sup>, Costa Rica explicitly excluded the options "deferral", "passing the issue over to UNESCO" and "compromise on substance" and did not make any statement regarding a possible vote. The topic of cloning had to be addressed as quickly as possible, he said. Suggestions made by other delegations to defer the issue for one or two more years were unacceptable. Also, Costa Rica pointed at the respectable number of 56 co-sponsors to their draft resolution.

 $<sup>^{570}</sup>$  The author was present at all meetings which she is reporting on in the following.

<sup>&</sup>lt;sup>571</sup> See statement by the delegation of Costa Rica, Introduction of the draft resolution on Human Cloning before the Sixth Committee, 20 October 2003, New York (which is at the hands of the author).

On the same day, Belgium, on behalf of the group of sponsors, introduced draft resolution A/C.6/58/L.8.<sup>572</sup> He pleaded for holding on to the consensus principle and explicitly rejected a vote.

On 31 October 2003, the representative of Iran, on behalf of the states members of the Organization of the Islamic Conference, announced that it intended to request, under rule 116 of the Rules of Procedure of the General Assembly, that the debate be adjourned on the item until the 60<sup>th</sup> session of the General Assembly (2005).<sup>573</sup>

Finally, on 6 November 2003, the Sixth Committee came to discuss this motion presented orally. Two states supported the motion proposed by Iran, namely Belgium, on behalf of the sponsors of draft resolution L.8, and India. Likewise two states opposed it, namely Uganda and Spain.<sup>574</sup> According to rule 116 of the Rules of Procedure of the General Assembly, the motion should, after this, immediately be put to the vote.

This session of the Sixth Committee was the last in the year 2003 and was marked by some dramatic elements. The vote took place in front of running TV cameras and was attended by almost all delegations, at times by ambassadors, in particular in delegations which were supporting the U.S./Costa Rican proposal. From the same circle however, some decisive voters were also missing – due to "diplomatic illness". Symptomatic for the politicization of the vote

<sup>&</sup>lt;sup>572</sup> See statement by the delegation of Belgium, Convention Internationale contre le clonage d'etres humains a des fins de reproduction, le 20 octobre 2003, New York (which is at the hands of the author).
<sup>573</sup> See statement by the delegation of the Islamic Republic of Iran to the United

<sup>&</sup>lt;sup>573</sup> See statement by the delegation of the Islamic Republic of Iran to the United Nations, International Convention against the Reproductive Cloning of Human Beings, 31 October 2003, New York (which is at the hands of the author). Iran stated that the motion was intended to be without prejudice to any positions that delegations may have on either proposal. It was taken due to the lack of consensus on how to proceed on substance and the uncertainty among the scientific community about the promises of therapeutic cloning

<sup>&</sup>lt;sup>574</sup> The choice of Uganda and Spain as the two delegations opposing the motion was obviously made in order to counter the OIC motion with an OIC member (Uganda) and the Belgians with another member of the European Union (Spain). Both states however made it known that they were not very happy with being chosen for that role.

was that the chairman's reminder to vote according to one's conscience was met with great laughter among delegations.

The Sixth Committee voted and adopted the motion by a vote of 80 to 79, with 15 abstentions.<sup>575</sup> The Chairman then announced that it was his understanding that it necessarily followed that the Sixth Committee, in effect, was recommending to the General Assembly that it include the item in its agenda for the sixtieth session (2005). Accordingly, no action was taken on draft resolutions A/C.6/58/L.2 and A/C.6/58/L.8.

Then, the Sixth Committee finalized its report<sup>576</sup> in which it included the two draft resolutions L.2 and L.8 and summarized the results of the vote on the motion to adjourn the debate on the item until 2005.

<sup>&</sup>lt;sup>575</sup> See UN Doc. A/58/520 at 6-7.

**In favour**: Algeria, Argentina, Armenia, Azerbaijan, Bahamas, Bahrain, Belarus, Belgium, Botswana, Brazil, Brunei Dar-Salam, Bulgaria, Cambodia, China, Comoros, Croatia, Cuba, Cyprus, Czech Republic, Democratic Peoples Republic of Korea, Denmark, Djibouti, Egypt, Estonia, Finland, France, Gabon, Germany, Greece, Hungary, Iceland, India, Indonesia, Islamic Republic of Iran, Japan, Jordan, Kuwait, Latvia, Lebanon, Liechtenstein, Lithuania, Luxembourg, Malaysia, Maldives, Mali, Mauritania, Mauritius, Mexico, Monaco, Morocco, Myanmar, Namibia, Netherlands, New Zealand, Niger, Oman, Pakistan, Qatar, Republic of Korea, Russian Federation, Saudi Arabia, Senegal, Singapore, Slovenia, South Africa, Sri Lanka, Sudan, Swaziland, Sweden, Switzerland, Syrian Arab Republic, Thailand, Tonga, Tunisia, Turkey, United Arab Emirates, the United Kingdom, Viet Nam, Yemen and Zimbabwe.

Against: Albania, Andorra, Angola, Antigua and Barbuda, Australia, Austria, Barbados, Belize, Bolivia, Bosnia and Herzegovina, Burundi, Central African Republic, Chile, Costa Rica, Democratic Republic of Congo, Dominica, Dominican Republic, Ecuador, El Salvador, Equatorial Guinea, Eritrea, Ethiopia, Fiji, Gambia, Georgia, Grenada, Guatemala, Guinea, Guyana, Haiti, Honduras, Ireland, Israel, Italy, Kazakhstan, Kenya, Kyrgyzstan, Lesotho, Madagascar, Malawi, Malta, Marshall Islands, Micronesia (the Federated States of), Nauru, Nepal, Nicaragua, Nigeria, Norway, Palau, Panama, Papua New Guinea, Paraguay, Philippines, Poland, Portugal, Rwanda, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Samoa, San Marino, Sao Tome and Principe, Sierra Leone, Slovakia, Solomon Islands, Somalia, Spain, Suriname, Tajikistan, Timor-Leste, Trinidad and Tobago, Tuvalu, Uganda, United Republic of Tanzania, United States of America, Uzbekistan, Vanuatu, Venezuela and Zambia.

**Abstentions:** Bangladesh, Bhutan, Burkina Faso, Cameroon, Canada, Cape Verde, Colombia, Jamaica, Peru, Republic of Moldova, Romania, Serbia and Montenegro, The Former Yugoslav Republic of Macedonia, Ukraine and Uruguay.

When the number of votes was at 81:78, Venezuela changed its vote from Yes to No, probably following the request of interested delegations and, at the last minute, changed the vote to 80:79. It did not however affect the majority in favour of the motion.

<sup>&</sup>lt;sup>576</sup> See UN Doc. A/58/520.

The report ends with the recommendation of the Sixth Committee to the General Assembly that the item entitled "International Convention against the reproductive cloning of human beings" be included in the provisional agenda of the sixtieth session of the General Assembly.

### 7. Analysis of the third round of negotiations

The vote was won albeit very tightly. Delegations were assuming that the United States and Costa Rica would try to re-open the issue in the General Assembly and change the result in their favour. Such attempts however would have been useless because procedural decisions – and this motion clearly was procedural, not only according to the statement of the chairman but also according to the official UN document through which the vote was published – do not need to be confirmed by the General Assembly. They take direct effect.

The German-French initiative at the United Nations until this point had at least achieved one thing: It had placed the political issue of bioethics more firmly on the international agenda than ever before and raised awareness of developments in genetic technology. Other than this, however, the results had yet to be seen. Many of the participants in the negotiations were dissatisfied with the adjournment decision and accepted it only as the lesser evil in comparison with negotiations that would have been condemned to failure owing to the lack of a sound basis.

Out of the two options to vote on, either the adjournment proposal (procedural decision) or the two rivalling draft resolutions (substantive decision), the adjournment was the better option. Nevertheless, in view of time pressure to draft an effective ban on reproductive cloning as soon as possible, the result of the Sixth Committee meeting was not satisfying.

As the distribution of votes of delegations shows, the United Nations was split almost equally into two, with all regional groups being represented on both sides. Once more, it has become evident that, at this point in time, negotiations on substance on either of the two rivalling draft resolution would be illusionary – universally valid results could never be achieved. The German-French initiative was now shelved.

### 8. Follow-up decision of the General Assembly

On 9 December, the plenary session of the General Assembly decided<sup>577</sup> that the item entitled "International Convention against the reproductive cloning of human beings" would be included in the provisional agenda of its fifty-ninth session. Thus, it shortened the period of adjournment from two to one year, i.e. until fall 2004.<sup>578</sup>

### 9. **Options for moving on**

Should the will to compromise develop after all, there were several possible ways out of the current dilemma. Different ideas were circulating among delegations and in ministries.<sup>579</sup> The member states could initially pass a "Convention against the reproductive cloning of human beings". Within this Convention, a legally binding decision would have to be made as to whether this should be directly followed by negotiations concerning further forms of genetic manipulation. These negotiations could result in a further Convention or a supplementary Protocol to the Convention against reproductive

<sup>&</sup>lt;sup>577</sup> See GA decision in UN Doc. 58/523, in: Resolutions and decisions adopted by the General Assembly during its fifty-eighth session, vol. II at 14.

<sup>&</sup>lt;sup>578</sup> Costa Rica proposed a revised resolution to the General Assembly than the one it had proposed to the Sixth Committee, see UN Doc. A/58/L.37. The General Assembly decided to include the item at its next session and not to take any action on either the recommendation of the Sixth Committee or the draft resolution proposed by Costa Rica, see UN Doc. A/58/PV.72 of 9 December 2003.

The United Kingdom, in explanation of position after the vote, stated that it will neither participate in drafting a Convention that would ban therapeutic cloning, nor become a party to such a treaty, see *id*.

<sup>&</sup>lt;sup>579</sup> The author was following the debates among UN delegations and, more importantly, German diplomats. The following report is based on her own observations and minutes from discussions between the German UN delegation and its Berlin headquarters.

cloning. At most, the demand for the *absolute protection of the embryo* might mean that two separate, successive sets of negotiations will be required, especially if the outcome of the second phase of the negotiations is left open.

Alternatively, the Convention against the reproductive cloning of human beings could contain a binding ruling that an assembly of the signatory states is to draw up a decision on the prohibition of *therapeutic* cloning after a certain number of years. Then there would be sufficient time to prepare this decision without blocking the negotiations on reproductive cloning.

If both the models presented should unexpectedly fail, a draft Convention could be developed whereby the demands of the "maximalists" are met without removing the freedom demanded by the "minimalists". Such a draft Convention would contain the following elements: Every state is permitted to forbid the cloning of embryos in toto; states that do not forbid cloning in toto, are obliged to forbid reproductive cloning and to allow therapeutic (and other cloning) only in accordance with certain ethical criteria (e.g. only using supernumerary IVF embryos) and security precautions (e.g. a register and other measures to ensure against abuse and misemployment). National and international monitoring of security precautions would have to be arranged as well as international cooperation to prevent abuse and circumvention and to help developing countries benefit from possible advances (in medicine or pharmaceuticals). The regulations on therapeutic cloning could be reviewed after five years, in consultation with the World Health Organization.

This approach would make it clear that therapeutic cloning is not being given implicit approval. There would also be an unprecedented clause requiring review after five years. It would provide the "minimalists" with legal security for the foreseeable future and would not deprive them of anything that they are not prepared to give up voluntarily. Even states that wish to keep the door to therapeutic cloning open do not deny that internationally binding rules are needed in this sphere (e.g. China and the United Kingdom).

# V. A fourth round of negotiations days before the U.S. presidential elections

One year later, on 21 October 2004, the delegates to the Sixth Committee resumed their discussion on the two rivalling proposals.<sup>580</sup> New scientific findings published in the meantime had once more proven the need for a speedy decision of the United Nations, most prominently the article published in *Science* by South Korean researchers detailing a major breakthrough in therapeutic cloning<sup>581,582</sup> The researchers reported the derivation of a pluripotent embryonic stem cell line from a cloned human blastocyst. Diplomats now were hoping that this scientific development would breathe life into the seemingly moribund exercise at the UN.

Informal channels among delegations were however lying idle. It was clear, that progress in this years' Sixth Committee meeting mainly depended on the U.S. delegation to either push L.2 through by calling for a vote, or remaining silent. Any U.S. strategy would undoubtedly be targeting at undecided U.S. voters in the upcoming U.S. presidential election which was to take place on 2 November 2004. President Bush was opposed to the method of procuring embryonic stem cells through cloning, and he had banned Federal support of any work with stem cells created after 9 August 2001. His opponent in the presidential campaign, Senator John Kerry, supported Federal funding for such experiments.

<sup>&</sup>lt;sup>580</sup> The author was present at this fourth round of negotiations. The following report is based on her own observations and minutes.

<sup>&</sup>lt;sup>581</sup> See *Hwang* et al. (2004) at 1669-1674.

<sup>&</sup>lt;sup>582</sup> Which later turned out to be a lie, see only *Zinkant* (2006)

Two strategies were imaginable: One possible strategy of the Bush administration could be not to push a broad ban through the United Nations, since Bush would thus lose his pro-research voters who favour stem cell research. Likewise, she would not agree to a partial ban on reproductive cloning either, since Bush would thus lose the conservative, religious voters. By doing nothing at all, however, Bush would keep both the conservative voters, since his position is in any case more conservative than Kerry's, and keep the more liberal voters at the same time.

However, Bush was under political pressure to reach *some* tangible outcome. The Boston Globe, for instance, had written in an editorial: "US researchers are already working under the cloud of President Bush's 2001 order that forbade US funds for stem cell experiments using any but a few lines of cells. Congress should ban reproductive but not therapeutic cloning and should liberalize stem cell research by permitting US funding for it both on embryos left over at fertility clinics and on cloned embryos. Sufferers of diseases should not be denied the best efforts of US scientists."<sup>583</sup>

## 1. In the meantime: Revised draft resolutions and extended co-sponsor lists

Minor changes had in the meantime been made in both draft resolutions.

The Costa Rican draft resolution A/C.6/59/L.2 of 29 September 2004 was almost identical to the one of the year before (A/C.6/58/L.2). Besides stylistic changes, and some changes in the list of co-sponsors<sup>584</sup>, the dates for reconvening an Ad Hoc Committee to be

<sup>&</sup>lt;sup>583</sup> See *Globe Editorial*, The Boston Globe Online of 13 February 2004, http://www.boston.com/news/globe/editorial\_opinion/editorials/articles/2004/02/13 /clonings\_new\_frontier/.

<sup>&</sup>lt;sup>584</sup> **New Co-sponsors**: Albania, Angola, Australia, Burundi, Chad, Chile, Equatorial Guinea, Georgia (announced orally) Guinea, Ireland (announced orally) Liberia, Malawi, Papua New Guinea, Rwanda, Saint Lucia, Sao Tome and Principe, Solomon Islands, Tuvalu, and Uzbekistan (announced orally).

entrusted with the elaboration of a draft Convention text were now suggested for 2005 (operative paragraph 1). In operative paragraph 3 stronger language was used:

"Solemnly declares that, pending the adoption of an international Convention against human cloning, states shall Urges states to prohibit any research, experiment, development or application in their territories or areas under their jurisdiction or control of any technique aimed at human cloning, pending the adoption of an international Convention against human cloning."

The Belgian draft resolution A/C.6/59/L.8 of 6 October 2004 also had minor changes,<sup>585</sup> see operative paragraph 2 (b):

"An obligation on all contracting parties to take action to control other forms of human cloning by adopting a ban or imposing a moratorium or regulating them by means of national legislation, including strict controls, inter alia, to ensure that the results of therapeutic cloning are not used to advance reproductive cloning."

Former Co-sponsors that have withdrawn: Dominica, Georgia, Kazakhstan, and Spain.

Altogether, that makes a co-sponsor list of 60, including 22 from Africa, 13 from Central America/Caribbean, 11 from the Pacific, 2 from South America, 5 from Eastern Europe/Central Asia, 3 from the European Union, and 3 from the "Western European and Others group" (WEOG).

The complete list of Co-sponsors for L.2 is: Albania, Angola, Antigua and Barbuda, Australia, Benin, Burundi, Chad, Chile, Costa Rica, Côte d'Ivoire, Democratic Republic of the Congo, Dominican Republic, El Salvador, Equatorial Guinea, Eritrea, Ethiopia, Fiji, Gambia, Georiga, Grenada, Guinea, Haiti, Honduras, Ireland, Italy, Kenya, Kyrgyzstan, Lesotho, Liberia, Madagascar, Malawi, Marshall Islands, Micronesia, Nauru, Nicaragua, Nigeria, Palau, Panama, Papua New Guinea, Paraguay, Philippines, Portugal, Rwanda, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, San Marino, Sao Tome and Principe, Sierra Leone, Solomon Islands, Suriname, Tajikistan, Timor-Leste, Tuvalu, Uganda, United Republic of Tanzania, United States of America, Uzbekistan, Vanuatu and Zambia, see UN Doc. A/C.6/59/L.2.

<sup>&</sup>lt;sup>585</sup> New Co-sponsors: Cambodia, Cuba, Estonia, and France (announced orally).

**Former Co-sponsors** that have withdrawn: Brazil, Slovenia, and Liechtenstein. Altogether, that makes a co-sponsor list of 22, including 11 from the European Union, 5 from Asia, 3 from WEOG, and South Africa, Cuba and Belarus.

**The complete list of Co-sponsors** for L. 8 is: Belarus, Belgium, Cambodia, China, Cuba, Czech Republic, Denmark, Estonia, Finland, France, Greece, Iceland, Japan, Latvia, Lithuania, Republic of Korea, Singapore, South Africa, Sweden, Switzerland, Turkey and United Kingdom, see UN Doc. A/C.6/59/L.8.

The new co-sponsor lists revealed that Spain had left the group of "maximalists". Also, and more importantly, France joined the "minimalists" and left the liason with Germany opting for a "middle ground" solution. As of now, Germany and France had agreed to remain silent and only take a position in the case of a vote.

Then, a group of eight states (four states per group, Costa Rica, the U.S., Portugal, Uganda – Belgium, U.K., Japan, Korea) met prior to the negotiations in the Sixth Committee to determine a possible consensus. Two options were debated<sup>586</sup>, without a definite agreement. One was to hold a conference in 2005 in which the scientific and ethical debate should be further investigated. The other option was to agree on a short resolution or declaration, in which concern regarding all forms of human cloning would be expressed, all states would be called upon to prohibit reproductive cloning through national legislation, and the UN General Assembly asked to assist states in exchanging information about their respective national legislation.

Until the beginning of negotiations, it was unclear whether the U.S. delegation would call for a vote. Some delegations were interpreting this open-ended dialogue with the U.S. in such a way, that the U.S. delegation did not know how it could agree to a compromise when President Bush in his address to the UN General Assembly on 21 September 2004 had expressly supported the Costa Rican proposal, i.e. that the delegation was unsure of its own tactics and ultimate goals. Others thought that the U.S. delegation wanted to win time before the national elections in November 2004 and then make a decision on where she would stand.

<sup>&</sup>lt;sup>586</sup> The author was not present at this meeting, but received information about the meeting through informal channels from the "minimalists".

#### 2. Negotiations: A final attempt

Not knowing, where the deliberations would take them, the Sixth Committee delegations considered the item on 21 and 22 October and on 19 November 2004.<sup>587</sup>

#### a) The first round of speakers: A majority of "minimalists"

On the first meeting day, 21 October, Costa Rica and Belgium introduced their draft resolutions as amended over the past year.

The Belgium delegation stressed that its draft should not be seen as a contradiction to the Costa Rican draft.<sup>588</sup> Like the latter, it neither supportes therapeutic cloning, nor does it preclude the possibility of a ban on therapeutic cloning. On the contrary, it expressly opens up the possibility of a ban on therapeutic cloning. The envisaged Convention could entail three alternatives regarding therapeutic cloning: a ban, a moratorium, or a strict reglementation. By doing so, Belgium wants to focus on a common denominator among all states, instead of on aspects that split the United Nations into two. Finally, delegations should ask themselves what they wanted: An effective Convention or a political effect in the sense of a "symbolic victory". For the latter, the Sixth Committee would not be the apt forum and a Convention not the apt means.

The delegation of Costa Rica, on the other hand, stressed that only a comprehensive legal framework prohibiting all forms of human

<sup>&</sup>lt;sup>587</sup> Altogether, statements were made by the representatives of Costa Rica, Belgium, Indonesia, Korea (Rep. of), Japan, Turkey (on behalf of the Organization of the Islamic Conference), Namibia, Finland, the United Kingdom, Portugal, Brazil, Singapore, France, India, Cuba, New Zealand, Panama, China, Botswana (on behalf of the Southern African Development Community as well as the candidate country of Madagascar), Greece, South Africa, Zimbabwe Slovakia, Ghana, Jordan, Cyprus, Nigeria, Kenya, Honduras, Fiji, Italy, Norway, Sudan, Malaysia, Sweden, Thailand, Sierra Leone, Germany, Ethiopia, Philippines, Uganda, United States of America, El Salvador, Viet Nam, the Gambia, Timor Leste, Mexico, Senegal, Paraguay and Nicaragua. Statements were also made by the Permanent Observer of the Holy See, the Permanent Observer of the Sovereign Military Order of Malta, and by the representative of UNESCO.

<sup>&</sup>lt;sup>588</sup> See statement by the delegation of Belgium, Convention Internationale contre le clonage d'etres humains a des fins de reproduction, le 21 octobre 2004, New York (which is at the hands of the author).

cloning would adequately protect the dignity of human embryos.<sup>589</sup> By opening the door to some, albeit limited, cloning of human embryos, scientists would be able to perfect their techniques thereby increasing the possibility of a human clone being born. Reference was also made to the prospect of the exploitation of women, particularly in developing countries, by "scientific entrepreneurs" seeking to harvest millions of human eggs in order to undertake such research. In response to the call by the proponents of the opposing draft resolution for respect for the diversity of views among nations and societies, the analogy was drawn to the debate on cultural relativism versus the universality of human rights, where the United Nations had decided to adopt a common universal standard, despite divergences in practices at the national level.

An overwhelming majority of speakers that day called for consensus and dismissed the option of a divisive vote:<sup>590</sup> The Convention against reproductive cloning could have entered into force by now, if negotiations had not been overloaded (Belgium, Indonesia, Finland, Brazil, U.K., France); the ethical dissent regarding therapeutic cloning was a reality that could not simply be removed through a vote (China, Korea, Singapore, Greece); more tolerance was due, since nobody should impinge his own ethics on others (the U.K., Japan, and Finland).

The delegation of Singapore critically discussed a position paper from the Vatican<sup>591</sup> and concluded that no one holds a 'monopoly on truth'. To assume the contrary would be the start of a scourge.<sup>592</sup>

<sup>&</sup>lt;sup>589</sup> See statement by the delegation of Costa Rica before the Sixth Committee, Draft resolution on Human Cloning, 21 October 2004, New York (which is at the hands of the author).

<sup>&</sup>lt;sup>590</sup> Altogether, 21 states and UNESCO made statements (India, Korea, Japan, Turkey, Namibia, Finland, the U.K., Portugal, Brazil, Singapore, France, Cuba, New Zealand, Panama, China, Botswana, Greece, South Africa, Zimbabwe, the Vatican). 17 of those supported the Belgian proposal L.8, 3 supported the Costa Rican proposal L.2. (Portugal, Panama, the Vatican).

<sup>&</sup>lt;sup>591</sup> See "Considerations of the Holy See on human cloning", contained in UN Doc. A/C.6/59/INF/1.

The delegation of France, in a spontaneous intervention, explained why it was supporting an approach that was falling short compared to its national legislation: The biggest danger at the time would either lie in the continuation of a state of anarchy, or in a Convention that wanted to achieve too much and therefore remained without any actual force or effect. Therefore, an immediate prohibition of reproductive cloning was the highest priority while national laws could regulate therapeutic cloning.<sup>593</sup>

The following was noteworthy during the debate: Among the many delegations who took the floor, two were speaking on behalf of a group of states: First, the delegation of Turkey spoke on behalf of the OIC (Organisation of Islamic Conference).<sup>594</sup> The OIC said it is aiming at a solution that is acceptable to all states. This could not lie in a "forced" mandate. A wide-spread tendency of Islamic states towards the Costa Rican draft was not noticeable.<sup>595</sup>

Second, the delegation of Botswana spoke on behalf of the Southern African Development Community (SADC)<sup>596,597</sup> The SADC-Council

<sup>&</sup>lt;sup>592</sup> See statement by the delegation of Singapore, International Convention against the reproductive cloning of human being, 21 October 2004, New York (which is at the hands of the author). The Vatican's reaction was unhappy and clumsy. Its paper was not promoting any underlying dogma, rather it rested on `true` reason, the delegate responded.

<sup>&</sup>lt;sup>593</sup> A similar argument was made by Brazil in a spontaneous intervention.

<sup>&</sup>lt;sup>594</sup> This statement was not distributed among delegations.

<sup>&</sup>lt;sup>595</sup> On the contrary, it seemed that many were favouring the Belgian proposal, most notably Indonesia, the biggest Islamic state in the world.

<sup>596</sup> The Southern African Development Community (SADC) has been in existence since 1980, when it was formed as a loose alliance of nine majority-ruled States in Southern Africa known as the Southern African Development Coordination Conference (SADCC), with the main aim of coordinating development projects in order to lessen economic dependence on the then apartheid South Africa. SADCC was formed in 1980, following the adoption of the Lusaka Declaration - Southern Africa: Towards Economic Liberation. The transformation of the organization from a Coordinating Conference into a Development Community (SADC) took place on 17 August 1992 in Windhuk, Namibia when the Declaration and Treaty was signed at the Summit of Heads of State and Government thereby giving the organization a legal character. The Member States are Angola, Botswana, the Democratic Republic of Congo, Lesotho, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, United Republic of Tanzania, Zambia and Zimbabwe. For more information, see http://www.sadc.int/index.php?action=a1001&page id=about corp profile.

of Ministers had endorsed a decision of the SADC-Ministers of Health which decided to appoint a SADC Committee to further explore the promises of therapeutic cloning. SADC would therefore not support proposals which would prematurely close the door to therapeutic potential. More concretly, this means that four SADC members, Angola, Lesotho, Malawi, and Zimbabwe, in spontaneous interventions, distanced themselves from the Costa Rican proposal.<sup>598</sup>

### b) The second round of speakers: A majority of "maximalists"

On the second meeting day, 22 October, many speakers<sup>599</sup> favoured the Costa Rican proposal with already known arguments, but still aimed at a compromise solution.

Later that day, it was known that the chairman of the Sixth Committee was planning to hold bilateral talks with both sides in order to explore room for a consensus. His plan made it clear that a vote would not take place, at least not before the U.S. presidential elections of 2 November 2004. Since the "minimalists" signalized their willingness to compromise, it would be up to the "maximalists" to react accordingly.

#### **3.** The decision: A political Declaration

Out of the discussion of the two options on the negotiating table, a third option emerged which would maybe forego a vote and leave a last chance for consensus: On 19 November, 2004, the Sixth

<sup>&</sup>lt;sup>597</sup> See statement by the delegation of Botswana on behalf of the Southern African Development Community, International Convention against the reproductive cloning of human beings, 21 October 2004, New York (which is at the hands of the author).

 <sup>&</sup>lt;sup>598</sup> On top of that, Namibia and Zimbabwe supported the Belgian proposal explicitly in spontaneous interventions.
 <sup>599</sup> Altogether 28 states and Malteserorden made statements. States in favour of the

<sup>&</sup>lt;sup>599</sup> Altogether 28 states and Malteserorden made statements. States in favour of the Costa Rican proposal were: Slovakia, Nigeria, Kenia, Honduras, Fiji, Italy, Norway, Sierra Leone, Ethiopia, Philippines, Uganda, the U.S., Slovenia, Guinea-Bissau, Timor-Leste, Paraguay, Nicaragua. States in favour of the Belgian proposal were: Ghana, Jordan, Cyprus, Sudan, Malaysia, Sweden, Thailand, Vietnam, Mexico, Senegal. This list is based on observations the author made during the session and minutes taken. Most states did not distribute their short statements.

Committee decided by consensus and without further deliberations to pass a "Declaration"<sup>600</sup> which had been negotiated between the delegations of Costa Rica and Belgium and would have to be finalized by a three-day Working Group meeting in 2005. The draft Declaration, submitted by Italy, reads as follows.

"United Nations Declaration on Human Cloning

The General Assembly,

*Guided* by the purpose and principles of the Charter of the United Nations,

*Recalling* the Universal Declaration on the Human Genome and Human Rights, adopted by the General Conference of the United Nations Educational, Scientific and Cultural Organization on 11 November 1997, and in particular article 11 thereof, which states that practices which are contrary to human dignity, sich as the reproductive cloning of human beings, shall not be permitted,

*Recalling also* its resolution 53/152 of December 1998, by which it endorsed the Universal Declaration on the Human Genome and Human Rights,

Aware of the ethical concerns that certain applications of rapidly developing life science may raise with regard to human dignity, human rights and the fundamental freedoms of individuals,

<sup>&</sup>lt;sup>600</sup> For the first draft of the "UN Declaration on Human Cloning", see the annex of UN Doc. A/C.6/59/L.26.

*Reaffirming* that the applications of life science should seek to offer relief from suffering and improve the health of individuals and humankind as a whole,

*Emphasizing* that the promotion of scientific and technical progress in life sciences should be sought in a manner that safeguards respect for human rights and the benefit of all,

*Mindful* of the serious medical, physical, psychological and social dangers that human cloning may imply for the individuals involved, and also conscious of the need to ensure that human cloning does not give rise to the exploitation of women,

*Convinced* of the urgency of preventing the potential dangers of human cloning to human dignity,

Solemnly devlares the following:

(a) Member States are called upon to prohibit any attempts to create human life through cloning processes and any research intended to achieve that aim;

(b) Member States are called upon to ensure that, in the application of life science, human dignity is respected in all circumstances and, in particular, that women are not exploited;

(c) Member States are also called upon to adopt and implement national legislation to bring into effect paragraphs (a) and (b) above;

(d) Member States are further called upon to adopt the measures necessary to prohibit applications of genetic engineering techniques that may be contrary to human dignity.

The background to the elaboration of a Declaration was as follows. Intensive and repeated attempts of reaching a consensus between the two rivalling draft resolutions had been unfruitful. Both groups were unsure as to whether they would actually reach a majority for their proposal in case of a vote – especially since a great many states would have abstained. The compromise of a legally non-binding Declaration<sup>601</sup> was then invented on 16 November by the OIC – which had in the past repeatedly played the role of a mediator that pushed for a consensus solution for the sake of upholding the Sixth Committee tradition.

Both sides of the table accepted it after internal consultations<sup>602</sup> with Costa Rica under the premise, that the two draft resolutions L.2 and L.8 would not be withdrawn formally, but only put aside for the moment. The Chairman of the Sixth Committee, on 19 November, announced that it was being proposed that the Sixth Committee establish a Working Group to finalize the text of a United Nations Declaration on human cloning, on the basis of the current draft resolution L.26 and to report to the Sixth Committee. At the same meeting, the Sixth Committee adopted, without deliberations and in consensus, a decision to establish a Working Group and, in its final report to the General Assembly,<sup>603</sup> recommended to the General Assembly the adoption of its draft decision.<sup>604</sup>

Although Italy appears as the main sponsor of the draft Political Declaration, it had no role in drafting it. Its wording is almost entirely the outcome of negotiations between the delegations of Belgium and Costa Rica – with the exception that Italy decided to include in

<sup>&</sup>lt;sup>601</sup> The term "Declaration" is used by the General Assembly for resolutions "which claim to express political or legal principles of particular importance", see *Hailbronner/Klein*, in: Simma (2002) at article 10, margin no. 41. They are legally non-binding, see *Carter/Trimble* (1999) at 138-139 with further references. See also above at C.I.2.b).

<sup>&</sup>lt;sup>602</sup> Which were reported orally to the plenary as a whole.

<sup>&</sup>lt;sup>603</sup> See UN Doc. A/59/516.

<sup>&</sup>lt;sup>604</sup> See UN Doc. A/59/516, at 7.

operative paragraph (a) of the Declaration the term "attempts to create human *life*", rather than "attempts to create human *beings*".<sup>605</sup>

## 4. Analysis of the fourth round of negotiations: Future prospects of the passing of the Declaration

As for the Declaration, it had yet to be finalized, and negotiations of a Working Group established for that purpose were scheduled for February 2005. Following that, the Sixth Committee would meet, discuss the report of the Working Group and decide.

The commonly agreed aspects of the Declaration seemed to be (b) to respect human dignity, (c) to adopt national legislation, and (d) to adopt national measures that prohibit other applications of genetic engineering techniques that are contrary to human dignity.

The contentious point of the Declaration was exposed in the formulation in (a), namely to "prohibit any attempts at the creation of *human beings/human life* (the latter being the formulation favoured by Costa Rica and its group) through cloning processes." Here, the future discussion would certainly focus on the central question of when human life, and with it its protection begins. As we know, a clear scientific answer does not exist, and ethically well-grounded answers diverge.

The term "human beings" would accept this existing ambivalence and leave it to the national sphere to decide on the definition of the starting point of human life. This approach would be the same as the one chosen for the Additional Protocol to the Council of Europe's Biomedicine Convention.

The term "human life" on the other hand would try to fade out the ambivalence by choosing a pure biological approach, detached from the process of coming into being.

<sup>&</sup>lt;sup>605</sup> See below at C.V.4.

It was foreseeable that the attempts of the Working Group in 2005 to solve this ambivalence would only be successful - if at all - through a stereotyped compromise. In any case, the forecast on the follow-up talks shows that the contentious issues of the future Convention had now been shifted into the talks of the future Declaration. Insofar, significant progress was lacking.

For the case that a greater willingness to compromise should in the future allow an international Convention, it was reiterated that the Costa Rican and the Belgian proposals did not fall flat: Rather, both were still on the negotiating table since a decision on either of the two was not taken through a vote and no delegation withdrew its proposal.

As a short-term goal, in order not to fully loose sight of the goal that France and Germany once envisaged, it was suggested by the German minister of state Kerstin Mueller,<sup>606</sup> to anchor in the Declaration the call for a global Convention to ban cloning.

## VI. A fifth and final round of negotiations in an attempt to save face

The negotiations to finalize the Declaration on Human Cloning in the venue of a Working Group of the Sixth Committee in February  $2005^{607}$  were based on a draft submitted by the chairman of the Sixth Committee (L.27/Add.1), Morocco's Ambassador Bennouna, according to which the Declaration would have read as follows<sup>608</sup>:

<sup>&</sup>lt;sup>606</sup> Minister of State Kerstin Mueller on the UN decision to ban cloning, Press Declaration of 20 November 2004, see http://www.auswaertiges-amt.de/www/en/ausgabe\_archiv?archiv\_id =6474.

<sup>&</sup>lt;sup>607</sup> The author was present at these meetings, the following report is based on her observations and minutes. Where delegations' statements were distributed in the plenary, the author will indicate it. In all other cases, statements were either spontaneous or short, and therefore not handed out to delegations in writing. Besides her minutes, her report also relys on the detailed reports of German diplomats in New York back to Berlin headquarters (which are also at the hands of the author).

<sup>&</sup>lt;sup>608</sup> See Annex of draft resolution in UN Doc. A/C.6/59/L.27/Add.1.

"United Nations Declaration on Human Cloning

The General Assembly,

*Guided* by the purposes and principles of the Charter of the United Nations,

*Recalling* the Universal Declaration on the Human Genome and Human Rights, adopted by the General Conference of the United Nations Educational, Scientific and Cultural Organization of 11 November 1997,

*Aware* of the ethical concerns that certain applications of rapidly developing life sciences may raise with regard to human dignity, human rights and the fundamental freedom of individuals,

*Reaffirming* that the application of life sciences should seek to offer relief from suffering and improve the health of individuals and humankind as a whole,

*Emphasizing* that the promotion of scientific and technical progress of life sciences should be sought in a manner that safeguards respect for human rights and the benefit of all,

*Mindful* of the serious medical, physical, psychological and social dangers that human cloning may imply for the individuals involved, and also conscious of the need to prevent the exploitation of women,

*Convinved* of the urgency of preventing the potential dangers of human cloning to human dignity,

Solemnly declares the following:

(a) Member States are called upon to adopt all measures necessary to protect adequately human life in the application of life sciences;

(b) Member States are called upon to prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life;

(c) Member States are further called upon to adopt the measures necessary to prohibit the application of genetic engineering techniques that may be contrary to human dignity;

(d) Member States are called upon to take measures to prevent the exploitation of women in the application of life sciences;

(e) Member States are also called upon to adopt and implement without delay national legislation to bring into effect paragraphs (a) to (d);

(f) Member States are further called upon, in their financing of medical research, including of life sciences, to take into account the pressing global issues such as HIV/AIDS, tuberculosis and malaria, which affect in particular the developing countries."

Since it seemed that the draft would not serve well as a basis for consensus-making as it was criticized to favour the demands of the "maximalists" more than those of the determined "minimalists"<sup>609</sup>, the draft Declaration which had been submitted earlier in January 2005 by Italy<sup>610</sup> (L.26) was re-considered. Bennouna eventually declared that he would withdraw his proposal (L.27/Add.1) due to a

<sup>&</sup>lt;sup>609</sup> Especially so in operative paragraph (b) of the Declaration: "Member States are called upon to prohibit *all forms of human cloning*…".

<sup>&</sup>lt;sup>610</sup> See the Annex of draft resolution in UN Doc. A/C.6/59/L.26.

lack of consensus. Honduras however, reacted immediately by submitting the withdrawn proposal of the chairman according to 122 of the Rules of Procedure of the General Assembly as its own. Honduras was supported by Germany in its suggestion that Italy's rather than the chairman's proposal should be withdrawn so that the Sixth Committee would continue to negotiate on the basis of what then was the Honduran document L.27/Add.1. Germany's proposal was also supported by Costa Rica and Nigeria. L.26 was however not withdrawn although Italy itself offered to do so. The Sixth Committee thus continued to have before it two draft texts – a situation that was understood as the sad continuation of the previous rounds of negotiations in the years before. The vote on substance was now inevitable.

Prior to the adoption of one of the draft texts, the Sixth Committee voted to reverse the order of texts to be acted on, thereby taking the Honduran proposal (L.27/Add.1) first before taking up the Italian one (L.26). Also, before the adoption, the Committee discussed three amendments to L.27/Add.1, all of which were proposed by Belgium.

The first amendment concerned preambular paragraph 2 which added the words "and in particular article 11 thereof, which states that practices which are contrary to human dignity, such as the reproductive cloning of human beings, shall not be permitted". It was adopted by a vote of 59 in favour to 47 against, with 41 abstentions.<sup>611</sup> It is noteworthy that this amendment reintroduces to

<sup>&</sup>lt;sup>611</sup> See UN Doc. A/59/516/Add.1 at 3-4.

In favour: Argentina, Armenia, Bahamas, Belarus, Belgium, Botswana, Brazil, Bulgaria, Cambodia, Canada, Chile, China, Colombia, Croatia, Cuba, Cyprus, Czech Republic, Democratic People's Republic of Korea, Denmark, Ecuador, Estonia, Finland, France, Germany, Ghana, Greece, Grenada, Hungary, Iceland, India, Jamaica, Japan, Latvia, Lithuania, Luxembourg, Mali, Mauritius, Mexico, Monaco, Mongolia, Morocco, Namibia, Netherlands, New Zealand, Poland, Republic of Korea, Russian Federation, Singapore, South Africa, Sri Lanka, Sweden, Switzerland, Thailand, Tonga, United Kingdom, Uruguay, Venezuela, Viet Nam, Zimbabwe.

Against: Albania, Antigua and Barbuda, Australia, Bangladesh, Belize, Bolivia, Bosnia and Herzegovina, Burundi, Costa Rica, El Salvador, Eritrea, Ethiopia,

the Declaration the majority's understanding – disputed by the U.S. – that there is a distinction between reproductive and therapeutic cloning, and that the former meets with particularly elevated concerns.

The second amendment concerned operative paragraph (a) that would have to be deleted. This amendment was rejected by a vote of 48 in favour to 57 against, with 42 abstentions.<sup>612</sup>

The last amendment concerned operative paragraph (b) which would have replaced it by the following: "Member states are called upon to prohibit the reproductive cloning of human beings; they are also

<sup>612</sup> See UN Doc. A/59/516/Add.1 at 4.

Gambia, Georgia, Guatemala, Haiti, Honduras, Ireland, Italy, Kazakhstan, Kenya, Kyrgyzstan, Lesotho, Madagascar, Malta, Marshall Islands, Federated States of Micronesia, Nicaragua, Nigeria, Panama, Papua New Guinea, Philippines, Portugal, Rwanda, Saint Kitts and Nevis, Saint Lucia, San Marino, Saudi Arabia, Slovakia, Sudan, Suriname, Timor-Leste, Trinidad and Tobago, Uganda, United Arab Emirates, United States, Uzbekistan.

Abstentions: Algeria, Austria, Azerbaijan, Bahrain, Barbados, Brunei Darussalam, Burkina Faso, Comoros, Congo, Democratic Republic of the Congo, Djibouti, Egypt, Indonesia, Iran, Iraq, Jordan, Kuwait, Lebanon, Liechtenstein, Malaysia, Maldives, Nepal, Norway, Oman, Pakistan, Paraguay, Peru, Qatar, Republic of Moldova, Romania, Senegal, Serbia and Montenegro, Sierra Leone, Slovenia, Spain, Syria, The former Yugoslav Republic of Macedonia, Tunisia, Turkey, Ukraine, Yemen.

In favour: Argentina, Armenia, Bahamas, Belarus, Belgium, Botswana, Brazil, Bulgaria, Cambodia, Canada, China, Colombia, Cuba, Czech Republic, Democratic People's Republic of Korea, Denmark, Estonia, Finland, France, Ghana, Greece, Grenada, Hungary, Iceland, India, Jamaica, Japan, Latvia, Lithuania, Luxembourg, Mali, Mongolia, Namibia, Netherlands, New Zealand, Poland, Republic of Korea, Russian Federation, Singapore, South Africa, Sri Lanka, Sweden, Switzerland, Thailand, Tonga, United Kingdom, Venezuela, Zimbabwe.

Against: Albania, Antigua and Barbuda, Australia, Bangladesh, Belize, Bolivia, Bosnia and Herzegovina, Brunei Darussalam, Burundi, Chile, Costa Rica, Croatia, Democratic Republic of the Congo, Ecuador, El Salvador, Eritrea, Ethiopia, Gambia, Georgia, Guatemala, Guyana, Haiti, Honduras, Ireland, Italy, Kazakhstan, Kenya, Kyrgyzstan, Lesotho, Madagascar, Malta, Marshall Islands, Mauritius, Mexico, Federated States of Micronesia, Morocco, Nicaragua, Nigeria, Panama, Papua New Guinea, Philippines, Portugal, Rwanda, Saint Kitts and Nevis, Saint Lucia, San Marino, Saudi Arabia, Slovakia, Sudan, Suriname, Timor-Leste, Trinidad and Tobago, Uganda, United Arab Emirates, United Republic of Tanzania, United States, Uzbekistan.

Abstentions: Algeria, Austria, Azerbaijan, Bahrain, Barbados, Burkina Faso, Congo, Cyprus, Djibouti, Egypt, Germany, Indonesia, Iran, Iraq, Jordan, Kuwait, Lebanon, Liechtenstein, Malaysia, Maldives, Nepal, Niger, Norway, Oman, Pakistan, Paraguay, Peru, Qatar, Republic of Moldova, Romania, Senegal, Serbia and Montenegro, Sierra Leone, Slovenia, Spain, Syria, The former Yugoslav Republic of Macedonia, Tunisia, Turkey, Ukraine, Uruguay, Yemen.

called upon to prohibit other forms of human cloning inasmuch as they are incompatible with human dignity". It was rejected by a very small margin of votes: 52 in favour to 55 against, with 42 abstentions.<sup>613</sup>

The negotiations on the amendments seemed overly dramatic, considering the actual content that was to be amended. What Belgium was trying to achieve was to echo the views of a number of delegations which were against L.27/Add.1 in an attempt to preserve, in the interest of science, at the national level, the possibility of cloning for therapeutic purposes and through the establishment of appropriate controls. For this purpose, the last amendment was the most important as it would have made a distinction between an imperative prohibition of reproductive cloning and the differentiation to other forms of cloning. But the Honduran version can also be interpreted as giving research-minded nations sufficient leeway, as is apparent in paragraph (a): "...adopt all measures necessary to protect *adequately* human life" and paragraph (b): "...prohibit all forms of human cloning *inasmuch* as they are incompatible with human

<sup>&</sup>lt;sup>613</sup> See UN Doc. A/59/516/Add.1 at 5.

In favour: Argentina, Armenia, Bahamas, Belarus, Belgium, Botswana, Brazil, Bulgaria, Cambodia, Canada, China, Colombia, Cuba, Cyprus, Czech Republic, Democratic People's Republic of Korea, Denmark, Estonia, Finland, France, Ghana, Greece, Grenada, Hungary, Iceland, India, Jamaica, Japan, Latvia, Lithuania, Luxembourg, Mali, Mauritius, Mongolia, Namibia, Netherlands, New Zealand, Poland, Republic of Korea, Russian Federation, Singapore, South Africa, Sri Lanka, Sweden, Switzerland, Thailand, Tonga, United Kingdom, Uruguay, Venezuela, Viet Nam, Zimbabwe.

Against: Albania, Antigua and Barbuda, Australia, Bangladesh, Belize, Bolivia, Bosnia and Herzegovina, Burundi, Comoros, Costa Rica, Croatia, Democratic Republic of the Congo, El Salvador, Eritrea, Ethiopia, Gambia, Georgia, Guatemala, Guyana, Haiti, Honduras, Iraq, Ireland, Italy, Kazakhstan, Kenya, Kyrgyzstan, Lesotho, Madagascar, Malta, Marshall Islands, Federated States of Micronesia, Morocco, Nicaragua, Nigeria, Panama, Papua New Guinea, Paraguay, Philippines, Portugal, Rwanda, Saint Kitts and Nevis, Saint Lucia, San Marino, Saudi Arabia, Slovakia, Sudan, Suriname, Timor-Leste, Trinidad and Tobago, Uganda, United Arab Emirates, United Republic of Tanzania, United States, Uzbekistan.

Abstentions: Algeria, Austria, Azerbaijan, Bahrain, Barbados, Brunei Darussalam, Burkina Faso, Chile, Congo, Djibouti, Ecuador, Egypt, Germany, Indonesia, Iran, Jordan, Kuwait, Lebanon, Liechtenstein, Malaysia, Maldives, Mexico, Nepal, Niger, Norway, Oman, Pakistan, Peru, Qatar, Republic of Moldova, Romania, Senegal, Serbia and Montenegro, Sierra Leone, Slovenia, Spain, Syria, The former Yugoslav Republic of Macedonia, Tunisia, Turkey, Ukraine, Yemen.

dignity and the protection of human life...". This ambiguity may have allowed for the Honduran proposal to prevail in a rather narrow vote.

When it finally came to the voting on the text L.27/Add.1 as it had been amended, China raised a question regarding the wording "inasmuch" in operative paragraph (b) of the Declaration ("prohibit all forms of cloning inasmuch as they are incompatible with human dignity..."). The Committee Chairperson, Ambassador Bennouna, clarified that the word was not identical with "because", thereby leaving some scope of discretion.

Eventually, the draft resolution L.27/Add.1 was voted on in the Sixth Committee with 71 in favour to 35 against with 43 abstentions.<sup>614</sup> It reads:

<sup>&</sup>lt;sup>614</sup> See UN Doc. A/C.6/59/L.27/Rev.1.

In favour: Albania, Andorra, Antigua and Barbuda, Australia, Austria, Bangladesh, Belize, Bolivia, Bosnia and Herzegovina, Brunei Darussalam, Burundi, Chile, Comoros, Costa Rica, Croatia, Democratic Republic of the Congo, Ecuador, El Salvador, Eritrea, Ethiopia, Gambia, Georgia, Germany, Grenada, Guatemala, Guyana, Haiti, Honduras, Hungary, Ireland, Italy, Kazakhstan, Kenya, Kyrgyzstan, Lesotho, Liechtenstein, Madagascar, Malta, Marshall Islands, Mauritius, Mexico, Federated States of Micronesia, Monaco, Morocco, Nicaragua, Nigeria, Panama, Papua New Guinea, Paraguay, Peru, Philippines, Portugal, Qatar, Russian Federation, Rwanda, Saint Kitts and Nevis, Saint Lucia, San Marino, Saudi Arabia, Slovakia, Slovenia, Sudan, Suriname, Switzerland, The former Yugoslav Republic of Macedonia, Timor-Leste, Uganda, United Arab Emirates, United Republic of Tanzania, United States, Uzbekistan.

Against: Belarus, Belgium, Brazil, Bulgaria, Cambodia, Canada, China, Colombia, Cuba, Cyprus, Czech Republic, Democratic People's Republic of Korea, Denmark, Estonia, Finland, France, Greece, Iceland, India, Jamaica, Japan, Latvia, Lithuania, Luxembourg, Netherlands, New Zealand, Norway, Poland, Republic of Korea, Singapore, Sweden, Thailand, Tonga, United Kingdom, Venezuela.

Abstentions: Algeria, Argentina, Armenia, Azerbaijan, Bahamas, Bahrain, Barbados, Botswana, Burkina Faso, Congo, Djibouti, Egypt, Ghana, Indonesia, Iran, Iraq, Jordan, Kuwait, Lebanon, Malaysia, Maldives, Mali, Mongolia, Namibia, Nepal, Niger, Oman, Pakistan, Republic of Moldova, Romania, Senegal, Serbia and Montenegro, Sierra Leone, South Africa, Spain, Sri Lanka, Syria, Tunisia, Turkey, Ukraine, Uruguay, Yemen, Zimbabwe.

Absent: Afghanistan, Angola, Benin, Bhutan, Cameroon, Cape Verde, Central African Republic, Chad, Côte d'Ivoire, Dominica, Dominican Republic, Equatorial Guinea, Fiji, Gabon, Guinea, Guinea-Bissau, Israel, Kiribati, Lao People's Democratic Republic, Liberia, Libya, Malawi, Mauritania, Mozambique, Myanmar, Nauru, Palau, Saint Vincent and the Grenadines, Samoa, Sao Tome and Principe, Seychelles, Solomon Islands, Somalia, Swaziland, Tajikistan, Togo, Trinidad and Tobago, Turkmenistan, Tuvalu, Vanuatu, Viet Nam, Zambia.

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*Emphasizing* that the promotion of scientific and technical progress of life sciences should be sought in a manner that safeguards respect for human rights and the benefit of all,

*Mindful* of the serious medical, physical, psychological and social dangers that human cloning may imply for the individuals involved, and also conscious of the need to prevent the exploitation of women,

*Convinved* of the urgency of preventing the potential dangers of human cloning to human dignity,

Solemnly declares the following:

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(b) Member States are called upon to prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life;

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(d) Member States are called upon to take measures to prevent the exploitation of women in the application of life sciences;

(e) Member States are also called upon to adopt and implement without delay national legislation to bring into effect paragraphs (a) to (d);

(f) Member States are further called upon, in their financing of medical research, including of life sciences, to take into account the pressing global issues such as HIV/AIDS, tuberculosis and malaria, which affect in particular the developing countries."

Among the states in favour were the U.S., Costa Rica, Mexico, Russia and Germany. Many EU member states voted against the resolution, mainly due to the trouble they were having with the unsettled term "human life". Also, two states that prohibit all human cloning domestically, the delegations of Norway and Canada, voted against the resolution. So did the delegation of Sweden which is planning to introduce legislation prohibiting all forms of human cloning. Interestingly, the number of votes in favour of the Declaration (71) was lower than the number of votes against it and abstentions counted together (78).

As the delegate of Finland (voted against) pointed out, the Sixth Committee had failed to send to the world a strong and unanimous message regarding human cloning; the long-awaited consensus, even on a political Declaration, was missing.<sup>615</sup> The delegation of Singapore (voted against) took this as a sign that, on issues founded on values and beliefs, no single state should be allowed to hold sway over other states. Trying to impose a uniform set of values on others only deepened the divide between parties. The delegate of Korea (voted against) made a similar statement in an explanation of vote, stressing that the term "human life" meant different things in different countries, cultures and religions. It was therefore inevitable that the meaning of that ambiguous term was subject to an interpretation which should be left to each state. The delegation of Syria (abstained) agreed on this point in an explanation of vote and so did the delegations of Singapore, China<sup>616</sup>, Japan, and Russia which all voted against the Declaration. The member countries of the Organization of Islamic Conference altogether, as stated by the delegate of Turkey, abstained regretting that a vote had been required on the issue and that consensus could not be reached.

The delegate of the United Kingdom<sup>617</sup> stressed once more its interest in therapeutic cloning and the non-binding nature of the Declaration which did not reflect a consensus within the Sixth Committee. It would not affect the country's approach to stem cell research which

<sup>&</sup>lt;sup>615</sup> See statement by the delegation of Finland, Declaration on Human Cloning - explanation of position after the vote, 18 February 2005, New York (which is at the hands of the author).

 <sup>&</sup>lt;sup>616</sup> See statement by the delegation of China, Explanation of position after the vote: United Nations Declaration on Human Cloning, 18 February 2005, New York (which is at the hands of the author).
 <sup>617</sup> See statement by the delegation of United Kingdom of Great Britain and

<sup>&</sup>lt;sup>617</sup> See statement by the delegation of United Kingdom of Great Britain and Northern Ireland, explanation of position after the vote, 18 February 2005, New York (which is at the hands of the author).

would continue to be permitted in the United Kingdom. A similar point was made by the delegations of China, Japan, France<sup>618</sup>, Belgium, and the Netherlands.

The delegate of Costa Rica said that the Committee had done right in adopting a decision that recognized the ethical and practical aspects of human cloning and gave a negative reaction to cloning. Also, it had emphasized the importance of human life. The delegate of the United States however went further when she expressed her contentment with the Declaration as it had issued a call to all member states to prohibit all forms of human cloning.<sup>619</sup>

The delegate of France strongly regretted that the Committee had been unable to adopt a text based on consensus and voted against it since the Declaration could be interpreted as banning therapeutic cloning.<sup>620</sup> The delegate of Germany who voted in favour of it said that it was not the day to celebrate since the Declaration, which did not even muster 50 percent of the votes, was unlikely to have great impact.

## VII. The outcome of the negotiations: The Declaration on Human Cloning

Eventually, on 8 March 2005, the General Assembly adopted the Declaration as drafted and voted on by the Sixth Committee.<sup>621</sup> The final text was adopted by a vote of 84 in favour to 34 against, with 37 abstentions.<sup>622</sup> As can be seen in comparison with the previous vote

<sup>&</sup>lt;sup>618</sup> See statement by the delegation of France, Explanation of Vote, 18 February 2005, New York (which is at the hands of the author).

<sup>&</sup>lt;sup>619</sup> See Statement by Carolyn Willson, Minister Counselor for Legal Affairs, United States, on Human Cloning, in the Sixth Committee, February 18, 2005, New York, see http://www.un.int/usa/05\_025.htm.

<sup>&</sup>lt;sup>620</sup> See statement by the delegation of France, Explanation of Vote, 18 February 2005, New York (which is at the hands of the author).

<sup>&</sup>lt;sup>621</sup> See UN doc. A/59/516/Add.1.

<sup>&</sup>lt;sup>622</sup> See annex to UN doc. A/RES/59/280.

In favour: Afghanistan, Albania, Andorra, Australia, Austria, Bahrain, Bangladesh, Belize, Benin, Bolivia, Bosnia and Herzegovina, Brunei Darussalam, Burundi, Chile, Comoros, Costa Rica, Cote d'Ivoire, Croatia, Democratic Republic of the Congo, Djibouti, Dominican Republic, Ecuador, El Salvador, Equatorial

in the Sixth Committee, the votes in favour have increased significantly, while the votes against the Declaration remained almost the same. Now, at least, the number of votes in favour of the Declaration (84) was higher than the number of votes against and abstentions counted together (71). Other than in the Sixth Committee, the adoption of the Declaration passed without procedural controversies.

However, in a final analysis, the attempt of the Sixth Committee in November 2004 to resort to a political Declaration in order to avert a divisive vote on the question of an international convention against human reproductive cloning have not been successful. The agreement on a Declaration lags far behind the initial expectations that were kindled by the German-French initiative of 2001. On the level of legally non-binding Declarations, UNESCO's Human Genome

Guinea, Eritrea, Ethiopia, Georgia, Germany, Grenada, Guatemala, Guyana, Haiti, Honduras, Hungary, Iraq, Ireland, Italy, Kazakhstan, Kenya, Kuwait, Lesotho, Liberia, Liechtenstein, Madagascar, Malta, Marshall Islands, Mauritius, Mexico, Federated States of Micronesia, Monaco, Morocco, Nicaragua, Nigeria, Palau, Panama, Paraguay, Philippines, Poland, Portugal, Qatar, Rwanda, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Samoa, San Marino, Sao Tome and Principe, Saudi Arabia, Sierra Leone, Slovakia, Slovenia, Solomon Islands, Sudan, Suriname, Switzerland, Tajikistan, The former Yugoslav Republic of Macedonia, Timor-Leste, Trinidad and Tobage, Uganda, United Arab Emirates, United Republic of Tanzania, United States, Uzbekistan, Zambia.

Against: Belarus, Belgium, Brazil, Bulgaria, Cambodia, Canada, China, Cuba, Cyprus, Czech Republic, Democratic People's Republic of Korea, Denmark, Estonia, Finland, France, Gabon, Iceland, India, Jamaica, Japan, Lao People's Democratic Republic, Latvia, Lithuania, Luxembourg, Netherlands, New Zealand, Norway, Republic of Korea, Singapore, Spain, Sweden, Thailand, Tonga, United Kingdom.

Abstentions: Algeria, Angola, Argentina, Azerbaijan, Bahamas, Barbados, Botswana, Burkina Faso, Cameroon, Cape Verde, Columbia, Egypt, Indonesia, Iran, Jordan, Lebanon, Malaysia, Maldives, Mongolia, Namibia, Nepal, Oman, Pakistan, Republic of Moldova, Romania, Serbia and Montenegro, Somalia, South Africa, Sri Lanka, Syria, Tunisia, Turkey, Ukraine, Uruguay, Yemen, Zimbabwe.

Absent: Antigua and Barbuda, Armenia, Bhutan, Botswana, Central African Republic, Chad, Congo, Dominica, Fiji, Gambia, Ghana, Greece, Guinea, Guinea-Bissau, Kiribati, Kyrgyzstan, Libya, Malawi, Mauritania, Mozambique, Nauru, Niger, Nigeria, Papua New Guinea, Peru, Russian Federation, Senegal, Seychelles, Swaziland, Togo, Turkmenistan, Tuvalu, Vanuatu, Venezuela, Viet Nam.

The change in voters had, *inter alia*, the following reasons: 5 states switched from an abstention to a vote in favour of the Declaration (Bahrain, Djibouti, Kuwait, Iraq, Sierra Leone); several, mainly African and Pacific states took part in the vote, other than before in the Sixth Committee; Poland switched from its initial vote against the Declaration to a vote in favour of it. This is the distribution of votes:

Declaration continues to be the decisive and main document while the UN Declaration on human cloning will probably remain politically insignificant, not least because of its mediocre outcome of the General Assembly vote.<sup>623</sup> The General Assembly might have chosen the more nuanced out of two overall unsatisfying Declarations, but it did not progess by any means towards a legally binding regulation of human cloning.

As regards delegations' views on the outcome altogether, a number of them said that they had voted against the text because the reference to "human life" could be interpreted as a call for a total ban on all forms of human cloning. Several states indicated that the Declaration was legally non-binding and that it would not influence their national stance on therapeutic cloning.<sup>624</sup> Due to a lack of differentiation between reproductive cloning and other forms of cloning, some found the Declaration confusing in its actual content.

The delegation of Singapore regretted that the important German-French initiative had been hijacket. The delegations of France and the United Kingdom said that the prohibition of reproductive cloning through a United Nation's Convention had been possible; only, it failed because of the intolerance of a small number of states. The delegation of South Africa, which abstained, said it understood therapeutic cloning to be aimed at protecting human life and not to be, therefore, inconsistent with the Declaration. It would continue to control therapeutic cloning strictly.

The delegation of Belgium regretted that the vote on the text reflected a wide divergence in the international community on the text. Rather than bringing states together, it had divided them. The delegations of

<sup>&</sup>lt;sup>623</sup> This analysis becomes more apparent when comparing the result of the vote on the Declaration on human cloning with the UN General Assembly's endorsement of the Human Genome Declaration which was consensual, see above at B.II.1.c)bb).

<sup>&</sup>lt;sup>624</sup> These states were China, India, Belgium, the United Kingdom, Korea, Thailand, Japan, Brazil, Singapore, and the Netherlands. These and most of the following statements were not distributed in writing.

Hungary and Libya were hoping that the Declaration could nevertheless serve as an intermediary step towards a Convention.

The delegations of the United States<sup>625</sup> and Costa Rica gave rather reserved declarations of vote, in which they pointed at the importance of protecting human life. Ethiopia's representative added that the text sent a clear message against unethical research which made human life the object of experimentation.

The delegate of Mexico, in his explanation after the vote, stressed once more that there was a dichotomy between reproductive and therapeutic cloning and eventually announced its accession to the Council of Europe's Biomedicine Convention and its Additional Protocol.

When considering the history of negotiations, we may be startled by some final observations. Once lead partners, Germany and France remained split over the contents of the Declaration. The German delegation, in line with its domestic legislation and the task given by the German Parliament, voted in favour of the text promoted mainly by former "maximalists". Eventually, Germany found itself in the same circle of states whose "maximalist" position Germany had been trying to loosen over the past three years.

The delegation of France on the other hand, whose domestic legislation had been liberalized in the meantime, voted against the Declaration. Thus, the two engines of the whole process of talks at the UN had been separated over the very question of the scope of a prohibition – which both delegations had been trying to circumvent by focusing on the narrow mandate of reproductive cloning from the very start.

<sup>&</sup>lt;sup>625</sup> See Explanation of Vote by Ambassador Sichan Siv, U.S. Representative to the Economic and Social Council, on the Declaration on Human Cloning, General Assembly, March 8, 2005, New York, see http://www.un.int/usa/05\_042.htm.

Also, the delegation of Spain, which had once been a fierce promoter of a "maximalist" approach to a prohibition and would have, supposedly, been welcoming of the contentious formulation "human life" and the inherent indication of a broad ban on human cloning, voted against the Declaration, mainly due to shifting domestic politics. Spain thus declared in an explanation of its vote that the term "human life" was confusing and should be replaced by the term "human being" as used in scientific texts. The Declaration did not cover the well-known fundamental differences between the two types of cloning. The fact that there had been no consensus on the issue after a number of years showed just how precarious the text was as adopted. Spain favoured therapeutic cloning, which was looked upon positively by the scientific community and the issue would now be passed on to the National Parliament. Spain thus altogether sided with the former group of "minimalists".

Such a serious shift in positions of some main players – Germany and Spain had both switched sides - shows that the issue of human therapeutic cloning is still under fundamental debate within national boundaries – an oberservation that may have lead the Dutch delegate to his conclusion that the topic of therapeutic cloning was altogether for the moment not ripe for international codification and that it was therefore premature to force states into binding international rules at this moment in time.

#### D. Conclusion

The three-year efforts of launching negotiations on an international Convention against the reproductive cloning of human beings have stranded and ultimately failed. Tedious, intensive debates over three years, only on the scope of a prohibition, have proved that such attempts cannot be fruitful at this point in time with positions being entreched as they are – at least not if consensus is desired. Instead of a legally binding instrument, the UN member states were only able to

adopt a political Declaration by a majority vote, calling on all UN member states to ban all forms of human cloning, including cloning for medical treatment, as incompatible with human dignity and the protection of human life. In its contents, specifically with regard to the formulation "to prohibit *all forms of human cloning*" in operative paragraph (b) of the text, the Declaration thus reaches much farther than originally envisionaged by France and Germany. In its political and legal impact and also in its acceptance among the UN member states, it lags far behind the initial idea and the possibilities that came with it.

#### I. Negotiating in the shadow of U.S. powerplay

The overall political context that the negotiations on a UN cloning treaty were embedded in might serve as one explanation for the threeyear rigidity of the German-French initiative. Common to most efforts of drafting international laws, the successful negotiation of the cloning treaty was, at least to a considerable extent, dependent on the United States' final objectives. Towards the end of the UN negotiation process, the U.S. was starting to dissociate herself from the goal of a comprehensive UN Convention, despite contradicting official statements: The decision of a few U.S. states to support embryonic stem cell research (most notably California, but also New Jersey)<sup>626</sup> made it more and more unlikely that the U.S. would ever ratify a Convention.<sup>627</sup> She drew states on her side and pushed for a mandate that was too broad to ever be acceptable to the community of states – a tactic that would defeat the purpose of the whole exercise not through undermining, but through overload.<sup>628</sup>

<sup>&</sup>lt;sup>626</sup> See above at B.II.2d).

<sup>&</sup>lt;sup>627</sup> Also, the U.S. delegation probably would not want the discussion regarding a prohibition on therapeutic cloning to turn into a discussion among different groups within the Republican Party.

<sup>&</sup>lt;sup>628</sup> Others have interpreted the U.S.' international policy at the United Nations as U.S. domestic policy in disguise, see above at C.III.6. The U.S. was taking a position at the UN whose real addressee would have been the U.S.-Senate: President Bush might have wanted to push a broad ban on all forms of human

She withheld from a dialogue even more so ever since the Security Council debate regarding the Iraq war where, by coincidence, similar antagonistic groups had formed. *Any* ethical opinions from France and Germany were then without prospects; attempts to win U.S. support were shelved for higher political reasons detached from the actual substance at stake.

A co-operation of the U.S. delegation could have pushed the initiative forward. That there was no vote in the end and thus no action taken aiming at a legally-binding instrument must be attributed to the U.S.' hesitation to draw the negotiations in either direction. The ostensible "result" of drafting a Declaration steered the U.S. closer to its assumed goal of obstructing ways towards binding international law on human cloning; presumably, she decided that bioethics was to be a "home grown product" and not more than that.

Under different circumstances, the attempts of France, Germany, Belgium and others would have won the support of a great number of states. It was, for instance, considered possible that the Holy See, Costa Rica, Italy and others would have joined in a consensusmaking on a prohibition of reproductive cloning once such a mandate would have been elaborated with the consent of the U.S. How could they have not voted in favour of a prohibition?

## II. Coherence and viability of the initative

Apart from an unfortunate political constellation and for the purpose of future legislative attempts, we may however explore if the UN initiative was in itself compelling and stringent, i.e. if the topic of human cloning was apt for international treaty making. For this purpose we may distinguish particularly two aspects which seemed most relevant for the success of negotiations, namely the need for a

cloning through the Senate. Should the UN follow his track, the Senate could possibly react by passing a corresponding law and one that would be substantively broader than the bill passed by the House of Representatives.

regulation of the topic through international law and a consensus among states on the direction of the topic.<sup>629</sup>

There are some doubts as to a need to address the topic of reproductive cloning at the international level. As we have seen, it is not clear if the reproductive cloning of human beings will ever be successful. The few states that have sufficient technological and scientific resources to experiment with cloning human beings have a ban on reproductive cloning or are in the process of adopting one. Beyond this, we may doubt that a serious, dedicated researcher would risk his reputation and engage in research outside these countries which is apparently rejected around the world and, even if uncodified, considered contrary to human dignity. The few instances where the media reported attempts at reproductive cloning are attributed to researchers whose reputation is hampered and highly questionable and who represent a fringe group within the world-wide scientific community.

While a need could thus be counterargued, much however speaks for a high degree of consensus among states about the general direction of the topic and political commitment on the part of a significant number of states to work on the topic. Paradoxical as it may seem, the one component evident throughout the course of the past three years was the overall agreement of states that reproductive cloning should be banned: All documents tabled from either side were insisting on a ban. One may adjudge to the protagonists of the initiative that if such a rare, universal congruity exists, it may well be fielded, even for a remote scenario that human reproductive cloning will seriously be undertaken one day: Surely, once a cloned baby is born, the drafting of provisions would be completely useless.

<sup>&</sup>lt;sup>629</sup> For a detailed discussion on both, see also *Arsanjani*, in: Vöneky/Wolfrum (2004) at 146, 159, 160.

The consensus only goes so far as reproductive cloning is concerned. There is no general consensus among states on the direction of the topic of therapeutic cloning. On the contrary, the views of states are sharply divided and there seems to be no possibility of consensus on a direction acceptable to all.

As we know, the cloning technique of somatic cell nuclear transfer can be used to produce embryos. The legal and ethical dilemma that arises therefrom is twofold, the protection of *human dignity* when the technique is used for reproductive purposes and the protection of early *human life* as far as therapy and research are concerned.

A technical identity of the biological procedure does not prejudge a normative identity with regard to all objectives of the use of somatic cell nuclear transfer. On the contrary, the different legal protection schemes under which the particular intent of the use of the technique would be administered justify a normative dichotomy. The safeguarding of human dignity is one end; the protection of early stages of human life is another. Restricting the scope of a Convention to reproductive cloning in order to safeguard human dignity thus is a coherent approach.<sup>630</sup>

Insofar, we disagree with the view that human cloning can or should be administered under a linear protection scheme, from the earliest possible starting point of a totipotent cell all the way to the birth of a cloned baby. Under such a scheme, it is said, countries would, as UNESCO's Human Genome Declaration and the Council of Europe's Biomedicine Convention and its Additional Protocol suggest, decide,

<sup>&</sup>lt;sup>630</sup> The concept of human dignity was never defined in detail in our negotiations. However, that human dignity would be violated by reproductive cloning was expressed as a given fact by all member states. For the states which supported a comprehensive ban, the violation of human dignity was closely linked to the asexual creation of human beings. Other states expressed concerns about the fate of children created through cloning whose inalienable rights may be whittled away by social stigma and ill health arising from cloning defects. Also, individual human beings would be devaluated since they could easily be replaced.

at what stage of early life development a prohibition is placed.<sup>631</sup> On the contrary, the interpretation of the two documents mentioned shows that they are generally understood to serve the purpose of the protection of human dignity, and not early human life. It thus shows that until now, this dichotomy has been treated as such.

With regard to the argument of a practical unfeasibility of a partial ban on reproductive cloning, it shall only be pointed to *in vitro* fertilization which also produces embryos. There is the possibility of a trespass of permissible research inherent in the procedure since the technique produces more embryos than are needed for fertilization. This did not keep states from permitting it as such while making considerable efforts in enforcing its limits. Here, at least, the danger of a violation of the law did not result in a total ban of the procedure.

With regard to human cloning, a widening of the scope would mean an overall protection of the cloned embryo, regardless of the purpose - similar to the laws in Germany and Spain. Such an envisioned protection scheme would however leave other realms of the protection of early life, including *in vitro* fertilization and the use of supernumerary embryos, and abortion, untouched – issues that are until today in want of international codification. The choice of a protection of *cloned* embryos only seems arbitrary and incomplete and would fall short of a systematic embryo protection scheme that, at this point in time, can only be found in national legislations.

National legislations have been developed and adjusted according to new scientific findings within the respective cultures and societies over many decades. They are based on a definition of "human life" or "human being" which differs from state to state. As we have seen, even within the boundaries of one state there might not be a coherent

<sup>&</sup>lt;sup>631</sup> See *Kersten* (2004) at 64-66 in his analysis of the scope of the prohibition in the Council of Europe's Addition Protocol to the Biomedicine Convention.

concept in all its aspects.<sup>632</sup> The definition is the focal point of embryo protection, i.e. an early form of human life, and one that the international community of states will probably never be able to agree on.

As was already seen in our negotiations, the supporters of a comprehensive ban granted the embryo the same legal status as that of a fully developed human being which is hence entitled to all the protections available to persons. The supporters of a partial ban rejected, implicitly or explicitly, both the notion of an early embryo as a human being and that it is entitled to the same degree of protection. They stringently argued that IVF treatment, certain forms of birth control and abortion all involve destruction of embryos. There is therefore no justification to ban therapeutic cloning on that ground while those other procedures are allowed.

This dissent was not resolved by the passing of a Declaration either. As the last round of negotiations shows, it has been carried into negotiations on the Declaration. The formulations in operative paragraphs (a) and (b) are too vague to make a decisive step in the direction of neither the "maximalists" nor the "minimalists". If states procure such disconcert in an attempt to pass a legally non-binding text, this allows the following prognosis for future attempts: As the Dutch delegate pointed out in his declaration after the last vote, states will never be able to pass binding international law regarding early life protection in the field of biomedicine.

In general, the world-wide experience with other aspects of the life sciences and reproductive technologies, most prominently abortion, teaches us that the *scope* of protection of the embryo is highly contentious, mainly due to differing understandings of the quality of the fertilized egg and the very beginnings of human life.

<sup>&</sup>lt;sup>632</sup> See, for instance, the comparison of the protection of the embryo *in vitro* and *in vivo* under German law, as discussed above at B.II.2.c) bb), or the comparison of U.S. State and Federal law as outlined above at B.II.2.d) aa) and bb).

In retrospect, it is thus hardly surprising that in our negotiations the danger of failure arose just at the moment when consensual and nonconsensual elements were brought together – specifically, when the U.S. and other states demanded that therapeutic cloning be included in the negotiations. However consistent that may have been from a certain ethical standpoint, it meant that the negotiations were faced with two different ethical concepts, both stringent in themselves. Looking at the phenomenon "embryo" – an early form of human life - one side argued that life is always life and deserves the same scope of protection all along, from its very beginnings. The other side argued that the protection may vary depending on the particular state of development. Achieving another therapeutic "good" for living persons may justify a lower protection level in the earliest stages of life.

The main ethical arguments behind both sides are based on many conflicting premises. The term human life has different meanings to different people. To proceed on the basis of such a term with the goal of formulating universal laws is only possible if they are understood to have the same meaning to *all* people. However, on the question of earliest stages of human life, fundamental ethical positions come into play. In fact, it is not different views on cloning itself that have to be weighed up against each other - it is fundamental positions on human life, its meaning and purpose, that within this discourse struggle against one another in what seems to be a battle without definite outcome. For just as those views on life and meaning cannot be proved or disproved as they are not strictly scientific nature but rather ethical, it seems that therapeutic cloning will always be subject to different evaluations. In the final analysis nothing can be done without a personal, deeply conscious decision of an entirely subjective nature.

The clashing of two ethical concepts explains the negotiating dilemma of UN member states.<sup>633</sup> Positions were, as our report shows, presented and reiterated time and again without however actually being opened up for a substantial discussion. States on either side could not procure flexibility which would threaten the entire value sytem behind those ethical concepts. With regard to that dilemma, the European Biomedicine Convention of 1997 was a shy, but noteworthy step forward as it left it to domestic law to deal with these issues. The Additional Protocol follows the same pattern as domestic laws are given substantial room for interpretation, especially for the determination of the term "human being".

The expectation that the one ethical position might be able to assert itself against the other and be universally established is unlikely. The universality of human rights is commonly deemed to be rooted in universal, "pre-cultural" experiences of injustice and suffering. This experience, however, is absent in the case of the right to life of the early embryo. It is not a human right rooted in experienced suffering or pain, but one deduced from rather modern ethical and religious concepts that are related to modern scientific findings<sup>634</sup>: Everyone would naturally feel an impediment to killing a born or even an unborn baby with its human shape – but would *everyone* feel the same facing a test tube which contains nothing humanoid in it?

The normative quality of the biological entity "embryo", i.e. the process of becoming a human being, the legal definition of "human being" and the required legal protection scheme can hardly be the

<sup>&</sup>lt;sup>633</sup> A concise and elaborate presentation is mirrored in the diverging opinions (*Stellungnahmen*) of the German National Ethics Council (*Nationaler Ethikrat*) on "Klonen zu Fortpflanzungszwecken und Klonen zu biomedizinischen Forschungszwecken of September 2004", see http://www.ethikrat.org/stellung nahmen/pdf/Stellungnahme\_Klonen.pdf.

<sup>&</sup>lt;sup>634</sup> For the development of modern Catholic and Christian moral theology, see *Schockenhoff* (1993) at 291-317. Schockenhoff argues that Christian moral theology started adopting its concepts of the beginning of life from the evolving natural sciences at the end of the 19<sup>th</sup> century, thereby abolishing the *Aristotelian* concept of animation (Beseelung).

subject of international codification. In this, a degree of consensus among states about the general direction of the topic cannot be found. Neither would such a legislative attempt appear to be a potentially effective instrument in dealing with it. On the contrary, experienced diplomats are anticipating years of negotiations which would remain fruitless in the end.

In the final analysis, the attempts to regulate a non-universal human right, namely the early embryo's right to life, in a Convention, a legal instrument that is subject to the rules of play pertaining to human rights and particularly the claim to universal applicability has proven to be impossible.

The only textual coherent approach to the issue of human cloning therefore was the initial idea of Germany and France which aimed at prohibiting human reproductive cloning in order to safegueard human dignity - a vision that was shared by all and deemed universal in its aim and content.

## III. The choice of a Convention as the appropriate legal instrument

Then, the next question is whether the approach to an eventual Convention was appropriate, i.e. whether the topic of human cloning should be addressed within the framework of a law enforcement instrument. This mainly pertains to the idea that the particular choice of the legal instrument will influence the probability of the successful elaboration and overall political acceptance of a text.<sup>635</sup>

With regard to this question and in their attempt to regulate human reproductive cloning, the UNESCO and the Council of Europe have made clear choices. With the Human Genome Declaration, the UNESCO resorted to a legally non-binding declaration, the classical human rights instrument, instead of a legally binding, enforceable

<sup>&</sup>lt;sup>635</sup> On the choice of human rights treaties as the stronger incentive states' accession to international law, see *Hathaway* (2004) at 1937-2042.

instrument, hoping that the legal nature of the document may give more of an incentive for states' accession to the text and help achieve international consensus. For the first time in the history of the UNESCO, the General Conference provided for implementation tools in the form of a monitoring mechanism. The monitoring mechanism is however as lax as it could possibly be: It calls, *inter alia*, on states to identify appropriate measures for the promotion of the principles of the Declaration, whether through the setting of standards or the provision of incentives<sup>636</sup> and the IBC is assigned to make recommendations in accordance with UNESCO's statutory procedures, addressed to the General Conference and give advice concerning the follow-up of this Declaration.<sup>637</sup> Altogether, the Declaration therefore still follows the approach of a human rights instrument.

Considering that international bioethics is a comparatively new area of law, the member states of the Council of Europe were willing to take a further step, compared to the UNESCO and to adopt a legally binding instrument. And yet they gathered that an intrusion upon national jurisdiction through a legally binding instrument should be as minimal as possible. As we have seen, the Biomedicine Convention and its Additional Protocol may serve as significant forerunners for future legislative attempts of such quality.<sup>638</sup> Here, acts are not criminalized, and, other than envisioned for the UN Convention<sup>639</sup>, a mechanism for sanctions on member states failing to implement the provisions into their national law was forgone. This means that the implementation is left to the practically uncontrolled discretion of the member states. Considering such soft provisions which *de facto* lack enforcement mechanisms, the Biomedicine

<sup>&</sup>lt;sup>636</sup> For the details of the monitoring mechanism, see above at B.II.1.c) bb).

<sup>&</sup>lt;sup>637</sup> See *id*. For a detailed report of the IBC on the follow-up of the implementation of the Universal Declaration on the Human Genome and Human Rights", see *UNESCO* (1998).

<sup>&</sup>lt;sup>638</sup> On the Biomedicine Convention, see above at B.II.1.b).

<sup>&</sup>lt;sup>639</sup> See the list of legal issues that may be addressed in the Convention as submitted by Germany and France, discussed above at C.II.3.

Convention reminds us of a human rights instrument much rather than of a legally binding law enforcement instrument.

Following those two examples of international rule-making, we may conclude that future attempts at regulating human reproductive cloning should likewise leave member states ample room in choosing appropriate means for the implementation of the prohibition and should also contain only limited enforcement mechanisms. This is all the more true for drafting rules on therapeutic cloning, a subject that is, as was seen, highly contentious. Proposals for provisions of an international Convention, such as the one Costa Rica submitted to the UN Secretariat,<sup>640</sup> are hence unrealistic as the unanimous disregard of UN delegations proved.

## **IV.** The negotiation strategy

Finally, let us revisit the negotiation strategy as designed by Germany and France. Both had an inductive approach to the negotiation on a Convention against reproductive cloning in mind. A joint learning process on the scientific background to human cloning and a joint elaboration of the mandate for the future Convention should ensure that delegations were moving ahead with collective knowledge, understanding and approval. This approach was meant to make a difference to most negotiations where a single or a small group of states ambush the plenary with ready formulated drafts. Rather, as many delegations as possible should participate in understanding the substance and contribute to the making of the mandate and ultimately also the text. This idea may have been successfully implemented as far as the introduction of the science of human cloning by experts was concerned.<sup>641</sup>

<sup>&</sup>lt;sup>640</sup> See the Costa Rican proposal on a draft Convention on the prohibition of all forms of human cloning, UN Doc. A/58/73, which views the subject more in the context of a criminal law and law enforcement instrument.

<sup>&</sup>lt;sup>641</sup> The idea of a joint learning process has been elaborated in a sophisticated manner in *Fisher/Ury/Patton* (1991). More specifically on conciliatory, consensus-

With regard to the elaboration of the mandate however, the chosen strategy turned out to be misleading, as it underestimated the unique dynamics that would be unleashed. The first General Assembly resolution 56/93 had clearly framed the efforts to be undertaken by the Sixth Committee. It established the prohibition of reproductive cloning as the goal of the future Convention. Some delegations may have questioned that later on, but no report from the time when resolution 56/93 was passed entails any other interpretation regarding the scope. This is why the resolution could generate so long a list of co-sponsors and why the initiative was supported enthusiastically throughout the assembly room.

The discussion on the mandate opened Pandora's Box. Therapeutic cloning was considered as a possible aspect to be included in the Convention. With that suggestion, the goal of the protection of human dignity got blended with the protection of early human life – a red rag for a considerable number of states. Political opportunists and thematically committed delegations grouped together and started campaigning. The way back to the single aspect of reproductive cloning was thus barred; appeals to delegations that pragmatism should rule over dogma were self-defeating. We may conclude that from this moment on, consensus solutions were impossible.

Germany and France may have felt too confident about their initiative. In an attempt to please all and forego the anticipated criticism of Western "bullying", they opened the stage for so wideranged a dialogue that the envisioned framework was torn apart. Sadly, this teaches us that more determined or aggressive tactics may have produced the outcome that transparency and open dialogue failed to achieve. Germany and France may have simply pushed for the initiation of negotiations on substance by submitting a draft Convention against reproductive cloning in the Sixth Committee on

oriented negotiation strategies in the context of international treaty making, see *Hathaway* (2004) at 1935-2042.

the basis of which the detailed provisions may have been negotiated. This is however only an *ex post* analysis.<sup>642</sup>

As we have argued earlier, the concept for a UN Convention regarding reproductive cloning as envisaged by Germany and France in 2001 was in itself compelling and stringent. However, besides a lack of U.S. support, it may have failed due to an overly conciliatory negotiation strategy at the very commencement of talks in 2001.

With regard to the maximalists' negotiation strategy, it was rooted in an all-or-nothing approach. As general experience at a multi-national negotiating table teaches, absolute, dogmatic positions run the risk of sacrificing the possibility of reaching any tangible result whatsoever. So it happened in the case of human cloning were no result, except a non-binding Declaration accepted by just half the UN General Assembly, was reached. It may be doubted, however, that the "maximalists" were satisfied with the outcome of their strategy. At least so much may be resumed: Negotiations cannot be successful if dogma hinders any attempts at compromising on substance.

The only UN member state that presumably reached her goal was the United States: If it was to destruct any attempts aiming at a legallybinding Convention on human cloning, she was certainly successful. As in the Kyoto Treaty, the International Criminal Court, and in the question of preemptive war, the U.S. was acting without much respect for and commitment to international consensus-making; a final analysis that must disappoint.

## V. Perspectives

What are the chances now for such a legally-binding, focused UN Convention? As was seen, the international community is by far not ready to agree *in toto* on the issues that are in want of international codification.

<sup>&</sup>lt;sup>642</sup> Also, it shall be noted that many diplomats, in retrospect, question whether even that would have changed the history of events.

In a comparable situation involving a conflict between ethical values, namely in the – in European eyes desirable, from the U.S. point of view disfavoured – abolition of the death penalty, article 6 of the International Pact on Civil and Political Rights (Civil Pact) came to the conclusion that the death penalty, if it cannot be abolished altogether, should at least be subject to considerable restrictions. This has been accepted by both the Europeans and the U.S., the former seeing it as the minimum and the latter as the maximum acceptable solution. It was a consensus, yet not based on a common rationality.

Some view it possible that the two camps reach a similar compromise regarding human cloning – whilst retaining their different convictions and legal positions. States, for that purpose, would need to acknowledge the impediments already encountered in this and previous drafting attempts and commit themselves to accepting that the forthcoming rules can only provide a standard of protection that reflects the minimal existing consensus whilst individual states may strive for a stronger protection scheme.

Others however believe that with the end of negotiations in the framework of the Sixth Committee of the United Nations it is unlikely that a similar initiative as that of Germany and France would be taken in the framework of an international organization. Rather, for the next years, attempts at prohibiting reproductive cloning through international, legally binding norms are barred.

Considering the consensus among states, the prohibition against reproductive cloning may become customary international law according to article 38 paragraph 1 (b) ICJ Statute.<sup>643</sup> At least generally speaking, a General Assembly declaration conveys strong

 $<sup>^{643}</sup>$  See *Kersten* (2004) at 296-306 who reaches the conclusion that, on a universal level, there already exists customary international law with regard to the reproductive cloning of human beings. On the development of rules into customary international law, see above at C.I.2.c) with a further reference.

indications of elements of a common international intent.<sup>644</sup> It may function as a "starting point, frame, and scheme" for building rules of customary international law.<sup>645</sup> Our UN negotiations have shown an international consensus on the issue of reproductive cloning. The seemingly divergent General Assembly vote on the declaration is not an antimony. The elaboration and interpretation of UNESCO's Human Genome Declaration and a look at the biopolitical literature supports this possibility as well.<sup>646</sup>

Ultimately, member states which are committed to regulating or prohibiting reproductive and therapeutic cloning now have ample time to develop their own national legislation. Also, member states could strive for solutions that neither raise claims to universality nor seek to be universalized. In concrete terms, this might mean that the cloning of human beings (and other disconcerting developments in genetic technology) could be regulated in other frameworks such as regional Conventions reflecting the particular ethical convictions of each region.

Alternatively, two parallel model laws could be drafted at a multilateral level, e.g. in a conference of states with an interest in this matter: one for states that desire a total ban that is as watertight as current scientific knowledge will permit, and one for states that wish to conduct research on therapeutic cloning subject to responsible control mechanisms. As soon as such model draft laws exist, a group of concerned states should make it a political priority that all states should integrate either of the two draft laws into their national law.

This would be an alternative way of achieving what the Convention set out to do - that is, to overcome at last the present anarchy in the field of human cloning.

<sup>&</sup>lt;sup>644</sup> See *Hailbronner/Klein*, in: Simma (2002) at article 10, margin no. 49.

<sup>&</sup>lt;sup>645</sup> See Simma (1994) at 95, 99.

<sup>&</sup>lt;sup>646</sup> See *Enquete-Kommission Deutscher Bundestag* (2001) at 31; *Honnefelder*, in: Taupitz (2002) at 190; *Deutsche Forschungsgemeinschaft* (1999) at 11, 12.