BioRN Lounge

Tonight's speakers

Speakers: Tade Spranger & Tobias Schulz

Title: „CRISPR/Cas – Genomeediting in biopolitics and biolaw"

RITTERSHAUS
Rechtsanwälte

CRISPR/Cas – Genomeediting in biopolitics and biolaw

Prof. Dr. Dr. Tade M. Spranger/Dr. Tobias Schulz LL.M.

27. February 2018

Tade Spranger

1995 First Juridical State Examination

1997 Dr. iur.

1998 Second Juridical State Examination, 1998

2002 Dr. rer. pol.

2002 Visiting Professor, University of São Paulo

2003-present Member of the Ethics Committee, School of Medicine, University of Bonn

2004-2005 Visiting Professor University of Technology Sydney

2006-2015 Head of the BMBF Research Group "Norm-Setting in the Modern Life Sciences"

2008 Habilitation and venia legendi for Public Law, European Law, International Economic Law, and Biotechnology Law

2009-present Extraordinary Professor, University of Bonn

2014-present Member of the Ethics Advisory Board of the Human Brain Project, 2016-present Lawyer at RITTERSHAUS

More than 350 publications on German Administrative and Constitutional Law, International Biomedical and Biotechnology Law, Intellectual Property Law

Tobias Schulz

2004 – 2010 Studied law at the University of Bonn and the Universidad Autónoma Madrid

2010 – 2011 Research assistant and assistant lecturer at the University of Bonn (Institute for Public Law, Department for European Law)

2012 – 2015 Legal traineeship at the Regional Court of Düsseldorf 2013 Obtained degree of Dr. jur. from the University of Bonn

2015 Admitted to the bar in Germany

2015 Lawyer at Freshfields, Bruckhaus & Deringer LLP, Berlin

2016 Obtained a Master of Laws degree (LL.M.) ("Innovation, Technology and the Law"), University of Edinburg;

2016 - present RITTERSHAUS law firm

GMO???

- Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms

- Art. 2 (2): "genetically modified organism (GMO)" means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination;

- Within the terms of this definition:

- (a) genetic modification occurs at least through the use of the techniques listed in Annex I A, part 1;

- (b) the techniques listed in Annex I A, part 2, are not considered to result in genetic modification;

ANNEX I A

TECHNIQUES REFERRED TO IN ARTICLE 2(2)

PART 1

Techniques of genetic modification referred to in Article 2(2)(a) are inter alia:

(1) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;

(2) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;

(3) cell fusion (including protoplast fusion) or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

PART 2

Techniques referred to in Article 2(2)(b) which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms made by techniques/methods other than those excluded by Annex I B:

(1) in vitro fertilisation,

(2) natural processes such as: conjugation, transduction, transformation,

(3) polyploidy induction.

Article 3

Exemptions

1. This Directive shall not apply to organisms obtained through the techniques of genetic modification listed in Annex I B.

ANNEX I B

TECHNIQUES REFERRED TO IN ARTICLE 3

Techniques/methods of genetic modification yielding organisms to be excluded from the Directive, on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques/methods listed below are:

(1) mutagenesis,

(2) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.

Case C-528/16

Opinion of Advocate General Bobek, delivered on 18 January 2018

"Thus, on the textual level alone, it is already quite clear that it is incorrect to state that under the GMO Directive, there would be a straightforward and unqualified exemption for any and all mutagenesis techniques. On the contrary: the Annex I B caveat provides a significant qualification.

A contextual reading of the GMO Directive confirms the importance of this 2001 addition. The use of recombinant nucleic acid molecules is indeed expressly mentioned in Part 1 of Annex I A as a technique of genetic modification referred to in Article 2(2)(a) — the positive list. The use of such molecules may even lead to the rebuttal of the presumption that the techniques enumerated in Part 2 of Annex I A (namely in vitro fertilisation, natural processes and polyploidy induction) are not considered to result in genetic modification.

Accordingly, it follows that mutagenesis techniques that meet the criteria laid down in Article 2(2) are exempt from the obligations of the GMO Directive provided that they do not involve the use of recombinant nucleic acid molecules or GMOs other than those produced by mutagenesis or cell fusion of plant cells of organisms, which can exchange genetic material through traditional breeding methods. If that latter condition contained in Annex I B is not satisfied, all the obligations laid down by the Directive will apply."

Red area: moratorium (cf. DFG/Leopoldina Statement)

Summary

Modern molecular techniques often referred to as "genome editing" or "genome surgery" are currently revolutionising molecular biology research. Technologies such as CRISPR-Cas9 allow for surprisingly simple, controlled gene modifications that are more efficient than the previously available methods. This opens up new scope for molecular biological basic research, particularly into organisms that were not previously accessible for molecular genetic purposes, and for elucidating poorly understood gene functions. This methological innovation also allows for far-reaching applications, from new options for plant breeding and biotechnology to somatic gene therapy for human genetic diseases. Focused basic research is still required, and Germany should be contributing on all levels to these important developments, as well as helping to ensure a safe and responsible application of genome editing that respects the needs of humanity and the environment.

In April 2015, Chinese researchers studied the potential CRISPR-Cas9 has to change the human genome in non-viable human embryos. The results of the study show that the methods behind such an application are far from adequately

The National Academy of Sciences Leopoldina, acatech – the National Academy of Science and Engineering, the Union of German Academies of Sciences and Humanities, and the German Research Foundation (*Deutsche Forschungsgemeinschaft* – DFG) stress the great scientific potential of genome editing. They point out that it is ethically and legally acceptable in many areas. The new techniques should not be automatically equated with sporadic cases of improper use or with applications whose ethical and legal ramifications have not yet been assessed. The DFG and the academies endorse the call for an international moratorium on all forms of human germline engineering that could have an impact on the genome of the offspring. The moratorium should give scientists, politicians and society the opportunity to discuss unresolved questions in a transparent and critical way, to evaluate the benefits and potential risks of the techniques, and to develop recommendations for future regulations. However, the moratorium should not constitute a general restriction on methodological developments and thus limit any promising new genome editing approaches for use in research and application.

Further challenges

Applicability of other EU secondary law measures

Example 1:

➔ EU legislation No. 1179/2009 on Plant Production Products

"products, in the form in which they are supplied to the user, consisting of or containing active substances […], and intended for one of the following uses:

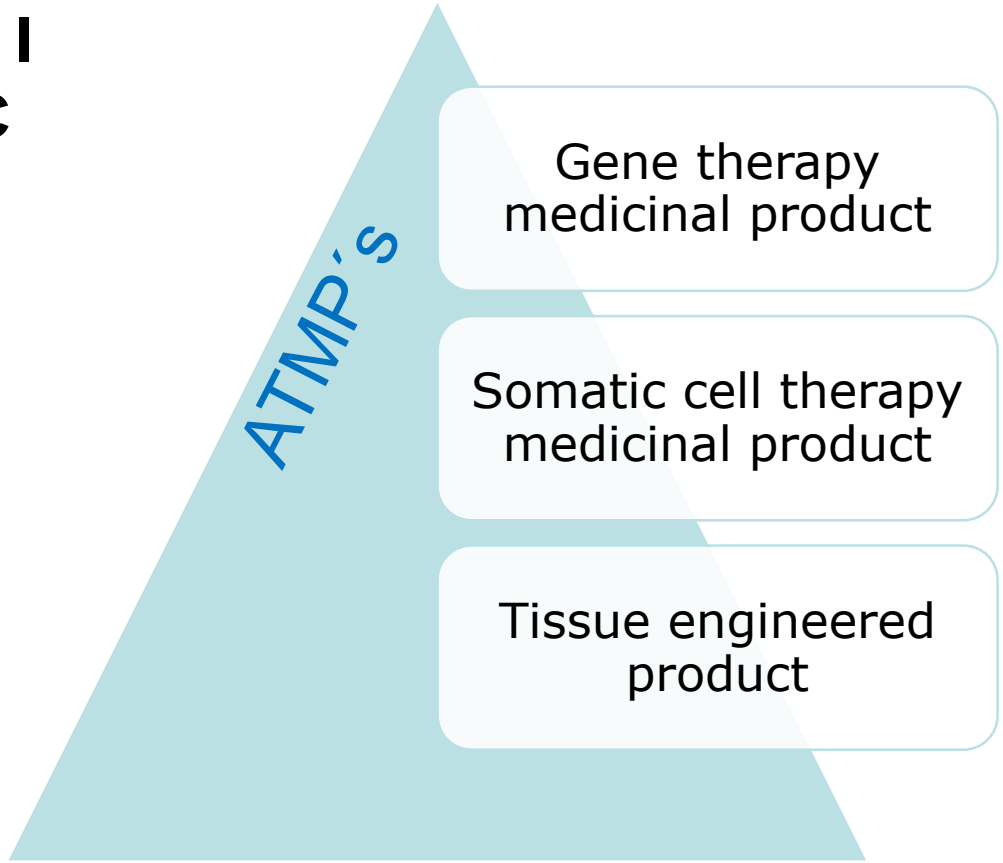
(a) protecting plants or plant products against all harmful organisms or preventing the action of such organisms,

unless the main purpose of these products is considered to be for reasons of hygiene rather than for the protection of plants or plant products;"

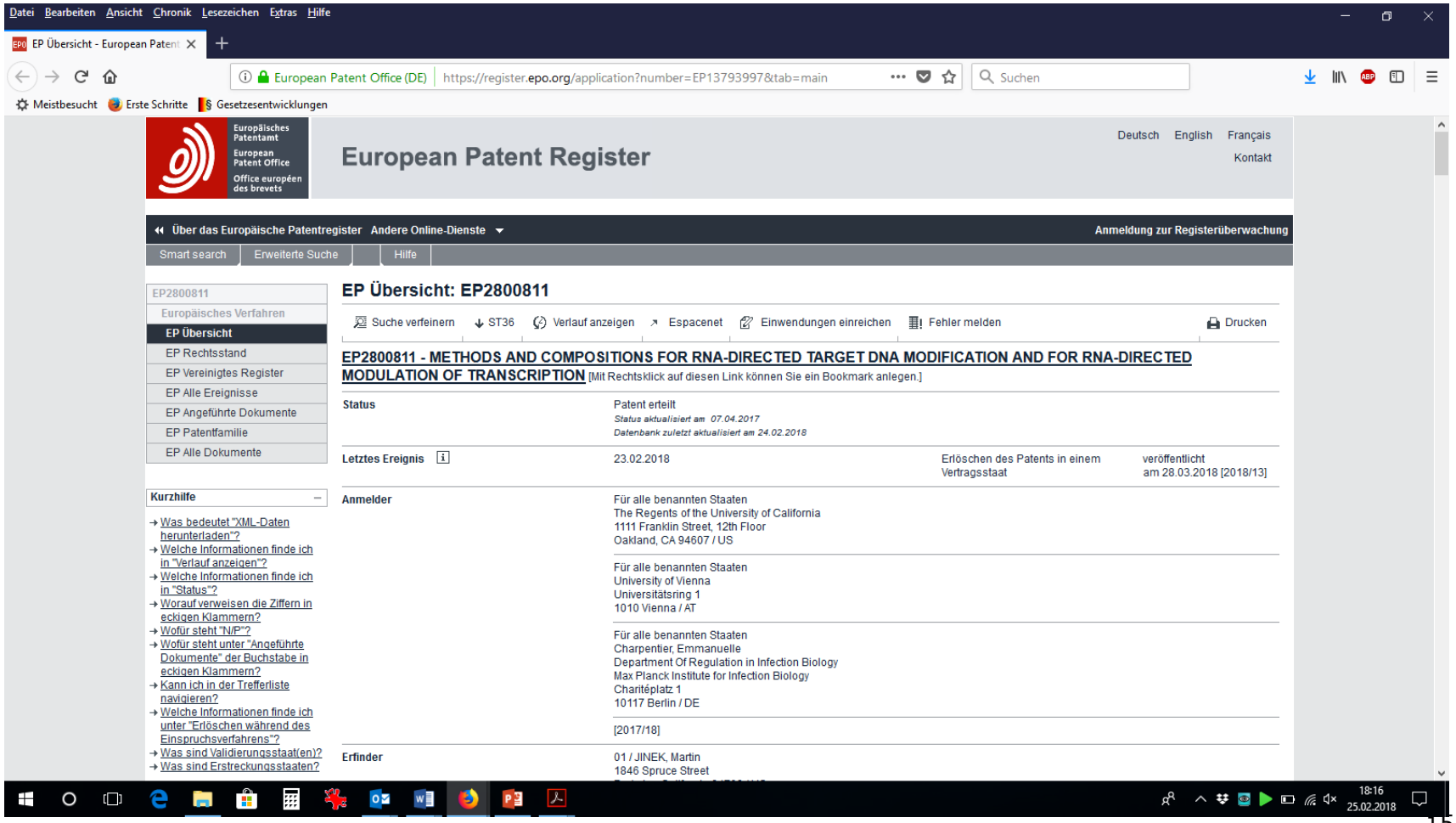
CRISPR/Cas a substance??

Further challenges

Art. 2 Abs. 1 ATMP-VO and Annex I 2001/83/EC



Further challenges



Thank you for your attention!

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Next Lounge

March 20, 2018

Speaker: Marc Stanke, Accantec

Topic: “Data Science”