

The Japanese Approach to the Regulation of Human Cloning*

Tade Matthias Spranger

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I. INTRODUCTION

On 30 November 2000, the Japanese Parliament enacted the Human Cloning Regulation Act.¹ In its core, the Act prohibits transfer of human embryos and human-animal cloned embryos made by somatic nuclear transfer, as well as human-animal chimeric embryos, to a human or animal uterus. These provisions are more than mere lip service, as a breach of this prohibition of human cloning can be punished by as much as 10 years' imprisonment, a fine of ¥ 10 million, or both.² According to a widely held opinion, the Act has to be seen as a general ban on human reproductive cloning.³ Nevertheless, many questions remain unanswered. Not all cloning techniques are mentioned in the Act, nor are all possible applications forbidden. The following remarks examine the Act's provisions in detail. Subsequently, the question whether the Human Cloning Regulation Act reflects an original Japanese approach to human cloning will be the object of analysis. Finally, in case of an affirmative answer to this question, its compatibility with international law will be scrutinized.

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1 The Law Concerning Regulation Relating to Human Cloning Techniques and Other Similar Techniques (*Hito ni kansuru kurôn gijutsu-tô no kisei ni kansuru hôritsu*), Law No. 146/2000 (provisional English translation at: http://www.mext.go.jp/a_menu/shinkou/seimei/eclone.pdf).

2 Art. 16 of the Act.

3 Cf. NUDESHIMA, *Human Cloning Legislation in Japan*: 11 *Eubios Journal of Asian and International Bioethics* 2 (2001).

II. THE ACT'S CENTRAL PROVISIONS

The Human Cloning Regulation Act contains detailed provisions on a large scale. By listing no less than twenty-four central definitions (and dozens of sub-definitions), Art. 2 of the Act reflects the subject's complexity in a very impressive way. The differentiations between human fertilized embryos (Art. 2, no. 6), human split embryos (Art. 2, no. 8), human embryonic clone embryos (Art. 2, no. 9), human somatic clone embryos (Art. 2, no. 10), human-human chimeric embryos (Art. 2, no. 12), human-animal amphimictic embryos (Art. 2, no. 13), human-animal hybrid embryos (Art. 2, no. 14), human-animal chimeric embryos (Art. 2, no. 15), animal embryos (Art. 2, no. 18), animal-human hybrid embryos (Art. 2, no. 19), and animal-human chimeric embryos (Art. 2, no. 20) scare off the lawyer. Nevertheless, these complex regulations take into consideration that a general prohibition of "human cloning" is absolutely inadequate with regard to the possible benefits arising from this new technique. The potential for new medical applications which will serve the interests of the ill and disabled calls for a distinction between different types of "cloning". Therefore, the Japanese regulation reacts to practical necessities.

It is unclear whether the Act also applies to human stem cell procedures. Although the research on human stem cells is still in its early stages, experts agree that the potential of this field of knowledge for medical progress is enormous.⁴ The term "stem cell" applies to any cell of the embryo, fetus, or an adult human that possesses the capacity to reproduce indefinitely by division ("immortal" cell) and to develop into cells of different degrees of specialization (differentiate).⁵ One has to distinguish between totipotent stem cells, which have the capacity to differentiate into extra-embryonal tissues and all post-embryonic tissues and organs; pluripotent stem cells, which give rise to all the various types of body tissues; and organ-specific stem cells, which have already acquired determination for a particular cell type.⁶ Art. 2 (1) no. 1 of the Act defines as an embryo a cell (except a germ cell) or cells possessing the potential to grow into an individual through the process of development *in utero* of a human or an animal and has/have not yet begun formation of a placenta. Hence, the Act applies to totipotent stem cells.⁷ On the other hand, pluripotent or organ-specific stem cells do not fall within the scope of the law, as they do not have the potential to grow into an individual.

Article 1 defines the purpose of the Act. Its aim is to prevent and restrain creation of a human clone individual and an amphimictic individual and to regulate artificial creation of individuals set forth herein, by means of prohibiting transfer of embryos pro-

4 NATIONAL BIOETHICS ADVISORY COMMISSION, *Ethical Issues in Human Stem Cell Research*, Vol. I (1999) 20.

5 DEUTSCHE FORSCHUNGSGEMEINSCHAFT, SENATE COMMISSION ON GENETIC RESEARCH (ed.), *Genome Research – Perspectives and Consequences*, Report 2 (2000) 87.

6 HERDEGEN, *Die Patentierbarkeit von Stammzellenverfahren nach der Richtlinie 98/44/EG, Gewerblicher Rechtsschutz und Urheberrecht Internationaler Teil* (2000), at 859.

7 Dissenting opinion: NUDESHIMA (*supra* note 3).

duced by cloning techniques or specific fusion/aggregation techniques into a human or an animal uterus, by means of regulating production, assignment and import of such embryos, and by means of taking other necessary measures to secure appropriate handling of such embryos.

This provision requires closer analysis. First, the Act tries to prevent and restrain the creation of individuals. Necessarily, then, the creation of mere parts of individuals, *e.g.* tissues or organs, does not fall within the scope of the Act. Furthermore, the Act does not place a total ban on human cloning. Instead, only the transfer of embryos produced by cloning or similar techniques is prohibited. The production, assignment and import of embryos is not the object of prohibition but of mere regulation in the interest of the secure and appropriate handling of embryos. In other words, the Act encourages efforts in the field of research and development, even if cloning techniques or the handling of embryos is involved. This differentiation between transfer of embryos on the one hand and all other procedures on the other hand is also elucidated by Art. 3 of the Act, which reads as follows:

“No person shall transfer a human somatic clone embryo, a human-animal amphimictic embryo, a human-animal hybrid embryo or a human-animal chimeric embryo into an uterus of a human or an animal.”

This provision, headed “Prohibited Acts”, applies only to the transfer of some types of embryos into an uterus of a human or an animal. *Vice versa*, all other handlings are left aside. Article 3 of the Act does not even prohibit the whole range of possible transfers. For example, the transfer of a human split embryo, *i.e.* an embryo produced by a split of a human fertilized embryo or a human embryonic clone embryo outside a human uterus⁸ into an uterus of a human is not prohibited. The paramount importance of this assessment is emphasized by Art. 4, which states:

“Under the circumstances where there is apprehension that a human split embryo, a human embryonic clone embryo, a human-human chimeric embryo, a human-animal amphimictic, a human-animal hybrid embryo, a human-animal chimeric embryo, an animal-human hybrid embryo or an animal-human chimeric embryo (hereinafter referred to as “a Specified Embryo”) transferred into a human or an animal uterus could develop to an individual, or affect preservation of human dignity, safety for human life and body, and maintenance of the social order, the Minister of Education, Culture, Sports, Science and Technology (hereinafter referred to as “the Minister”) shall prescribe guidelines in relation to handling of Specified Embryos (hereinafter referred to as “Guidelines”) in order to secure appropriate production, assignment or import of Specified Embryos and in handling Specified Embryos after such acts (hereinafter referred to as “Handling of Specified Embryos”), taking into consideration scientific knowledge related to the clarification of the phenomenon of life.”

8 Cf. Art. 2 no. 8 of the Act.

From a European point of view, this type of legislation appears remarkable. For example, in Germany, the *Wesentlichkeitstheorie* (essentiality doctrine) forces the legislature, *i.e.* the *Bundestag* (Lower House of Parliament) and the *Bundesrat* (Upper House of Parliament), to enact provisions of paramount importance by themselves and thus imposes strict limits on the delegation of legislative powers to the executive. Hence, a Ministry, as an executive authority, is constitutionally not authorized to impose such regulations. Nevertheless, Japanese legal tradition differs. As in all other areas of Japanese biotechnology law⁹, guidelines represent the major instrument of regulation¹⁰. Thus, the delegation of specific regulatory power is not extraordinary in Japanese practice.

Nevertheless, the provision's importance results from the clearly limited scope of its material statement. By introducing the term "Specified Embryo", Art. 4 specifically defines eight types of embryos for which transplantation into a human or an animal uterus is not prohibited.¹¹ From this point of view, Art. 4 is absolutely revolutionary. It appears that, as of now, no other legal system allows transplantation of clones into the human uterus whatsoever. Even mere cloning procedures *in vitro* seem to be restricted without exception. The reason for this prohibition seems to be that benefits of human cloning are being underestimated while risks are overstated.¹² Hence, Japan enters unknown territory. Regarding the fact that the international debate on human cloning reached a deadlock, this innovative step is a merit in itself.

However, in case of mere transplantation of a Specified Embryo, Art. 4 of the Act detects a weakened need for regulation. Only if the transplanted embryo could develop into an individual, affect preservation of human dignity or safety of the human life and body, or adversely affect maintenance of the social order do measures using Specified Embryos have to be taken. The upcoming guidelines then provide for the appropriate production, assignment or import of Specified Embryos. In any other case, *i.e.* in case of "normal handling" of Specified Embryos, Art. 6 and the following provisions contain detailed instructions. Hence, the Act accepts *in vitro* human embryo research very widely. It permits cloning of a human embryo by somatic nuclear transfer, and making human-human, human-animal, or animal-human chimeric embryos. It also permits cloning embryos by animal somatic cell nuclear transfer to a human oocyte. According to one

9 Guidelines for Recombinant DNA Experiment; Guidelines for Industrial Application of Recombinant DNA Technology; Guidelines for Manufacturing Drugs etc. by Application of Recombinant DNA Technology; Guidelines for Manufacturing Foods and Food Additives by Application of Recombinant DNA Techniques; Guidelines for Safety Assessment of Foods and Food Additives Produced by the Recombinant DNA Techniques; Guidelines for Application of Recombinant DNA Organisms in Agriculture, Forestry, Fisheries, The Food Industry and Other Related Industries.

10 HERDEGEN, in: HERDEGEN (ed.), *Internationale Praxis Gentechnikrecht*, Part 4 Q I, No. 1.

11 *Cf.* also NUDESHIMA (*supra* note 3).

12 LUPTON, *Human Cloning – The Law's Response*: 9 *Bond Law Review* 123, 129 (1997).

scholar's assessment, this last exception to the ban surprised conscientious researchers working in this field.¹³

Some critics comment on the fact that selling human embryos and oocytes is not prohibited by the Act. This is regarded as in striking contradiction to the fact that the sale of human solid organs such as the heart or liver is legally prohibited by the Organ Transplantation Act of 1997.¹⁴ This assessment fails to consider that problems arising from organ trade¹⁵ are not connected specifically to biotechnology. The nuclear level of DNA defies traditional legal structures. Instead, a new concept called a "life unit" might be required in addition to the existing legal dichotomy of "persons" and "things".¹⁶ In fact, in other countries, such as the United Kingdom¹⁷, so-called preembryos, *i.e.* the earliest stages of the developing embryo¹⁸, are protected by law to a much lesser extent. In Germany, some scholars also try to differentiate between the two-, four-, eight- or sixteen-cell stadium of human development on the one hand and a more elaborated status on the other hand.¹⁹ Actually, strong arguments call for a status *sui generis* with specific regard to the earliest stages of human life. Not from an ethical, religious, or moral, but from a strictly legal perspective, a community that allows abortion, *i.e.* selection several weeks after fertilization, should also allow experimentation on a few cells.

According to Art. 6 (1) of the Human Cloning Regulation Act, a person who will produce, be assigned, or import a Specified Embryo shall provide notice of any of the different items listed in Art. 6 (1) no. 1-6 to the Minister pursuant to the provisions under an ordinance of the Ministry of Education, Culture, Sports, Science and Technology. If any modification to the items related to the notice arises, an additional notice is required. If a method of handling a Specified Embryo described in the modified notification is deemed not to comply with the Guidelines, the Minister may, within sixty days from the date of acceptance of the notice, order changes in, or cancellation of, the plan or take other necessary measures (Art. 7 [1] of the Act). The period prescribed in Art. 7 (1) may be shortened if the description of the notice given under Art. 6 (1) or (2) is deemed appropriate (Art. 7 [2]).

Article 8 is of great practical importance. According to this provision, the notifying party shall not produce, be assigned from others, or import any Specified Embryo related to the notice, or modify the items related to the notice until 60 days have passed

13 NUDESHIMA (*supra* note 3).

14 NUDESHIMA (*supra* note 3).

15 See BERNAT, Marketing of Human Organs?, in: MAZZONI (ed.), A Legal Framework for Bioethics (1998) 161.

16 KITAGAWA, The Law of "Life Units" as a New Legal Order, in: FUJIKI/MACER (eds.), Bioethics in Asia (1998) 56, 57.

17 British law imposes a restriction that research can only take place for up to 14 days after fertilization; *cf.* ROGERS, Prenatal issues: life before life ?, in: ROGERS/DURAND DE BOUSINGEN (eds.), Bioethics in Europe (1995) 55.

18 LUPTON (*supra* note 12), at 133: "a human embryo prior to implantation".

19 HERDEGEN (*supra* note 6), at 859, 861.

from the date of acceptance of the notice or until the expiration date specified in Art. 7 (2). Hence, the Ministry's failure to observe the deadline results in an approval of the intended measure.

Article 9 of the Act provides notification requirements for, and regulation of, the production of Specified Embryos by so-called contingent causes. This is all the more logical as a Specified Embryo derived from another Specified Embryo is a *new* Specified Embryo. Therefore, it is necessary to submit this new embryo to the regulations described above. Nevertheless, Art. 9 contains an important exemption: it shall not apply when another such Specified Embryo is discarded immediately after production. To some extent, this provision raises the risk of circumvention. Without an effective control, produced Specified Embryos could be labeled as discarded, although in fact, they are not discarded at all. Therefore, Art. 15 of the Act is of specific importance. Paragraph 1 of this provision makes allowance for a Ministry official to access and enter the office or laboratory of a notifying party. Furthermore, it empowers officials to inspect documents and other necessary property, and ask questions of the participants.

Different matters in connection with the Specified Embryo shall be recorded (Art. 10). Corresponding to this article, the Minister may, to the extent necessary to enforce the law, ask the notifying party for reports concerning the conditions in which the Specific Embryo was handled and other necessary items related to the notice (Art. 14). If the Specified Embryo related to the notice is assigned to others, exported, lost, or discarded, Art. 11 of the Act demands notification of specific items enumerated in Art. 11 no. 1-4. If a method of handling a Specified Embryo described in the notice is found to be not in compliance with the Guidelines, the Minister may order the notifying party to suspend handling the Specified Embryo, to improve the method of handling or to take other necessary measures (Art. 12).

Each notification can present some risk to the notifying party's commercial interests.²⁰ Therefore, many laws applying to biotechnology procedures contain specific provisions that try to protect the notifying party's proprietary rights. Article 13 of the Japanese Human Cloning Regulation Act is headed "Protection of Private Information". Nevertheless, it was not enacted in view of the notifying party's interests. Instead, Art. 13 guarantees the fundamental rights of the donor. According to this provision, the notifying party shall endeavour to take measures necessary to prevent disclosure of any private information concerning any donor of embryos or cells used to produce the Specified Embryo related to the notice. Such private information means information concerning an individual including the name, date of birth, and other data from which the individual may be identified – including information from which the individual may be identified by cross-checking with other information.

20 Cf. SPRANGER, Schutz von Unternehmensdaten im Lichte der EG-System- und der Umweltinformationsrichtlinie: 10 Europäisches Wirtschafts- und Steuerrecht 292 (1999).

Articles 16 through 20 contain different penal provisions. According to Art. 16, the violation of Art. 3 shall be punished with imprisonment for not more than 10 years or a fine of not more than ¥ 10 million, or with both of these penalties cumulatively. The violation of the notifying party's liability in compliance with Art. 6 (1) or (2) or rather of the order provided under Art. 7 (1) or Art. 12 shall be punished with imprisonment for not more than 1 year or a fine of not more than ¥ 1 million. However, Art. 17 does not provide the possibility of cumulative punishment. If the 60-day waiting period after notification required by Art. 8 is ignored, the penalty is up to 6 months of imprisonment or a fine of not more than ¥ 500,000 (Art. 18). Various other violations enumerated by Art. 19, *e.g.* the evasion of an inspection or the giving of a false report, are punished with a fine of not more than ¥ 500,000. If a representative of a legal entity, or an agent, a trade employee or other employees of a legal entity, or a person has committed an act in violation of the provisions from Art. 16 to Art. 19, the perpetrator shall be punished, and the legal entity or the person shall be punished with a fine. The latter provision constitutes a punishment because of some kind of neglect of supervision or vicarious liability although the legal entity is free from fault itself.

III. COMPATIBILITY WITH INTERNATIONAL LAW

Up to now, international law has provided no comprehensive framework for human cloning. However, UNESCO, although its activities concern the field of culture in particular, published the Universal Declaration on the Human Genome and Human Rights 4 years ago. This legally non-binding document is expected to serve as pattern for international law as well as a source of knowledge for national courts.²¹ Hence, its influence on the development of an international treaty regulating human cloning is of paramount importance. Reflecting the minimum standard of international consensus, the Declaration gives a general idea *de lege ferenda*.

Although it tries to set minimal standards in general, the Declaration contains specific provisions relating to human cloning. Art. 7 of the Declaration states:

“Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. [...]”

This provision is of specific interest in several respects. First, Art. 7 of the Declaration applies only to *reproductive* cloning. Keeping in mind that the term “cloning” circum-

21 See also HERDEGEN / SPRANGER, in: HERDEGEN (ed.) (*supra* note 10), Part 5 I 6, No. 1; SPRANGER, What is wrong about Reproductive Human Cloning ? – A Legal Perspective: 11 *Eubios Journal of Asian and International Bioethics* 101 (2001).

scribes nothing but the mere duplication of genetic information²², the restraint on *reproductive* cloning introduces an element of “end product-orientation”. Not the duplication of human genetic information but the duplication of a human being as a whole is the provision’s center of interest. Therefore, Art. 7 does not deal with cloning procedures aiming at the mere generation of tissue aggregates or whole organs, because they are not designed to reproduce human beings as a whole. For the same reason, the reproductive cloning of animals is not prohibited even if the used technique or its results are applicable to human beings.

Furthermore, Art. 7 of the Declaration links the prohibition of cloning with the protection of human dignity. This seems to be a futile attempt to legitimate the unanimous ban on reproductive cloning. Human dignity as a legal term is not a justification for such a prohibition nor does it demand an interdiction of reproductive cloning. According to human dignity as a legal term, not mankind as a whole, but the individual is the focus of attention²³. This leads to the question of the prioritization of individual interests. Human dignity, seen as the core of human self-determination, also protects the individual’s decision for reproductive cloning. If, for example, a married couple is not able to give birth to children, reproductive cloning could be a solution. From this point of view, the prohibition of human cloning must be seen as an intervention in the couple’s rights²⁴. Thus, any restriction of this individualistic approach to human dignity requires a total reform of human rights’ basic principles.

However, the advantages arising from biotechnology are reflected by the UNESCO Declaration itself. Its preamble recognizes that research on the human genome and the resulting applications open up vast prospects for progress in improving the health of individuals and of humankind as a whole.²⁵ Nevertheless, such research should fully respect human dignity, freedom, and rights, as well as the prohibition of all forms of discrimination on the basis of genetic characteristics.²⁶

As a result, UNESCO’s Universal Declaration on the Human Genome and Human Rights prohibits reproductive human cloning without legal necessity. Moreover, insofar as the Japanese Act allows reproductive cloning, it is incompatible with the Declaration. Nevertheless, because of its lack of legal power, the Declaration cannot force the Japanese legislature to change its mind. Besides, the situation described above also explains

22 Hence, even potatoes are clones, *cf.* ESER / FRÜHWALD / HONNEFELDER / MARKL / REITER / TANNER / WINNACKER, *Klonierung beim Menschen. Biologische Grundlagen und ethisch-rechtliche Bewertung*: 2 *Jahrbuch für Wissenschaft und Ethik* 357, 358 (1997).

23 *Cf.* HOWARD, *Dignity, Community, and Human Rights*, in: AN-NA’IM (Ed.), *Human Rights in Cross-Cultural Perspectives* (1992) 81.

24 WU, *Family Planning through Human Cloning: Is there a Fundamental Right ?*: 98 *Columbia Law Review* 1461 (1998).

25 This applies also to human cloning techniques. A differing opinion is held by ATWILL, *Human Cloning: French Legislation and European Initiatives*: 28 *International Journal of Legal Information* 500, 502 (2000).

26 Preamble of the Declaration, no. 6.

Japan's sibylline statement during the negotiations: Japan pointed out that the Declaration should not be regarded as an unchangeable instrument but as a first step of the universal reflection on the human genome and human rights.²⁷

Other international efforts likewise do not limit the validity of the Japanese Human Cloning Regulation Act. The various activities of intergovernmental institutions with regard to the protection of human dignity²⁸ are of no direct significance for the regulation of human cloning procedures. Neither is the protection of the future human being indispensable for the protection of human dignity nor will reproductive cloning bring out new forms of discrimination.²⁹ In particular, human cloning is not objectification of the person to be born.³⁰ Even if, in case of cloning, the birth of human beings is not an end in itself but a simple instrument at the service of prior objectives that are totally foreign to these human beings, the donor's decision is protected by human rights. Furthermore, in many cases, the birth of human beings serves prior objectives. If, for example, a couple gives birth to a child to get an old-age pension, the birth is not an end in itself either. Nevertheless, this practice is not seen as a violation of human dignity. Parents, after all, seek to procreate for all sorts of reasons that sound like objectification of children – for instance, to replace a recently deceased child, to give their first child a playmate, to save their marriage, to stem boredom, or because the family already has two daughters and the father wants to try for a son.³¹

Finally, Art. 1 (1) of the Council of Europe's 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 Beings³², has to be mentioned. This provision prohibits any intervention seeking to create a human being genetically identical to another human being, whether living or dead.³³ Notwithstanding the fact that, by now, only Georgia, Greece, Romania, Slovakia, Slovenia, and Spain signed and ratified not only the Convention but also the Protocol, which is a *conditio sine qua non* for the Protocol's enforcement, Japanese regulation is far from being dependent on European regulatory efforts.

27 Cf. LENOIR, Universal Declaration on the Human Genome and Human Rights: The First Legal and Ethical Framework at the Global Level: 30 Columbia Human Rights Law Review 537, 560 (1999).

28 See MARKS, Human Rights, Activities of Universal Organizations, in: Encyclopedia of Public International Law, Vol. Two (1995) 893.

29 Dissenting opinion: ATWILL (*supra* note 24), at 505.

30 In this spirit: ATWILL (*supra* note 28), at 506.

31 WU (*supra* note 23), at 1505.

32 ETS No. 168.

33 In depth: HERDEGEN / SPRANGER (*supra* note 10), Part 5 I 5, No. 55 *et seq.*

IV. CONCLUSIONS

The Japanese Human Cloning Regulation Act is an important step toward a strictly legal view in bioethical decision-making. Thus, the Act's lack of fundamental ethical principles³⁴ should be welcomed. Any blending of ethical and legal issues involves, from a lawyer's point of view, exceptional risks for legal clarity and certainty.³⁵

After all, even if the driving force for the Act was the ethos to "catch up with the USA in the field of biotechnology"³⁶, this does not automatically have any disadvantageous impacts on the law's quality. Certainly, the possibilities arising from human cloning are not beneficial or advantageous *per se*. Nevertheless, one should never ignore the enormous potential for new medical applications. The genetic engineering made possible by biotechnology will likely yield some of the greatest technological breakthroughs for the new millennium.³⁷ Therefore, the Japanese Act is a landmark of paramount importance and a stimulus for further debate.

ZUSAMMENFASSUNG

Das Klonen von Menschen mit all seinen rechtlichen und ethischen Implikationen wird zur Zeit fast überall in der Welt diskutiert und ist dabei heftig umstritten. Der Beitrag befaßt sich mit dem rechtlichen Ansatz zur Lösung dieses Problems in Japan.

Am 30. November 2000 verabschiedete das japanische Parlament ein Gesetz erlassen, das bestimmte technische Verfahren im Zusammenhang mit dem Klonen von Menschen verbietet. Der Autor stellt die einzelnen Regelungen des Gesetzes vor und weist dabei auf verschiedene Detailprobleme hin. So enthalte die Regelung kein allumfassendes Verbot des Klonens von Menschen, sondern verbiete nur einzelne konkrete technische Verfahren. Dies sei grundsätzlich der richtige Weg bei einer Regulierung. Problematisch sei aber zum Beispiel, daß nicht klar hervorgehe, ob auch der Umgang mit Stammzellen vom Anwendungsbereich des Gesetzes umfaßt sei. Ferner sei es vom Standpunkt des deutschen Verfassungsrecht aus betrachtet bedenklich, daß wichtige Einzelheiten des Gesetzes in Japan der Bestimmung durch Richtlinien der zuständigen Verwaltungsbehörde überlassen würden.

34 Cf. NUDESHIMA (*supra* note 3). See also: MORIOKA, Commentary on Nudeshima: 11 *Eubios Journal of Asian and International Bioethics* 2, 3 (2001). In general: TAMAI, Ethical Guidelines for Clinical Genetics in Japan, in: FUJIKI/MACER (eds.), *Bioethics in Asia* (1998) 244.

35 SPRANGER, Ethical Aspects of Patenting Human Genotypes According to EC Biotechnology Directive: 31 *International Review of Industrial Property and Copyright Law* 373, 380 (2000); SPRANGER (*supra* note 20). In general: ZATTI, Towards a Law for Bioethics, in: MAZZONI (ed.), *A Legal Framework for Bioethics* (1998) 53.

36 See MORIOKA (*supra* note 33).

37 MURPHY, *Biotechnology and International Law*: 42 *Harvard International Law Journal* 47 (2001).

Der Beitrag prüft darüber hinaus, inwieweit dieses Gesetz mit bestehendem internationalem Recht in Einklang steht und erörtert dessen Verhältnis zur Deklaration der UNESCO und zur Konvention des Europarates. Nach Meinung des Verfassers ist es in jedem Fall ein wichtiger Schritt zur Klärung der rechtlichen Beurteilung von Techniken, die im Zusammenhang mit dem Klonen von Menschen stehe und ein bedeutender Stimulus für die weitere Diskussion.

(die Red.)