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The punishment of gene doping – The relation between WADA prohibited lists, German Medicinal Products Act, German Doping Agents Amounts Ordinance, and Basic Law of the Federal Republic of Germany

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The genetic constitution of athletes influences efficiency. Knowledge of genetic influences provides an opportunity for medical diagnostic and therapeutic attempts. Beside risks and therapeutic aspects, however, the possibilities of abuse for gene doping purposes in sports also exist. Genetic screening or gene therapy may have an advantage for athletes who use these methods. In juridical comments, it is pointed out that gene doping so far plays no role in sports, but that the legislator must consider a development in this area. Preventing abuse requires legal regulations. These regulations can include sanctions. This paper deals with the gene doping prohibition of the World Anti-Doping Agency (WADA) as confirmed and accepted by the monitoring group according to Articles 10 and 11 of the European Anti-Doping Convention by the Council of Europe, the prohibition of (gene) doping in sports of the German Medicinal Products Act (Arzneimittelgesetz - AMG) and the German Doping Agents Amounts Ordinance (Dopingmittel-Mengen-Verordnung–DmMV) of the German Federal Ministry of Health (BMG). The comprehensibility of the doping ban on the norm addressee was tested with a questionnaire. In connection with legal regulations of the German constitution, gene doping is discussed and problems which may arise by a state doping prohibition are pointed out. Copyright © 2011 John Wiley & Sons, Ltd.

Keywords: gene doping; punishment; International law; German law

Introduction

The genotype of the athlete influences his or her performance in sport as well as the daily training. By genetic screening and by gene therapy it may be possible to assist the sportsmen in nonacceptable manner to the success.^[1–4] In the meantime, beside sports-juridical sanctions (lex sportiva), numerous countries have sanctions for doping in sport in their state norms (lex extra sportiva). The sanctions can refer to the use of prohibited substances or prohibited methods, like gene doping. This paper first describes the development of the definitions of gene doping by the World Anti-Doping Agency (WADA). International arrangements in the fight against doping in sport as the European Anti-Doping Convention by the Council of Europe^[5] or the International Convention against doping in sport by the United Nations Educational, Scientific and Cultural Organization (UNESCO)^[6] refer to the prohibited lists of WADA. Then the prohibition of doping in sport and the criminal sanction possibilities for gene doping of the German Medicinal Products Act (Arzneimittelgesetz - AMG) are explained. The prohibition of doping in sport of the German Medicinal Products Act refers also to the European Anti-Doping Convention. Juridical difficulties which can arise by reason of the constitutional-juridical principles are explained by the jurisdiction of the German Federal Constitutional Court (Bundesverfassungsgericht). These principles contain basic values which also are followed in legal

systems of other countries. Therefore it is possible to draw conclusions in general for the punishment of gene doping with lawful means of state acts by the German legislator and not only by sanctions of lex sportiva.

On account of the new and partly different attempts with gene doping, considerable health risks exist whose effects can not currently evaluated according to the present scientific level of knowledge. As possible health risks, immunological reactions caused by the transfer of inactivated viruses, autoimmunological reactions, negative influence on the growth of the myocardium or leukaemia are described. Hence, beside possible punishments from the AMG, convictions also are possible because of sections in the criminal code (Strafgesetzbuch – StGB) such as offences against life (Section 211 StGB and following sections) or offences against the person (Section 223 StGB and following sections). The punishments in the AMG as described in detail are called supplementary penal provisions to the Criminal code.

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Gene Doping in the Juridical and Medical Literature

Up to now, gene doping plays no significant role in the juridical literature. The following results were found in March 2011 searching with the German keyword 'gene doping' in German juridical data banks:

- Beck Online four publications^[8–11] as well as one comment^[12]
- Lexis nexis two publications^[8,13] and one short comment^[14]
- Juris Online one publication^[8]

Indeed, only a short reference to gene doping occurs in most articles; a detailed scientific juridical discussion on gene doping does not take place in these publications. In juridical comments, it is also pointed out that gene doping still plays no role in sports, but that the legislator must consider a development in this area. [12,15]

In the medical literature, an increase in scientific articles which deal with gene doping and sports can be observed. A search for 'gene doping' and 'sports' in the medical data bank PubMed in March 2011 resulted in 118 hits. [16] Seventy-one (60.2%) articles were published in the years 2008–2010 (Figure 1).

The Changes of the Gene Doping Definitions in the Prohibited Lists of WADA

Criteria for including substances or methods on WADA's prohibited list are according to Article 4.3.1 of the WADA Code 2009 that a substance or a method like gene doping fulfils any two of three criteria:

- 'Medical or other scientific evidence, pharmacological effect or experience that the substance or method, alone or in combination with other substances or methods, has the potential to enhance or enhances sport performance.
- Medical or other scientific evidence, pharmacological effect or experience that the use of the substance or method represents an actual or potential health risk to the athlete.
- WADA's determination that the use of the substance or method violates the spirit of sport described in the introduction to the code.'

In addition, a substance or method also shall be included in the prohibited list according to Article 4.3.2 of the WADA Code

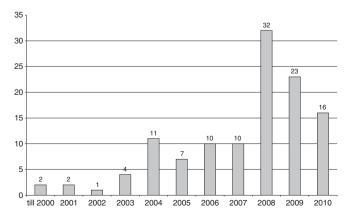


Figure 1. Medical articles including 'gene doping' and 'sports'.

2009, if there are effects and/or experience of a potential to mask, for instance, prohibited substances.

Since 2003, gene doping is specifically mentioned in WADA's prohibited lists. Five changes of the gene doping definition have taken place since the first definition in 2003. The development of the text and the definition of gene doping in WADA's prohibited list as confirmed and accepted by the monitoring group according to Articles 10 and 11 of the European Anti-Doping Convention^[5] are shown in Table 1, where the official versions of the English text are cited in the German *Federal Law Gazette*. Since 2009, it has become clear that the definition of gene doping has developed from a very

Table 1. Definitions of gene doping (prohibited method M.3) by WADA as published in the *German Federal Law Gazette*

2003^[17] 'Gene or cell doping is defined as the non-therapeutic use of genes, genetic elements and/or cells that have the capacity to enhance athletic performance.'

2004^[18] 'Gene or cell doping is defined as the non-therapeutic use of genes, genetic elements and/or cells that have the capacity to enhance athletic performance.'

2005^[19] The non-therapeutic use of cells, genes, genetic elements, or of the modulation of gene expression, having the capacity to enhance athletic performance, is prohibited.'

2006^[20] The non-therapeutic use of cells, genes, genetic elements, or of the modulation of gene expression, having the capacity to enhance athletic performance, is prohibited.'

2007^[21] 'The non-therapeutic use of cells, genes, genetic elements, or of the modulation of gene expression, having the capacity to enhance athletic performance, is prohibited.'

2008^[22] 'The non-therapeutic use of cells, genes, genetic elements, or of the modulation of gene expression, having the capacity to enhance athletic performance, is prohibited.'

The transfer of cells or genetic elements or the use of cells, genetic elements or pharmacological agents to modulating expression of endogenous genes having the capacity to enhance athletic performance, is prohibited. Peroxisome Proliferator Activated Receptor δ (PPAR δ) agonists (e.g. GW 1516) and PPAR δ -AMP-activated protein kinase (AMPK) axis agonists (e.g. AlCAR) are prohibited.'

2010^[24] The following, with the potential to enhance athletic performance, are prohibited:

- 1. The transfer of cells or genetic elements (e.g. DNA, RNA);
- The use of pharmacological or biological agents that alter gene expression.

Peroxisome Proliferator Activated Receptor δ (PPAR δ) agonists (e.g. GW 1516) and PPAR δ -AMP-activated protein kinase (AMPK) axis agonists (e.g. AICAR) are prohibited.'

The following, with the potential to enhance sport performance, are prohibited:

- 1. The transfer of nucleic acids or nucleic acid sequences;
- 2. The use of normal or genetically modified cells;
- 3. The use of agents that directly or indirectly affect functions known to influence performance by altering gene expression. For example, Peroxisome Proliferator Activated Receptor δ (PPAR δ) agonists (e.g. GW 1516) and PPAR δ -AMP-activated protein kinase (AMPK) axis agonists (e.g. AlCAR) are prohibited.'

2009^[23]

2011^[25]

Prohibition and p	unishment of medicinal products for doping purpo	oses in sports in the	e German Medicinal Products Act. ^[26]
Section 95 (1) Nr. 2a AMG Penal and blanket norm	Any person who: 2a. contrary to Section 6a sub-section 1, places on the market or prescribes medicinal products for doping purposes in the field of sport, or administers such medicinal products to others, shall be liable to imprisonment for a term not exceeding three years or to a fine.	Section 95 (1) Nr. 2b AMG Penal and blanket norm	Any person who: 2b. contrary to Section 6a subsection 2a, is in possession of non-small quantities of medicinal products for doping purposes in the field of sport, shall be liable to imprisonment for a term not exceeding three years or to a fine.
Reference to section in the Medicinal Products Act		Reference to section in the Medicinal Products Act	
Section 6a (1) AMG Ban norm	The placing on the market, prescribing or administering of medicinal products to others for the purpose of doping in sport, is prohibited.	Section 6a (2a) AMG Ban norm	The possession of medicinal products and active substances which are or contain substances
Restriction		Reference to annex of the Medicinal Products Act	
Section 6a (2) S. 1 AMG	Sub-section 1 shall apply only to medicinal products which contain substances	Section 6a (2a) AMG	listed in the annex to the present Act
Reference to act outside the Medicinal Products act		Restriction by DmMV	
Section 6a (2) S. 1 AMG	belonging to the groups of prohibited active substances or substances contained in the Appendix to the Anti-Doping Convention (Act of 2 nd March 1994 on the Anti-Doping Convention of 16 th November 1989, Federal Law Gazette 1994 II p. 334) which are intended for use in the prohibited measures listed therein in so far as human beings are or are intended to be the subjects of the doping.	Section 6a (2a) AMG	in non-small quantities for the purpose of doping in sports is prohibited in so far as human beings are to be the subject of doping.
		annex to the present Act	 • PPARδ (Peroxisome Proliferator Activated Receptor Delta) agonists synonyme PPAR-delta- agonists • GW 501516, synonyme GW 1516 • AMPK (PPARδ-AMP- activated protein kinase) axis

Table 2. (Continued)		
		agonists • Aminoimidazole carboxamide ribonucleotide (AICAR) • The annex includes although the different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivates.
	Reference to DmMV	
	DmMV ^[33]	 PPARδ (Peroxisome Proliferator Activated Receptor Delta) agonists synonyme PPAR-delta- agonists GW 501516, synonyme GW 1516: 75 mg AMPK (PPARδ-AMP- activated protein kinase) axis agonists Aminoimidazole carboxamide ribonucleotide (AICAR): 7000 mg

general to an explicit description; for example, the declaration of defined substances like Peroxisome Proliferator Activated Receptor δ (PPAR δ) agonists (e.g. GW 1516) and PPAR δ -AMP-activated protein kinase (AMPK) axis agonists (e.g. AICAR).

The Prohibition of Gene Doping in the German Medicinal Products Act (Arzneimittelgesetz – AMG)

The purpose of the German Medicinal Products Act also called the German Drug Law, is, according to § 1 AMG, to 'guarantee, in the interest of furnishing both human beings and animals with a proper supply of medicinal products, safety in respect of the trade in medicinal products, ensuring in particular the quality, efficacy and safety of medicinal products in accordance with the following provisions'. [26] In 1998, a doping ban was inserted in the German Drug Law that in 2007 inter alia was extended by prohibition of the possession of medicinal products or active substances in non-small quantities for the purpose of doping in sport.^[4,27,28] The substances such as Aminoimidazole carboxamide ribonucleotide (AICAR) affected by prohibition of possession of non-small quantity are laid down in an annex to the AMG. The non-small quantity is determined in the German Doping Agents Amounts Ordinance (Dopingmittel-Mengen-Verordnung - DmMV) of the German Federal Ministry of Health (BMG). The interaction between the penal norm (§ 95 AMG) and the ban norm (§ 6a AMG) as well as references to other law acts are shown in Table 2. In particularly serious instances (§ 95 (3) AMG), if for example doping in sports exposes another person to a fatal peril or serious health hazards, is performed on minors or by a member of a gang, penalty shall be imprisonment from one to ten years. According to § 95 (2) AMG, an attempt to commit such doping acts shall be punishable just as if the perpetrator, like a trainer or a physician, has acted negligently (§ 95 (4) AMG). Doping by the athlete cannot be punished on account of the rules of the AMG, unless he or she owns a not-small quantity of doping substances that is, in the opinion of the legislator, an indication for unpermitted trading with doping substances.^[29]

Though the AMG contains, referring to European rules, a definition for genetic transfer drug in § 4 (9) AMG, gene doping is not defined in the AMG legally. The WADA definition of 2010 is described by scientists as 'rather succinct'. [30] The AMG refers to the European Anti-Doping Convention. In the legal literature it is controversial, whether § 6a (2) S. 1 AMG refers statically to an outdated list or dynamically to a topical list. In any case it is questionable whether the ban norm shows the clarity and definiteness which is necessary for the criminal law. [31,32] This indefiniteness of the ban norms against doping in sport in the AMG is called into question even more for gene doping. [4]

Well-Chosen Aspects of Basic Law for the Federal Republic of Germany (Grundgesetz – GG) and Gene Doping

The principle of the due course of law binds the three state powers in the Federal Republic of Germany: legislative, judiciary, and executive power. This principle is concretized by Article 103 (Fair trail) (2) GG. According to Article 103 (2) GG 'may an act be punished only if it was defined by a law as a criminal offence before the act was committed'. Article 103 (2) GG as well similar

Table 3. Legality principle and gene doping

Lex scripta

Prohibition of customary

Lex certa:

Principle of clarity and definiteness

Lex stricta:

Prohibition of analogy

Lex praevia:

Prohibition on retroactive legislation

Through the prohibition of introducing or changing an element of a crime at the expense of the delinquent by common law, is guaranteed, that the criminal-justice is bound by written state law (nullum crimen sine lege scripta). Punishing gaps may originate, e.g., from the fact that doping methods or doping substances are not defined in the law yet. Punishing gaps can not be closed by common law. It is the decision of the democratically elected legislator, whether he closes this gap by a new norm or whether the gap is still retaining.^[37]

The principle of clarity and definiteness (nullum crimen sine lege certa) is on the one side an instruction of action for the legislative power and an action limitation for judiciary on the other side. [38] Facts constituting an offence must be well-defined and clear enough, so that the norm addressee can behave in accordance with law. [39] This principle is also valid for the state doping criminal law and contributes to the protection of freedom rights, [38] to the exclusion of arbitrary decisions [40] as well as to the legal security. [41]

Nevertheless, abstract legislative formulations are allowed. In particular, the German federal constitutional court declares that the principle of clarity and definiteness is no protection before 'objectively failed penal regulations'. [41] In doubtful cases, the interpretation of the regulation has to be done on the basis of the classic legal interpretation-methods by the justice. [42] In criminal law the interpretation after the wording is accentuated. [38] Whether the regulations are sufficiently clear and definite regarding to the gene doping, is doubted. [4] The numerous changes of gene doping definitions in the ban lists reflect the difficulty to describe gene doping even for sports law.

In contrast to allowed law interpretations it is denied to jurisdiction to determine the conditions of the punishability independently. An analogous use to loads of the delinquent is forbidden.

Thus it would not be allowed to condemn a pharmacist because of placing diazepam on the market for doping purposes in sport. The substance can be used to balance negative consequences of anabolic steroid consumption for example as a sleeping medicine. However, diazepam is not on the ban lists. An analogous valuation on diazepam as a prohibited substance is inadmissible. [34,43,44]

With the prohibition of retroactive legislation (nullum crimen, nulla poena sine lege praevia)^[45] it should be prevented on the one hand that the legislator enacts criminal laws retroactively or already aggravates existing laws retrospectively. On the other hand, it has to be noted by the administration of justice that the judge applies no penal laws which were not entry in force at the time of the action yet.

If certain methods of gene doping as well as substances are not on the prohibited lists in the law, a subsequent punishment of this gene doping act is not possible, even if this act turns out to be gene doping at the time of condemnation. According to Section 2 (1) StGB penalty has to be determined by the law, which is in force at the time of the action. A decisive point for punishability is the valid version of the law at the time of the action. Because the AMG came into force in 1998, an offence against the ban to place prohibited doping substances on the market or to prescribe medicinal products for doping purposes in the field of sport, or to administer such medicinal products to others, for doping purposes in the sport can not be punished before 1998 by regulations of the AMG.

content Section 1 StGB (German Criminal Code) contains as an ascertainment of the constitutional state order, the legality principle. From this norm, the administration of justice (Table 3) and the juridical literature^[35,36] derive numerous principles (lex scripta, lex certa, lex stricta, lex praevia) which are explained in view of genetic doping and the regulations in the AMG.

The interpretation of section 6a (2) AMG by addressees of the norm

To check the comprehensibility and the practise suitability of the doping ban norm in the German Medicinal Products Act, students of law, medicine, and biology were asked in November and December 2010 by questionnaire how they, as norm addressee and potential norm users, can ascertain with the help of the wording of the doping ban which drugs are forbidden for doping purposes in sport. The hypothesis was that the norm addressee may not be able to recognize that the legislator has intended a dynamic reference on a topical ban list.

The students were asked in which act or law they will find at time of questioning a 'forbidden active substance'. The questionnaire contained the following answers:

- Medicinal Products Act
- Annex to Medicinal Products Act

- DmMV (German Doping Agents Amounts Ordinance)
- Anti-Doping Convention of 16th November 1989
- Appendix to the Anti-Doping Convention of 16th November 1989
- Act of 2nd March 1994
- Federal Law Gazette 1994 II p. 334
- Free text field for own specifications

All together 56 students took part in the study: 7 biology students average age - 23 years; 30 jurisprudence students - average age: 22.9; and 19 medical students – average age: 21.3. Of these, 43 were female, 12 male, 1 unspecified. The results of the questionnaire are listed in Table 4. According to the intention of the legislator and in the view of the ministries section § 6a AMG refers dynamically to a topical ban list. At the time of questioning this has been the list of 2010.^[24] This topical ban list was not taken into consideration by any of the questioned students. The majority of students would have searched on account of the law text in an outdated list of forbidden substances. These results confirm another questionnaire study where those tested were physicians – this also indicated that the norm user had considerable difficulties in discovering the topical list of forbidden substances on account of the norm text.^[34] In the outdated reference of the years 1989 and 1994, gene doping was not yet included as a forbidden method or as using a forbidden substance.

	Students of biology	Students of jurisprudence	Students of human medicine	Total
Medicinal Products Act	2	4	3	9
Annex to Medicinal Products Act	4	12	1	17
DmMV (German Doping Agents Amounts Ordinance)	-	2	2	4
Anti-Doping Convention of 16 th of November 1989	1	10	7	18
Appendix to the Anti-Doping Convention of 16 th November 1989	-	13	12	25
Act of 2 nd March 1994	5	13	7	25
Federal Law Gazette 1994 II p. 334	6	11	5	22
Free text field for own specifications	-	2	-	2
Total	18	67	37	122

Conclusion

Numerous international and national regulations forbidding doping in sport and applying sanctions against the violators exist. State bans and punishments have to follow important principles (lex scripta, lex certa, lex stricta, lex praevia), which are relevant for fundamental rights. Therefore, doping sanctions and punishment requires clear and written law.

The German Medicinal Products Act (AMG) turned out to be not really effective in the fight against doping before the law was changed in 2007. Whether the law from 2007 to improve the fight against doping in sports has brought improvements will be soon become clear in an upcoming evaluation. As proved by questionnaire studies, the norms in the AMG show considerable difficulties for the norm addressee. It appears difficult to recognize in which ban list or reference forbidden substances or methods are listed.

With gene doping other problems exist. Considering the various influences on the genotype of the sportsman, an exact and short definition is difficult to achieve. Therefore, the concept of the gene doping was submitted to numerous changes by WADA during the last few years. Doping bans have to be carried out by a democratically elected legislator. Therefore, it is problematic if the legislator uses only WADA's prohibited list confirmed by the monitoring group of the European Anti-Doping Convention. [31,32,34,43]

In future, according to the state of science, the definition of gene doping may be changed again. In criminal law as well as in supplementary penal provisions, the legislator has to follow the principle of clarity and definiteness. It is necessary for a criminal punishment to define a clear ban of gene doping. The legislator should define (gene) doping after consulting scientists, even in the German Medicinal Products Act (AMG).

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