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Legal Opinion

Options for Action of the European Union in the Area of Human Genetics and Reproductive Medicine in the Light of the Proposal for a Regulation on In Vitro Diagnostic Medical Devices

by

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Contents

§ 1
Introduction and commissioning of the opinion

In August 2001 the Centre for European Law at the University of Passau ("CEP") provided an expert report on "Legislative powers of the European Community in the Area of Human Genetics and Reproductive Medicine" ("CEP-report 2001") on behalf of the Group of the European People's Party ("EPP-Group").

The CEP-report reached the conclusion that the (then) European Community was authorized on the basis of the so-called internal market competences to adopt legislation in the area of human genetics and reproductive medicine, in particular on the admissibility and conditions of DNA-analysis, for example with regard to the conclusion of employment or insurance contracts, as well as prenatal genome analysis. In doing so, the European legislator would have had to take into consideration, in addition to other substantive requirements, in particular the European fundamental rights as general principles of Union law as laid down in the – then not yet legally binding – Charter of Fundamental Rights of the European Union[1] ("Charter of Fundamental Rights").

Based on the so-called Damião-report[2], the European Parliament, in its Resolution on the Commission communication on life sciences and biotechnology - A Strategy for Europe[3] ("Resolution of 21 November 2002"), called on the Commission to draft a regulation for the introduction of a standard for genetic testing as well as EC-provisions on DNA-testing.[4] At the same time the European Parliament held,

> "that genetic testing and analysis must be conducted under clear rules within the frame of competent, independent and personal counselling which must cover medical, ethical, social, psychological and legal aspects;
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> … that genetic testing analysis and diagnosis data must remain confidential and should be used only for the benefit of the person requiring such tests, with the exception of tests undertaken for clearly defined scientific or criminal investigation purposes, therefore such tests should be inadmissible for social or recruitment purposes, and should not jeopardise personal privacy and dignity;
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> … that determination of sex in connection with prenatal diagnosis should be permitted only - if at all - if there is a risk of serious gender specific hereditary diseases."[5]

The Treaty of Lisbon of 13 December 2007 has, among others, changed the Treaty on European Union ("TEU"), incorporated the Treaty Establishing the European Community in

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1 Charter of Fundamental Rights of the European Union of December 7, 2000, OJ 2000, C 364, p 1.

2 Committee on Industry, External Trade, Research and Energy, Report of 23 October 2002 on the Commission communication on Life sciences and biotechnology - A Strategy for Europe (COM(2002)27 – C5-0260/2002 – 2002/2123(COS)), A5-0359/2002.

3 OJ 2004, C 25 E, p 384.

4 Resolution of 21 November 2002, paras. 51, 55.

5 Resolution of 21 November 2002, paras. 52, 54, 57.

a modified Treaty on the Functioning of the European Union ("TFEU") and declared the Charter of Fundamental Rights to be binding[6] (Article 6(1) TEU).

On 26 September 2012 the Commission published a Proposal for a Regulation of the European Parliament and the Council on in vitro diagnostic medical devices[7] ("planned IVD-Regulation" or "Commission Proposal") with the intention to replace Directive 98/97/EC on in vitro diagnostic medical devices ("IVD-Directive"). The Commission Proposal does not contain any provisions taking account of the findings or requests of the European Parliament's Resolution of 21 November 2002, in particular with regard to genetic counselling prior to genetic testing as well as the requirements of genetic testing, for example as far as the determination of sex is concerned.

Against this background, by letter dated 13 September 2012, Dr. Peter Liese, Member of the European Parliament, rapporteur of the European Parliament for the Commission Proposal, asked the CEP on behalf of the EPP-Group to examine the CEP-report 2001 with respect to its relevance. In particular, the following questions shall be answered:

1. Are the findings of the CEP-report 2001 still valid? In which areas might they have to be modified due to current developments? Which findings are even strengthened by current developments?

2. Is there a competence for the request raised by the European Parliament in the Damião-report, in particular with respect to genetic counselling before conducting genetic tests (and the possible limitation of performing DNA tests to the medical profession) and with respect to prenatal diagnosis?

3. Is it legally possible to introduce the requests for compulsory genetic counselling, for sex selection, as well as for a possible limitation of performing DNA tests to the medical profession in the Commission Proposal for the IVD-Regulation and if so what wording could be recommended and where?

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6 Consolidated version in OJ 2012, C 326, p 1 seq.

7 COM(2012)541 final.

§ 2
Results of the CEP-report 2001

In summary and taking account of the legal bases modified by the Treaty of Lisbon, the CEP-report 2001 reached essentially the following results:

I. Because of their economic significance, human genetics and reproductive medicine are economic activities within the meaning of Article 2 of the EC Treaty (now Article 2 TEU) and therefore fall within the scope of the EC Treaty (now TEU and TFEU), not least and in particular if moral and ethical issues are affected.

II. According to the principle of limited powers in Article 5(1) of the EC Treaty (now Article 2(1) and (2) TFEU), the Community legislator can only take action in the areas of human genetics and reproductive medicine in so far as, for each planned measure, there is a specific authorisation in the EC Treaty (now TFEU) which supports this measure.

III. In the area of human genetics and reproductive medicine, the internal market powers of the EC Treaty (now TFEU) are particularly suitable for legislation by the Community legislator. Alongside the general internal market competence of Article 95(1) of the EC Treaty (now Article 114(1) TFEU), Article 47(2) of the EC Treaty (now Article 53(1) TFEU) contains special harmonization competence for freedom of establishment and Article 47(2) in conjunction with Article 55 of the EC Treaty (now Article 53(1) in conjunction with Article 62 TFEU) contains special harmonization competence for freedom to provide services.

IV. A condition to be met in each case is that the Union legislator pursues internal market aims within the meaning of the EC Treaty (now TFEU) with the planned measure, both according to its subjective notions (to be verified with respect to the recitals in the preamble of the legal act) and objectively and genuinely. For this purpose the Union legislator must remove with the act obstacles to fundamental freedoms which exist at present or are likely to arise in the future stemming from different national provisions.

V. For the purposes of the specific content of the approximation measure to be taken, the Community legislator enjoys broad discretion, which is only exceeded if

- the act falls under an area exception under Article 95(2) of the EC Treaty (now Article 114(2) TFEU)
- a case of misuse of powers exists
- the general obligations of action under the EC Treaty (now TFEU) (general aims, special aims, Community fundamental rights, Community agreements) are not respected or
- the general limits on the exercise of competence in the EC Treaty (principle of subsidiarity and principle of proportionality) are not respected.

VI. A very important criterion for the exercise of the legislative powers of the European Union is met by the fundamental rights, as laid down in the Charter of Fundamental Rights which, unlike today, was not binding at the time of the preparation of the CEP-report 2001. For human genetics and reproductive medicine, Article 3(2) of the Charter of Fundamental Rights (informed consent and prohibition of eugenic practices, on making the human body and its parts as such a source of financial gain and of the reproductive cloning of human beings) as well as Article 21(2) of the Charter of Fundamental Rights (prohibition of genetic discrimination) contain important valuation requirements for the Community legislator. Some value decisions of the Bioethics Convention of the Council of Europe adopted on April 3, 1997[8] ("Bioethics-Convention"), which have been incorporated into the Charter of Fundamental Rights, in this way indirectly become the legal yardstick for the exercise of the legislative powers set out in the EC Treaty (now TFEU).

VII. The following was therefore noted by the CEP-report 2001 with regard to specific legislative plans in the area of human genetics and reproductive medicine:

1. *A directive on the permissibility of DNA analyses in the context of the conclusion of insurance contracts* could be adopted on the basis of Article 47(2) in conjunction with Article 55 of the EC Treaty (now Article 53(1) in conjunction with Article 62 TFEU), provided the Union legislator can accordingly provide evidence of appreciable distortions of competition as a result of the existing differences between national provisions in the EU. With respect to content, alongside the aim of consumer protection (Article 153(2) of the EC Treaty, now Article 12 TFEU) account would have to be taken particularly of the fundamental rights to human dignity (Article 1 of the Charter of Fundamental Rights), the right of the insured person to respect of his or her private life (Article 7 of the Charter of Fundamental Rights), the right to self-determination of information and protection of personal data (Article 8 of the Charter of Fundamental Rights) and the prohibition of genetic discrimination (Article 21 of the Charter of Fundamental Rights).

2. The Union legislator could adopt *a directive on the permissibility of DNA analyses in the context of the conclusion of employment contracts* on the basis of Article 137(1) and (2) of the EC Treaty (now Article 153(2) and (3) TFEU). Account would have to be taken in the content of such an act of the fundamental right to human dignity (Article 1 of the Charter of Fundamental Rights), the right of the employed person to respect of his or her private life (Article 7 of the Charter of Fundamental Rights), the right to self-determination of information and protection of personal data (Article 8 of the Charter of Fundamental Rights) and the prohibition of genetic discrimination (Article 21 of the Charter of Fundamental Rights).

[8] Published on www.conventions.coe.int.

3. The Union legislator could adopt a directive to regulate prenatal genome analyses on the basis of Article 47(2) in conjunction with Article 55 of the EC Treaty (now Article 53(1) in conjunction with Article 62 TFEU), provided it demonstrates that different provisions exist in this area in the Member States, with at least a probability of causing obstacles to freedom to provide services which lead to appreciable distortions of competition. In so doing, the Union legislator would have to take account in particular of the fundamental right to human dignity (Article 1 of the Charter of Fundamental Rights), right to life (Article 2 of the Charter of Fundamental Rights), physical integrity in the particular form of the prohibition of eugenic practices (Article 3(2) second indent of the Charter of Fundamental Rights), the protection of personal data (Article 8 of the Charter of Fundamental Rights) and genetic discrimination (Article 21 of the Charter of Fundamental Rights).

4. The Union legislator could adopt a legal act on the permissibility of research and intra-Union trade in embryos and embryonic stem cells on the basis of Article 95(1), Article 47(2) and Article 47(2) in conjunction with Article 55 of the EC Treaty (now Article 114(1), Article 53(1) and Article 53(1) in conjunction with Article 62 TFEU) and Article 152(4)(a) of the EC Treaty (now Article 168(4)(a) TFEU). The Union legislator would in particular have to respect the prohibition of eugenic practices and of financial gain with respect to the use of the human body and the prohibition of reproductive cloning under Article 3(2) of the Charter of Fundamental Rights.

5. The Union legislator could adopt a legal act on the permissibility of trade in embryos and embryonic stem cells with non-EU states on the basis of Article 133(1) of the EC Treaty (now Article 207(1) TFEU). Here again, the Union legislator would in particular have to respect the prohibition of eugenic practices and of financial gain for the purposes of the use of the human body and the prohibition of reproductive cloning under Article 3(2) of the Charter of Fundamental Rights.

§ 3
Legal Analysis

I. Question 1

With its first question the EPP-Group seeks to know in general to what extent the findings of the CEP-report 2001 can be maintained without change, if and in which areas they have to be modified due to recent developments or which findings of the CEP-report 2001 are even enhanced by the subsequent development.

This question is to be answered as follows:

- *Slight extension of competences*: The Treaty of Lisbon has slightly extended the competences of the Union in the context of the TFEU with respect to human genetics and reproductive medicine (see infra point 1.).
- *Specification and strengthening of internal market competences*: According to the jurisprudence of the Court of Justice of the European Union ("ECJ") the possibility to adopt legal acts in the area of human genetics and reproductive medicine based on the internal market competences has been further specified and strengthened (see infra point 2.).
- *Further development of the assessment criteria, especially of the protection of European fundamental rights*: The assessment criteria for Union legislation in the area of human genetics and reproductive medicine, in particular the protection of European fundamental rights, have further developed. According to Article 6(1) TEU the Charter of Fundamental Rights has gained binding force with the Treaty of Lisbon. The validity of the fundamental freedoms laid down in the European Convention for the Protection of Human Rights and Fundamental Freedoms of November 4, 1950[9] ("ECHR") as general principles of Union Law has been strengthened, too. Accordingly, indications of an intensification of the protection of fundamental rights can be found in the jurisprudence of the ECJ in accordance with the jurisprudence of the European Court of Human Rights (see infra point 3.).
- *Further development in the fields of human genetics and reproductive medicine*: Finally, new and important developments have taken place in particular in the fields of human genetics and reproductive medicine, that is in the jurisprudence of the ECJ and the European Court of Human Rights on the one hand, and on the international level in the context of the Bioethics-Convention as well as in the context of the United Nations and the Organization for Economic Cooperation and Development ("OECD") (see infra point 4.).

[9] Consolidated version on www.conventions.int.

1. Further development of competences

The CEP-report 2001 identified numerous possible competences for Union legislation in the areas of human genetics and reproductive medicine.[10] The TFEU has left these competences largely unchanged, although the provisions were renumbered. These are in particular the so-called internal market competences set forth by Article 114 TFEU (general internal market competence), Article 115 TFEU (subsidiary internal market competence), Article 46 (special internal market competence for the freedom of movement of workers), Article 53 TFEU (special internal market competence for the freedom of establishment), Article 53 in conjunction with Article 62 (special internal market competence for the freedom to provide services), as well as in addition to that, competences in different related policy areas, like Article 153 TFEU (social policy), Article 168 TFEU (health protection), Article 169 TFEU (consumer protection), Article 182 TFEU (research framework programme), Article 207 TFEU (trade policy) and Article 352 TFEU ("competence extension clause").

Furthermore, the Treaty of Lisbon has established a fundamentally new competence in the area of human genetics and reproductive medicine. In the context of the competences on health care a new competence has been introduced in Article 168(4)(c) TFEU. It authorizes to

> "measures setting high standards of quality and safety for medicinal products and devices for medical use"

While, until now, legal acts with respect to medicinal products and devices for medical use had to be based on Article 95 of the EC Treaty (now Article 114 TFEU), in future the Union legislator may in such cases also make use of Article 168(4)(c) TFEU, as it has been the case with the Commission Proposal for a regulation on in vitro diagnostic medical devices, since both, Article 114 TFEU and Article 168(4)(c) TFEU, are shared competences in the sense of Article 4(2) TFEU and the legislative procedure is identical. The Union legislator could even refer to Article 168(4)(c) TFEU only, without having to prove that the measure is conducive to the internal market. However, this does not bring about a substantial change in the division of competences due to the wide reach of the internal market competences. Nonetheless, the health and safety aspect has been given an additional central importance by the introduction of Article 168(4)(c) in the areas of regulations of medicinal products and devices for medical use.

The application of the existing competences, in particular of the internal market competences in relation to the trading competence of Article 207 TFEU, has been facilitated by the fact that the Treaty of Lisbon has aligned the legislative procedures. Now in both areas the so-

[10] CEP-report 2001, p. 16 seq.

called ordinary legislative procedure according to Article 289(1) TFEU applies (previously co-decision procedure according to Article 251(1) of the EC Treaty).[11]

2. Specification and strengthening of the internal market competences

Subsequent to the delivery of the CEP-report 2001, the ECJ has further specified the factual requirements of the internal market competences and, at the same time, strengthened their applicability, in particular that of the general internal market competence under Article 114 TFEU (previously Article 95 of the EC Treaty).

In the area of human genetics, the judgment *Netherlands/Parliament and Council* on the lawfulness of the so-called Biopatent-Directive 98/44/EC[12] ("Biopatent-Directive") demonstrates this development well. When assessing whether the Community legislator was competent to pass the Biopatent-Directive, the ECJ held that divergences in the national legal orders relevant to the internal market even exist if the Member States are parties of an international treaty – here: Convention on the Grant of European Patents, signed at Munich on 5 October 1973, ("the EPC") – and merely interpret this treaty differently in their national case-law and practice. The ECJ held:

> „In that regard, it must be borne in mind that recourse to Article 100a (now Article 114 TFEU) as a legal basis is possible if the aim is to prevent the emergence of future obstacles to trade resulting from multifarious development of national laws provided that the emergence of such obstacles is likely and the measure in question is designed to prevent them. […]
>
> The examples given by the Parliament and the Council suffice to establish that, even if the relevant national provisions predating the Directive are most often taken from […] the EPC, the differing interpretations to which those provisions are open as regards the patentability of biotechnological inventions are liable to give rise to divergences of practice and case-law prejudicial to the proper operation of the internal market.
>
> Moreover, in addition to the risk of divergent trends, at the time the Directive was adopted marked differences with significant consequences were already apparent between certain national laws on specific points such as the patentability of plant varieties and that of the human body.
>
> By requiring the Member States to protect biotechnological inventions by means of their national patent law, the Directive in fact aims to prevent damage to the unity of the internal market which might result from the Member States' deciding unilaterally to grant or refuse such protection."[13] (brackets added)

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11 Previously, according to Article 133(4) of the EC Treaty, the Council had the exclusive competence in the area of trade policy without participation of the European Parliament. That is why the delimitation problems in relation to Article 114 TFEU existing at the time of the preparation of the CEP-report (see p. 75 seq.) have become obsolete. Therefore, it is not necessary any more to adopt two separate legal acts on research and intra-Community trade on the one hand and on the import and export of embryos and embryonic stem cells in trade with third countries on the other hand. A corresponding legal act should be based on both competences.

12 Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ 1998, L 213, p 13.

13 ECJ, Case C-377/98 *Netherlands/Parliament and Council* 2001 [ECR] I-7079, paras. 15 et seq.

After these general considerations the ECJ confirmed once again that the general internal market competence as a *cross-cutting competence* which has to be interpreted functionally is not limited to one subject-matter, but is only construed functionally with regard to the aims of the internal market.[14] In particular its scope of application is not restricted to questions of movement of goods. Based on the general internal market competence, the Union legislator can include other competences (like health protection or scientific research and development), if the internal market objective as *main objective* corresponds with the purpose of the relevant legal act. With respect to the Biopatent-Directive the ECJ held the following:

> „The legal basis on which an act must be adopted should be determined according to its main object […].Whilst it is common ground, in that regard, that the aim of the Directive is to promote research and development in the field of genetic engineering in the European Community, the way in which it does so is to remove the legal obstacles within the single market that are brought about by differences in national legislation and case-law and are likely to impede and disrupt research and development activity in that field.
>
> Approximation of the legislation of the Member States is therefore not an incidental or subsidiary objective of the Directive but is its essential purpose. The fact that it also pursues an objective falling within Articles 130 and 130f of the Treaty [now Article 157 and 179 TFEU] is not, therefore, such as to make it inappropriate to use Article 100a of the Treaty [now Article 114 TFEU] as the legal basis of the Directive […] [15] (brackets added)

At the time of the preparation of the CEP-report 2001 it had not yet been finally clarified, whether the principle of subsidiarity also applies to internal market measures.[16]. This question was first answered by the ECJ explicitly in the affirmative.[17] Subsequently, it was definitively settled by Article 4(2) TFEU which has been newly introduced by the Treaty of Lisbon and included the internal market in the list of shared competences for which, according to Article 5(3) TEU, the principle of subsidiarity applies. Therefore, when making use of its legislative power according to Article 114, Article 53 and Article 53 in conjunction with Article 62 TFEU, the Union legislator has to take account of the individual requirements of subsidiarity resulting from Article 5(3) TEU as well as from Protocol No 2 on the application of the principles of subsidiarity and proportionality.[18]

3. Further development of the substantive assessment criteria, in particular the protection of European fundamental rights

The assessment criteria for the substantive examination of Union legal acts in the area of human genetics and reproductive medicine have further developed, too. This applies in particular to the protection of European fundamental rights.

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14 See CEP-report 2001, p 17-18.

15 ECJ, Case C-377/98 *Netherlands/Parliament and Council* 2001 [ECR] I-7079, paras. 27-28 .

16 CEP-report 2001, p 36 -37.

17 ECJ, Case C-491/01 *The Queen/ Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd.* 2002 [ECR] I-11453, paras. 177 et seq.

18 OJ 2012, C 326, p 206.

– Under the Treaty of Lisbon the Charter of Fundamental Rights has received the same legal value as the TEU and the TFEU (Article 6(1) TEU). It therefore constitutes primary Union law which is directly binding on the law-making bodies of the Union. This is confirmed by Article 51(1)(1) of the Charter of Fundamental Rights according to which the Charter has to be respected primarily by the Union institutions, in particular in the legislative procedure.

– The binding nature of the Charter of Fundamental Rights results in a further strengthening of health and consumer protection in the legal order of the Union. The binding character, for example, of the obligations contained in Article 3(2) of the Charter of Fundamental Rights in the fields of medicine and biology has been strengthened, that is the principle of free and informed consent (first indent), the prohibition of eugenic practices (second indent), the prohibition on making the human body and its parts as such a source of financial gain (third indent) as well as the prohibition of reproductive cloning. Those obligations also constitute assessment criteria for the Union institutions when adopting legal acts applicable to individuals.[19] According to Article 35, sentence 1, of the Charter of Fundamental Rights everyone now has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. Article 35, sentence 2, and Article 38 of the Charter of Fundamental Rights confirm and underline once again that a high level of human health and consumer protection shall be in all Union actions.

– Moreover, the Treaty of Lisbon has strengthened the validity of the ECHR in Union law. On the one hand Article 6(3) TEU regulates in primary law that these fundamental rights constitute general principles of Union law. Accordingly, Article 53 of the Charter of Fundamental Rights provides that no provision of the Charter shall be interpreted as restricting or violating human rights as recognized by the ECHR. In addition, Article 6(2) TEU stipulates that the Union shall accede to the ECHR. With the accession of the Union to the ECHR the latter – and especially the Charter of Fundamental Rights – will gain a value in the Union legal order virtually comparable to primary law if it has not gained such a value already.[20]

These developments on the level of primary law coincide with indications for an endorsement of the protection of the Union's fundamental rights by the ECJ. That means that the ECJ has increased the legal standards as regards the content and the justification of Union legal acts in

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[19] The specific normative content has not been clarified yet. Arguing for an interpretation as a protective provision e.g. Jarass, Charta der Grundrechte der Europäischen Union – Kommentar, Artikel 3, para. 10; supporting an interpretation as principles that could hardly be judicially controlled e.g. Streinz, in: ders. (ed.), EUV/AEUV – Kommentar, 2. Auflage, GR-Charta, Artikel 3, para. 7; supporting an interpretation as Union objectives e.g. Höfling, in: Tettinger/Stern (ed.), Europäische Grundrechte-Charta, Artikel 3, para. 16; supporting an interpretation of limiting provisions e.g. Rixen, in: Hesselhaus/Nowak (ed.), Handbuch der Europäischen Grundrechte, § 11, para. 30.

[20] See e.g. Streinz/Michl, in: Streinz (ed.), EUV/AEUV, Kommentar, 2nd edition., Artikel 6 EUV, para. 21.

the light of the further developed European fundamental rights thereby seeking coherence with the jurisprudence of the European Court of Human Rights under the ECHR.

This development is well illustrated by the ECJ's judgment in *Schecke* of 9 November 2010. In a preliminary ruling the ECJ had to decide on the validity of two regulations, according to which information on public aid, which was granted to farmers from EU-agricultural funds, had to be published in full. The ECJ considered that the provisions in question violated the fundamental rights to respect private and family life provided by Article 7 of the Charter of Fundamental Rights as well as to the protection of personal data pursuant to Article 8 of the Charter of Fundamental Rights and that this interference could not be justified. The ECJ held, referring to the jurisprudence of the European Court of Human Rights[21], that the interference with these fundamental rights could not be justified by the commonly accepted objective of transparency regarding the use of Union funds. In the view of the ECJ there were no indications that Commission and Council, when adopting the provisions in question, took sufficiently account of the methods of publishing information, thereby balancing the Union's interest in guaranteeing transparency with the fundamental rights according to Article 7 and Article 8 of the Charter of Fundamental Rights and limiting the interference to an absolute minimum.[22]

It follows from the changes of the Treaty of Lisbon and the recent jurisprudence of the ECJ with regard to fundamental rights that the Union legislator is subjected to increased standards for the assessment and justification of legislative acts with respect to the fundamental rights and interests concerned, in particular in the morally and ethically sensitive area of human genetics and reproductive medicine.

4. Further developments in the field of human genetics and reproductive medicine

Finally, both the ECJ (see infra point a)) and the European Court of Human Rights (see infro point b)) developed in their jurisprudence the first important, even though merely rudimentary requirements under primary law for Union legislation in the field of human genetics and reproductive medicine. Also, on the international level, especially within the framework of the Council of Europe, as well as the United Nations and the OECD, there have been important new developments in the field of human genetics and biomedicine (see infra point c)).

a) Jurisprudence of the ECJ

Concerning the jurisprudence of the ECJ, two judgments in relation to the Biopatent-Directive[23] are of particular importance.

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21 ECJ, Joined Cases C-92/09 and C-93/09 *Markus and Volker Schecke* 2010 [ECR] I-11063, paras. 52, 59, 72.

22 ECJ, Joined Cases C-92/09 and C-93/09 *Markus and Volker Schecke* 2010 [ECR] I-11063, paras. 77-83.

23 See above p. 10.

(1) Judgment *Netherlands/Parliament and Council*

In *Netherlands/Parliament and Council* of October 2001 the ECJ for the first time dealt with the fundamental right to human dignity. It established, that it is for the ECJ

> "in its review of the compatibility of acts of the institutions with the general principles of Community law, to ensure that the fundamental right to human dignity and integrity is observed."[24]

On this basis, the ECJ examined particular provisions of the Biopatent-Directive. It confirmed that respect of human dignity is basically guaranteed through Article 5(1) of the Biopatent-Directive, according to which the human body at the various stages of its formation and development cannot constitute a patentable invention. Nor are the elements of the human body in their natural environment and the discovery of individual DNA-sequences patentable.[25] It concluded from those provisions,

> "that, as regards living matter of human origin, the Directive frames the law on patents in a manner sufficiently rigorous to ensure that the human body effectively remains unavailable and inalienable and that human dignity is thus safeguarded."[26]

(2) Judgment *Brüstle/Greenpeace*

In *Brüstle/Greenpeace* of October 2011 the ECJ had to decide on the definition of human embryo within the framework of the Biopatent-Directive. The ECJ held that

> "as regards the meaning to be given to the concept of 'human embryo' set out in Article 6(2)(c) of the Directive, it should be pointed out that, although, the definition of human embryo is a very sensitive social issue in many Member States, marked by their multiple traditions and value systems, the Court is not called upon, by the present order for reference, to broach questions of a medical or ethical nature, but must restrict itself to a legal interpretation of the relevant provisions of the Directive […]"[27]

On this basis the ECJ determined the term of human embryo in the light of the objectives of the Biopatent-Directive. It indicated once more that,

> "although it seeks to promote investment in the field of biotechnology, use of biological material originating from humans must be consistent with regard for fundamental rights and, in particular, the dignity of the person […]
>
> […] that all processes the use of which offends against human dignity are also excluded from patentability […][and]

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24 ECJ, Case C-377/98 *Netherlands/Parliament and Council* 2001 [ECR] I-7079, para. 70.

25 ECJ, Case C-377/98 *Netherlands/Parliament and Council* 2001 [ECR] I-7079, paras. 71-74.

26 ECJ, Case C-377/98 *Netherlands/Parliament and Council* 2001 [ECR] I-7079, para. 77.

27 ECJ, Case C-34/10 *Brüstle/Greenpeace*, not yet published, para. 30.

> […] that the European Union legislator intended to exclude any possibility of patentability where respect for human dignity could thereby be affected. It follows that the concept of 'human embryo' […] must be understood in a wide sense."[28]

(3) Conclusions

As a result, the ECJ not only assessed for the first time Union legal acts in the field of human genetics by taking account of the fundamental rights to human dignity and integrity of the person, as they are provided by Article 1 and Article 3(1) of the Charter of Fundamental Rights. At the same time it has undertaken to give legally binding answers to genetic questions, that are morally and ethically very sensitive and are controversial in the Member States (e.g. the question of the definition of 'human embryo'), in the light of the fundamental rights that have to be guaranteed. Finally, it herewith attached central importance to the fundamental rights to human dignity and integrity of the person, also for prenatal life.

b) Jurisprudence of the European Court of Human Rights

Concerning the jurisprudence of the European Court of Human Rights, the most recent judgements in *S.H. and others/Austria* of 3 November, 2011[29] as well as in *Costa and Pavan/Italy* of 28 August 2012 are of importance.[30]

(1) Judgment *S.H. and others/Austria*

In *S.H. and others/Austria* the Court had to deal with the case of two Austrian married couples who challenged the Austrian prohibition of in vitro fertilization using a third-party's gamete with the argument that they could only conceive a child through an in vitro fertilization using sperm donation in the first case and an ova donation in the second.

The Court held, first of all, that the couple's right to conceive a child and to make use of medically assisted procreation comes within the scope of application of the protection of the fundamental right to private and family life according to Article 8 ECHR.[31] When assessing the justification of the prohibition the Court established that there were differences in the legal provisions of the Member States of the ECHR for gamete donations for in vitro fertilization. However, the Court concluded that there was a clear trend towards allowing this, which reflects an emerging European consensus.

> "Since the use of IVF treatment gave rise then and continues to give rise today to sensitive moral and ethical issues against a background of fast-moving medical and scientific developments, and since the questions raised by the case touch on areas where there is not yet clear common ground amongst the member States, the Court considers that the margin of appreciation to be afforded to the respondent State must be a wide one […]. The State's margin in principle extends both to its decision to

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28 ECR, Case C-34/10 *Brüstle/Greenpeace*, not yet published, paras. 32-34.

29 European Court of Human Rights, Judgment of 3 November 2011, 57813/00, *S.H. and others/Austria*.

30 European Court of Human Rights, Judgment of 28 August 2012, 54270/10, *Costa and Pavan/Italy*.

31 European Court of Human Rights, Judgment of 3 November 2011, 57813/00, *S.H. and others/Austria*, para. 82.

> intervene in the area and, once having intervened, to the detailed rules it lays down in order to achieve a balance between the competing public and private interests […]. However, this does not mean that the solutions reached by the legislator are beyond the scrutiny of the Court. It falls to the Court to examine carefully the arguments taken into consideration during the legislative process and leading to the choices that have been made by the legislator and to determine whether a fair balance has been struck between the competing interests of the State and those directly affected by those legislative choices […]"[32]

On the basis of the fast development of science and of the legal framework for its application, the Court accepted that the Member States act with particular caution in this field. As the Austrian legislator had not completely ruled out artificial procreation (but it allows the use of homologous techniques), it had not exceeded the margin of appreciation afforded to it.[33] The fact that it prohibited donation of sperm or ova for in vitro fertilisation, but did not at the same time prohibit sperm donation for in vivo fertilization, was a technique commonly accepted by society[34]. On this basis, according to the Court's findings, there was no breach of Article 8 ECHR.

(2) Judgment *Costa and Pavan/Italy*

In *Costa and Pavan/Italy* the Court had to decide on a case of an Italian couple that at the birth of their first child suffering from cystic fibrosis found out that they were genetically healthy carriers of this life-threatening disease. During a prenatal diagnostic screening in the second pregnancy it was established, that the second child had the disease as well. Thereupon Ms Costa had the pregnancy terminated on medical grounds, as it is allowed by Italian law. The couple now wanted to have a child by in vitro fertilisation ("IVF"). The embryo should be genetically screened prior to implantation. The Italian law allowed IVF for sterile couples or those in which the man has a sexually transmissible disease (e.g. hepatitis or HIV), to avoid the risk of transmitting the infection, however, it generally prohibited pre-implantation diagnosis.

Unlike in the case of *S.H. and others/Austria* the Court held, against the background of this specific case, that the Italian provision infringed Article 8 ECHR. It established that the couple's wish to have a child that does not carry the parents' genetic disease with the help of in vitro fertilization supported by pre-implantation diagnosis fell within the scope of Article 8 ECHR.[35] The Court considered that the interference with Article 8 ECHR was not justified for reasons of the protection of the child's and woman's health as well as the dignity and freedom of the medical profession. The central ground for that, from the point of view of the Court, was the inconsistency or incoherence of the Italian legal system. On the one hand, it

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32 European Court of Human Rights, Judgment of 3 November 2011, 57813/00, *S.H. and others/Austria*, para. 97.

33 European Court of Human Rights, Judgment of 3 November 2011, 57813/00, *S.H. and others/Austria*, paras. 103-104, 106.

34 European Court of Human Rights, Judgment of 3 November 2011, 57813/00, *S.H. and others/Austria*, para. 114.

35 European Court of Human Rights, Judgment of 28 August 2012, 54270/10, *Costa and Pavan/Italy, para.* 57.

prohibited an implantation of only such embryos that do not have their parents' disease. On the other hand, it allowed the killing of foetuses with this disease. That left the applicants only one possibility, which brought anxiety and suffering: starting a pregnancy by natural means and terminating it if prenatal tests showed the foetus to have the disease.[36] Despite the moral and ethical sensitivity of the question, the choice of the legislator was not excluded from judicial review.[37] Therefore in this specific case, which besides Italy affected only Austria and Switzerland as other Member States of the Council of Europe, an infringement of a fundamental right was established.[38]

The judgement of the Court is still not final. Italy has requested that the case be referred to the Grand Chamber of the Court according to 43(1) ECHR due to its general importance.

(3) Conclusions

Regardless of the evaluation of the concrete results of the Court's judgements, especially in *Costa and Pavan/Italy*, it appears in its jurisprudence, that is also relevant for the Union legislator, that despite the broad discretionary power and power of assessment concerning the morally and ethically sensitive and fast developing field of human genetics and reproductive medicine enjoyed by the legislator of a Member State of the ECHR, this discretion is subject to stricter control by the European Court of Human Rights. At the same time it becomes clear that the fundamental right of the parents to private and family life according to Article 8 ECHR, which is reflected in Article 9 of the Charter of Fundamental Rights, is of significant importance for legislative initiatives in the field of human genetics and reproductive medicine. An appropriate balance between this fundamental right, the right of the unborn child to human dignity, as well as further relevant fundamental rights, like the right to protection of personal data according to Article 8 of the Charter of Fundamental Rights, as well as freedom to conduct a business according to Article 16 of the Charter of Fundamental Rights, must be found.

c) International Developments

Also on the level of public international law there have been fundamental developments in the field of human genetics and reproductive medicine.

(1) Additional Protocol on Genetic Tests to the Bioethics Convention of the Council of Europe

On 27 November 2011 the Council of Europe adopted a new Additional Protocol to the Convention of Human Rights and biomedicine concerning genetic tests for health purposes[39]

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[36] European Court of Human Rights, Judgment of 28 August 2012, 54270/10, *Costa and Pavan/Italy*, paras. 64-66.

[37] European Court of Human Rights, Judgment of 28 August 2012, 54270/10, *Costa and Pavan/Italy*, paras. 67-68.

[38] European Court of Human Rights, Judgment of 28 August 2012, 54270/10, *Costa and Pavan/Italy*, paras. 69-70.

[39] Published on http://conventions.coe.int/Treaty/EN/Treaties/Html/203.htm.

("Genetic Testing Protocol"), which, as well as the Bioethics Convention itself, is open for signature and ratification by the European Union. So far the Union Member States Finland, France, Luxembourg and Slovenia have signed the Genetic Testing Protocol. The Genetic Testing Protocol as well as the Bioethics Convention itself constitute important assessment criteria for the Union legislator in the field of human genetics and reproductive medicine, even though the Union has not become a Member yet[40].

The Genetic Testing Protocol contains numerous substantive principles and requirements for genetic tests for health purposes. It holds that the welfare of the human being prevails over the interests of science and society (Article 3) and that any form of discrimination against a person, either as an individual or as a member of a group on grounds of his or her genetic heritage is prohibited (Article 4). The special provisions concern the access to genetic tests (Articles 5 seq.), information and genetic counselling as well as the consent to conduct genetic tests (Articles 8 seq.). Moreover, the Genetic Testing Protocol specifies the conditions according to which genetic tests can be conducted on persons not able to consent (Article 10 seq.) as well as the protection of private life and the right to information (Articles 16 seq.).

(2) UN Convention on the Rights of Persons with Disabilities

On 13 December 2006 the United Nations adopted the Convention on the Rights of Persons with Disabilities[41] ("UN Convention on disability rights"). The European Union signed the UN Convention on disability rights on its opening day for signature, 30 March 2007, and ratified it as the first international organization on 23 December 2010. Thereby the UN Convention on disability rights is binding as a Union agreement under Article 216(2) TFEU for the legislative bodies of the Union and hence also for the ECJ, when and as long as it decides on Union legislation in the light of the fundamental rights of the Charter of Fundamental Rights as well as the ECHR.

The UN Convention on disability rights shall ensure that persons with disabilities can fully and equally enjoy all human rights and fundamental freedoms on an equal basis with others (Article 1). For this purpose, it provides for general principles with regard to dignity, non-discrimination, respect for difference and acceptance of persons with disabilities as part of human diversity and humanity, equality of opportunity, etc. (Article 3). Any discrimination on the basis of disability shall be prohibited and appropriate legal protection must be provided (Article 5). Persons with disabilities shall enjoy the inherent right to life on an equal basis with others (Article 10) as well as the right to respect for their physical integrity on an equal basis with others (Article 17).

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40 See with regard to the Bioethics-Convention CEP-report 2001, pp. 35-36.

41 Published on www.un.org/disabilities.

(3) OECD Guidelines for Quality Assurance for Molecular Genetic Testing

In 2007 the OECD adopted Guidelines for Quality Assurance in Molecular Genetic Testing[42] ("OECD Guidelines"). These OECD Guidelines are not legally binding on the Union legislator. Nevertheless they, too, contain practically important principles for the quality-oriented conducting of genetic testing (by laboratories), among others the principle of quality assurance (Part I, 2.A.3), the principle of informed consent (Part I, 2.A.4), the principle of genetic counselling (Part I, 2.A.5) or the principle of protection of genetic information (Part I, 2.A.6).

II. Question 2

With its second question the EPP Group seeks to know whether the Union is competent to implement the requests, raised by the European Parliament in the Damião-report, in particular concerning genetic counselling before the application of a genetic test (and a possible limitation of performing DNA tests to the medical profession) as well as concerning prenatal diagnostics.

This question has to be answered in the affirmative in view of the above general considerations. The legal bases, referred to in the CEP-report 2001 for the regulatory areas, addressed in the resolution of 21 November 2002, are also valid in the same form, as it has been shown, in the renumbered edition of the Lisbon Treaty.

The question, which specific competence rules and which form of legal acts are available to the Union legislator for the measures that implement the requests of the European Parliament, should be viewed in a differentiated way on the basis of the content of the specific measure.

1. Application of the internal market competence for services (Article 53 (1) in conjunction with Article 62 TFEU)

Should the Union legislator want to regulate questions of counselling prior to the genetic test (and a possible limitation of performing DNA tests to the medical profession) and of prenatal diagnosis in a separate legal act on genetic examinations (similar to how e.g. Germany has done in its Genetic Diagnostics Act[43]), it can do so on the basis of the internal market competence for services according to the Article 53(1) in conjunction with Article 62 TFEU. As shown in the CEP-report 2001, examinations within the framework of prenatal diagnosis and pre-implantation diagnostics – regardless of their ethical and moral valuation and basically comparable to a pregnancy termination – constitute medical services.[44]

However, in this case the Union legislator could only act in the form of a directive. Unlike Article 114 TFEU, Article 53(1) in conjunction with Article 62 TFEU does not allow the

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42 Published on https://www.eshg.org/fileadmin/www.eshg.org/documents/QAGuidelineseng.pdf.

43 Act on genetic diagnostics of humans (*Gendiagnostikgesetz*) of July 31, 2009, *Bundesgesetzblatt* I p. 2529, 3672.

44 CEP-report 2001, p. 60 et seq.

adoption of all possible forms of legal acts, including regulations, but explicitly only directives

2. Application of the general internal market competence (according to Article 114 TFEU complemented by the health competence pursuant to Article 168(4)(c) TFEU)

Should the Union legislator intend to amend the planned IVD-Regulation, which mainly concerns bringing into circulation and providing in vitro diagnostics devices, in order to include more specific requirements for genetic counselling prior to applying genetic tests and a possible limitation of performing DNA tests to the medical profession as well as requirements for prenatal diagnosis, it could do so on the basis of the general internal market competence according to Article 114 TFEU. For this it would not have to apply in addition the special internal market competence for services according to Article 53(1) in conjunction with Article 62 TFEU.

Counselling and doctors' services relating to genetic tests as such are to be qualified as services pursuant to Article 56 TFEU. Still, a legislative act containing rules providing that a genetic test may be used only after counselling or only by doctors (or on their prescription) and within the framework of prenatal diagnosis could only be made available, put into service, and used under certain requirements, could still be characterised as a product related regulation, i.e. a regulation through which the way of making available, putting into service and using an in vitro diagnostic medical device is regulated.[45] Such a regulation is comparable to a medical prescription requirement, as is provided by Article 70 and Article 71 of Directive 2001/83/EC[46] for human medicines. Regulation 2001/83/EC, too, was solely based on the internal market competence of Article 95 EC Treaty (now Article 114 TFEU).

As the ECJ confirmed in its judgment *Netherlands/Parliament and Council* concerning the Biopatent-Directive as described above[47] such a regulation, whose main aim and nature are the functioning of the internal market, can be based on Article 114 TFEU, This also applies, if services are regulated alongside the main aim of the harmonization. Similarly, Directive 2011/24/EU[48] is solely based on Article 114 TFEU.[49]

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45 See ECJ, Case C-108/09 *Ker-Optika* 201 [ECR] I-12213, paras. 43-45, where the ECJ held that a Greek provision according to which contact lenses may only be sold in shops which specialise in the sale of medical devices by properly trained personnel constituted as a selling arrangement a limitation of the free movement of goods, but not of the free movement of services.

46 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ 2001, L 311, p 67.

47 See above pp. 10 et seq.

48 Directive 2011/24/EU of the European Parliament and the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ 2011, L 88, p 45.

49 Recital 2 holds: "Article 114 TFEU is the appropriate legal basis since the majority of the provisions of this Directive aim to improve the functioning of the internal market and the free movement of goods, persons and services."

In addition to that, the Union legislator can at the same time make use of the health competence according to Article 168(4)(c) TFEU.[50] Provisions on counselling prior to genetic testing as well as on conditions for prenatal diagnosis may be characterized as rules on standards of quality and safety for the use of in vitro diagnostics.

3. Requirements for the application of the internal market competences

In order to apply the internal market competences for providing a counselling requirement, a reservation of genetic testing to the medical profession, or for regulating prenatal diagnosis, the Union legislator would have to make clear in the recitals of the relevant legal act, e.g. in the extended IVD-Regulation, that through elimination of existing or possible national differences in relation to this counselling requirement, or in relation to prenatal diagnosis, the formation and functioning of the internal market in terms of providing, bringing into circulation or application of the in vitro diagnostic devices concerned will be improved.[51]

An extended IVD-Regulation would not only help to improve the free movement of goods if it completely allowed to make genetic tests available, put them into service or use genetic tests (in vitro diagnostics) without counselling or by any person not being a doctor, or within the framework of prenatal diagnosis. According to the principles described in detail in the CEP-report 2001, such an improvement would also be achieved by a legislative measure that would allow that genetic tests (in vitro diagnostics) were made available, put into service or used only subsequent to appropriate counselling, by a doctor or upon a doctor's prescription, or subject to requirements with regard to prenatal diagnosis, that regulated personal requirements for providing counselling or prenatal diagnosis services or even imposed an absolute prohibition of certain applications or certain genetic test products. Also with such content, the legislative measure would introduce common conditions across the Union concerning the making available, putting into service and use of the genetic tests (in vitro diagnostics) concerned. This is sufficient within the framework of Article 114 TFEU.[52]

4. Possibility to regulate morally and ethically controversial questions

Finally, under the general internal market competence according to Article 114 TFEU, complemented by the health competence pursuant to Article 168(4)(c) TFEU, the Union legislator could regulate morally and ethically controversial questions. As already shown in the CEP-report 2001, according to the jurisprudence of the ECJ, also areas, which pose sensitive questions of medical ethics on the level of the Member States, fall within the scope of application of Union law and thereby the competences of the Union legislator.[53]

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50 Both provisions do not only allow for directives, but also for regulations as harmonization measures and refer for the procedure applicable to the ordinary legislative procedure pursuant to Article 289(1) TFEU.

51 See CEP-report 2001, pp. 21 seq.

52 See in detail CEP-report 2001, p. 63.

53 See CEP-report 2001, pp. 12-13, 44 with reference to ECJ, Case C-159/99 *Society for the Protection of Unborn Children Irland/Grogan and others* 1991 [ECR] I-4685, paras. 16-21; confirmed by ECJ, Case C-34/10 *Brüstle/Greenpeace*, not yet published, para. 30; see above pp. 14 seq.

Also the Union legislator considers to be competent to address moral and ethical questions within the framework of health measures. Thus, within the context of Directive 2010/45/EU,[54] it regulated the principles of organ donations, according to which such donations should be voluntary and bring no financial gain.

III. Question 3

With its third question the EPP Group seeks to know, whether it's legally possible to address the requests for obligatory genetic counselling, on gender choice, as well as possibly for a reservation of genetic testing to the medical profession in the planned IVD-Regulation and if so, which wording could be recommended and where.

The EPP Group hereby addresses the question of substantive legality or requirements for Union legislation that would implement the requests of Resolution of 21 November 2002. This question has to be answered as follows:

1. Substantive legality of provisions implementing the requests of the European Parliament

It appears principally possible to implement the requests made in the Resolution of 21 November 2002 within the framework of the planned IVD-Regulation in accordance with the substantive requirements of Union law, in particular with the general objectives of the TFEU as well as the fundamental rights of the persons concerned, and with the principle of proportionality.

Basically, when adding provisions to the planned IVD-Regulation, the Union legislator enjoys a broad discretionary power. This discretion is particularly restricted by the obligation to respect the general objectives of the TFEU, the fundamental rights of the Charter of Fundamental Rights as well as requirements of Union agreements.[55]

The requests for obligatory genetic counselling or doctoral prscription, and on restrictions in relation to gender choice affect numerous objectives, fundamental rights and interests under the Charter of Fundamental Rights:

- the objectives (and the fundamental right) of a high level of health protection (Article 35 sentences 1 and 2), as well as a high level of consumer protection (Article 38)
- the fundamental right to respect of human dignity (Article 1) and protection of life (Article 2)
- the fundamental right to physical integrity (Article 3(1)), as well as the obligations contained in Article 3(2) in the field of medincine and biology, which constitute

[54] Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation, OJ 2010, L 207, p 14.

[55] See CEP-report 2001, pp. 29 seq.

substantive assessment criteria for the Union organs when adopting legislation applying to private persons[56]:

- requirement of free and informed consent of the person concerned (first indent);
- the prohibition of eugenic practices (second indent);
- the prohibition on making the human body and its parts as such a source of financial gain (third indent) as well as
- the prohibition of the reproductive cloning of human beings (fourth indent).

– the prohibition of genetic discrimination (Article 21).

– the fundamental right of parents to respect for his or her private and family life (Article 7)

– the fundamental right to the protection of personal data (Article 8) and

– the fundamental right to freedom to conduct a business of the concerned producers, traders and professional users of in vitro diagnostic devices, as well as of service providers, who provide pre-birth diagnostic services (Article 16).

In addition to that, the UN Convention on disability rights constitute a direct legal yardstick for the Union legislator, the Bioethics-Convention as well as the Genetic Testing Protocol at least an indirect one, and also the OCED guidelines factually provide legal guidance for an amended IVD-Regulation.

It is the task of the Union legislator to balance the fundamental rights of the persons concerned as well as public and private objectives and interests in a proportional manner.[57]

According to these principles, regulations aiming at implementing the requests of the Resolution of 21 November 2002, do not appear to be manifestly disproportionate.

2. Proposals for the implementation of the requests raised by the European Parliament

a) Possibility to adopt provisions on the use of in vitro diagnostics for the purpose of genetic and prenatal testing

With respect to the concrete implementation of the requests made by the European Parliament in the context of the planned IVD-Regulation it has to be taken into consideration first of all, that the planned IVD-Regulation is designed as a regulation on product safety,

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[56] See above p 12.

[57] The question to what extent the principle of coherence, applied by the European Court of Human Rights in its judgment of August 28, 2012, 54270/10, *Costa and Pavan/Italy*, paras. 64-66, see above pp. 16 seq. also constitutes a criterion for Union legislation, has not been settled yet. So far, the ECJ has applied this principle only when assessing the necessity of national measures restricting the European fundamental freedoms, see ECJ, Case C-28/09 *Commission/Austria*, not yet published, para. 126. Advocate General Trstenjak suggested to apply this principle also when assessing the proportionality of Union legal acts, see opinion in Case C-221/09 *AJD Tuna*, not yet published, para. 101. However, the ECJ has not adhered to this opinion yet.

which regulates in vitro diagnostics up to the point when they are made available and put into service, i.e. supplied for use by the end users (professional users or lay persons). The Commission Proposal does not contain rules on the use itself or on counselling or medical services related to it (such as are provided e.g. by the German Genetic Diagnostics Act). On the contrary, pursuant to Article 1(6) of the proposed IVD-Regulation national laws which require that certain devices may only be supplied on a medical prescription shall not be affected by the planned IVD-Regulation.

However, the planned IVD-Regulation recognizes that also the use of in vitro diagnostics can give rise to risks. This is apparent from the following provisions:

– Article 5(2), according to which in vitro diagnostic medical devices which are used in the context of a diagnostic or therapeutic service offered by means of information society services shall comply with the planned IVD-Regulation (however, this, too, is, strictly speaking, still a provision on product safety).

– Article 48(2) and (4), according to which clinical performance studies (intended to verify the design, the benefits and limits to the performance of in vitro diagnostic devices under normal conditions of use) shall be performed in circumstances similar to the normal conditions of use of the device and shall be designed and conducted in a way that the rights, safety and well-being of the subjects participating in such clinical performance studies are protected, in particular of their human dignity, the right to physical and mental integrity of the persons concerned and the principle of free and informed consent, as required by Articles 1, 3(1) and (2) of the Charter of Fundamental Rights.[58]

– Point I.2. of Annex I, according to which the manufacturer in the context of his risk management measures shall "provide training to users and/or inform users of any residual risks" of in vitro diagnostic devices.

There are other Union product related legal acts that do not only contain provisions on placing them on the Union market, but also regulate their use. Article 55 of Regulation (EC) No 1107/2009[59], for instance, contains the concrete obligation to use plant protection products properly, applying the principles of good plant protection practice.

On this basis it is systematically possible to include in the planned IVD-Regulation provisions on the use of in vitro diagnostic devices for the purpose of genetic testing and prenatal diagnosis which take account of the requests raised by the European Parliament. Corresponding provisions could be included, for example, in Chapter II, which then could be

[58] See justification of the Commission Proposal, p. 11, point 3.11.

[59] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ 2009, L 309, p 1.

called “Making available and use of devices, obligations of economic operators, CE marking, free movement”. Alternatively, an additional chapter called “Use of devices” could be added.

b) Recommendations for concrete provisions

The implementation of the requests raised by the European Parliament with regard to genetic testing and prenatal diagnosis could be based on the following proposals:

(1) Definition of genetic testing and if applicable specific genetic testing

If an extended IVD-Regulation contained rules on the use of in vitro diagnostic devices for the purpose of genetic testing, the terms “genetic testing” or “genetic examinations” would have to be defined. Moreover specific types of genetic testing such as diagnostic or predictive genetic examinations would have to be defined as far as the Union legislator intends to adopt differentiated rules in this respect.[60] With regard to the definition of genetic testing the following definition in Article 2 of the Genetic Testing Protocol to the Bioethics Convention could provide guidance for the Union legislator. Genetic testing could be defined as follows:

> “‘Genetic test’ means a test that is carried out for health purposes, involving analysis of biological samples of human origin and aiming specifically to identify the genetic characteristics of a person which are inherited or acquired during early prenatal development.“

(2) Taking account of specific fundamental rights, principles of medicine and biology as well as international treaties

It would be advisable to refer in recital 59, in addition to the fundamental rights already mentioned there, also to the obligations in the fields of medicine and biology contained in Article 3(2) of the Charter of Fundamental Rights, in particular to the principle of free and informed consent of the person concerned, to the rules of the UN Convention on disability rights that are binding on the Union legislator as well as, possibly, to the factually binding provisions of the Genetic Testing Protocol and, maybe, to the OECD Guidelines in order to clarify their impact on the interpretation and application of the planned (extended) IVD-Regulation.

Recital 59 could be extended as follows (additions in italics):

> “This Regulation respects the fundamental rights and observes the principles recognized in particular by the Charter of Fundamental Rights of the European Union and notably human dignity, the integrity of the person, *the principle of free and informed consent of the person concerned*, the protection of personal data, the freedom of art and science, the freedom to conduct business and the right to property *as well as the principles of the Convention on the Rights of Disabled People and of the Convention on Human Rights and Biomedicine as well as its additional Protocol*

[60] The German Genetic Diagnostics Act provides e.g. in Section 10(1)(1) only for a non-mandatory provision for genetic counselling. However, according to Section 10(1)(2) counselling is mandatory in case of an untreatable disease. Pursuant to Section10(2) genetic counselling is also obligatory, in general, for predictive genetic examinations. Yet, the person concerned can waive this right.

concerning Genetic Testing for Health Purposes. This Regulation should be applied by the Member States in accordance with those rights and principles."

Furthermore the Union legislator could consider to include in the planned IVD-Regulation a general rule governing the protection of people affected by genetic examinations. This rule could be worded in line with Article 48(4) of the planned IVD-Regulation which applies to clinical performance studies:

> "A product may be used for purposes of a genetic test only in a way that the rights, safety and well-being of the subjects are protected and that the clinical data generated in the course of the genetic testing are going to be reliable and robust."

(3) Genetic information, counselling and free consent

With respect to the request of the European Parliament relating to genetic counselling and the reservation of genetic testing to the medical profession, the Genetic Testing Protocol as well as existing national legislation, e.g. the German Genetic Diagnostics Act, contain differentiated rules. First of all, they distinguish between information obligations for purposes of the protection of the person concerned, but also for purposes of liability protection of the diagnostic or therapeutic service provider, i.e. in particular the examining doctor, and counselling for the special protection of the person concerned.[61] Moreover, they contain additional provisions on free and informed consent as well as special rules on persons not able to consent. Unlike the German Genetic Diagnostics Act[62] the Genetic Testing Protocol does not contain a specific doctoral prescription requirement or a limitation that genetic tests may only be conducted by doctors, but a general requirement according to which genetic tests may only be conducted by persons with appropriate qualifications.[63]

A short provision based on the Genetic Testing Protocol and taking account of the requests of the European Parliament could read as follows:

> „(1) Information. Before using a device for the purpose of a genetic test the person concerned shall be provided with appropriate information on the nature, the significance and the implications of the genetic test.
>
> (2) Genetic counselling. Before using a device for the purpose of a [predictive] genetic test the person concerned shall be provided with appropriate and comprehensible genetic counselling without prejudging the outcome. The genetic counselling shall include medical, ethical, social, psychological and legal aspects. The form and extent of this genetic counselling shall be defined according to the implications of the results of the test and their significance for the person or the

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61 See Article 8 of the Genetic Testing Protocol which requires that the person concerned shall be provided with prior appropriate information for all genetic tests and appropriate genetic counselling only for predictive genetic as well as Section 9 Genetic Diagnostics Act which requires that information is provided in all cases of genetic testing and Section 10 Genetic Diagnostic Act with a differentiated provision on counselling, see above footnote 60.

62 See Section 7 Genetic Diagnostics Act.

63 See Article 5(c) of the Genetic Testing Protocol.

members of his or her family, including possible implications concerning procreation choices.

(3) Consent. A device may only be used for the purpose of a genetic test after the person concerned has given free and informed consent to it. The consent has to be given explicitly and in writing. It can be revoked at any time in writing or orally. *[rules on persons who are incapable of giving consent may be added]*"

An additional limitation that genetic tests may only be conducted by doctors could be worded as follows:

"A device may only be used for the purpose of a genetic test if the test is conducted by persons admitted to the medical profession under the applicable national legislation."

(4) Determination of sex in connection with prenatal diagnosis

Concerning the request of the European Parliament that determination of sex in connection with prenatal diagnosis should be permitted only - if at all - if there is a risk of serious gender specific hereditary diseases, it should be noted that the planned IVD-Regulation, according to the proposed Article 2(1) and (2), only applies to devices which fulfil a medical purpose as defined by this Article. Devices intended to be applied in the context of genetic tests without any medical purpose (e.g. so-called life-style-test or certain other predictive tests), do not yet fall within the scope of application of the planned IVD-Regulation. Should the Union legislator have the intention to implement the requests of the European Parliament to regulate all types of genetic testing, not just those already falling under the IVD-Regulation, the scope of application would have to be extended specifically for the requested provision. A respective provision could read as follows: :

"A device may only be used for the determination of sex in connection with prenatal diagnosis, if the determination fulfils a medical purpose and if there is a risk of serious gender specific hereditary diseases. By way of derogation of Article 2(1) and (2) Article 2(1)(1) this also applies to products which are not intended to fulfil a specific medical purpose."

c) Maintaining and introduction of more stringent national provisions

The Union legislator should decide whether it wants to implement the requests of the European Parliament by way of full harmonization from which the Member States cannot deviate, or by way of minimum harmonization which entitles the Member States to maintain or introduce more stringent health-protection provisions.

The possibility to maintain more stringent national provisions after the adoption of a harmonization measure is explicitly provided for by Article 114(4) TFEU. This provision does not make a separate national approach subject to a specific form of the harmonization measure of the Union, e.g. a directive. It, therefore, also applies if the harmonisation measure is a regulation. By contrast, Article 114 TFEU does not contain any provision on the

subsequent introduction of more stringent national provisions for reasons of health or consumer protection.[64]

The health competence for setting high standards of quality and safety for medicinal products and medical devices in Article 168(4)(c) TFEU does not contain any explicit rule according to which Member States may maintain or introduce more stringent protective measures either. In this respect, Article 168(4)(c) TFEU differs from the corresponding provision concerning organs and substances of human origin in Article 168(4)(a) TFEU whose wording explicitly permits separate national approaches. Therefore, unlike the competence granted by Article 168(4)(a) TFEU, the Union competence pursuant to Article 168(4)(c) TFEU does not only constitute a competence to adopt measures of minimum harmonization, but also of full harmonization. Under Article 168(4)(c) TFEU the Member States have no mandatory right to introduce and maintain derogating national measures. However, the nature of Article 168(4)(c) TFEU as a full harmonization competence does arguably not exclude that the Union legislator also adopts on this basis a measure of minimum harmonization allowing for such a – also subsequent – derogation by the Member States.[65] In addition to the wording of Article 168(4)(c) TFEU ("standards") this assumption is supported by the nature of the health competence of Article 168(4)(c) TFEU as a shared competence according to Article 4(2)(k) TFEU as well as the central objective of this competence, i.e. the setting of high standards of quality and safety. It follows that under Article 168(4)(c) TFEU this health protection objective may prevail over the objective of full harmonization, in particular in the sensitive area of human genetics and reproductive medicine.

Against this background, the Union legislator could consider to introduce the following additional provision.

> "The above provisions on the use of devices for the purpose of genetic tests do not prevent the Member States from maintaining or introducing for reasons of health protection more stringent national legislation in this field."

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64 Article 114(5) provides for the possibility of a national derogation only for measures of environmental and employment protection. According to Article 114(8) in the case of a specific problem on public health the Member States enjoy a right of initiative for the examination and, if applicable, for the proposal of Union measures by the Commission. However, in this area there is no possibility for the Member States to "opt-out".

65 See e.g. in: Callies/Ruffert (ed.), EUV/AEUV Kommentar, Art. 168 AEUV, para. 22; Lurger, in: Streinz (ed.), EUV/AEUV, Art. 168 AEUV, para. 41; in a restrictive sense Schmidt am Busch, in: Grabitz/Hilf/Nettesheim (ed.), Das Recht der Europäischen Union, Kommentar, Art. 168 AEUV, para. 61. An analogy can be drawn to Regulation (EC) No 1107/2009 (see footnote 59 above) which is based, in addition to the internal market competence, on Article 152(4)(b) of the EC Treaty (now Article 168(4)(b) TFEU) and which contains different provisions according to which Member States for reasons of health or environment protection can deviate from authorization requirements for plant protection products of other Member States (see e.g. Article 36(3) for risk mitigation measures or Article 65(3) for special labeling requirements for reasons of health or environment protection).

§ 4
Executive Summary

The results of this opinion can be summarized as follows:

I. The general findings of the CEP-report 2001 that the then European Community (now European Union) was entitled, on the basis of the so-called internal market competences and taking account of the substantive conditions of primary Union law, in particular of the European fundamental rights as general principles of Union law as laid down in the then not yet legally binding Charter of Fundamental Rights, to adopt legal acts in the fields of human genetics and reproductive medicine, in particular concerning the admissibility and conditions of prenatal genome analysis, can be confirmed or have even been slightly endorsed by subsequent developments.

1. The TFEU has left the internal market competence and other relevant competences largely unchanged, although the provisions were renumbered. These competences are in particular the so-called internal market competences Article 114 TFEU (general internal market competence), Article 115 TFEU (subsidiary internal market competence), Article 46 (special internal market competence for the freedom of movement of workers), Article 53 TFEU (special internal market competence for the freedom of establishment), Article 53 in conjunction with Article 62 TFEU (special internal market competence for the freedom to provide services) as well as in addition competences in different related policy areas, like Article 153 TFEU (social policy), Article 168 TFEU (health protection), Article 169 TFEU (consumer protection), Article 182 TFEU (research framework programme), Article 207 TFEU (trade policy) and Article 352 TFEU ("competence extension clause"). Furthermore, the Treaty of Lisbon has introduced a fundamentally new competence in the area of human genetics and reproductive medicine in Article 168(4)(c) TFEU which authorizes measures setting high standards of quality and safety for medicinal products and devices for medical use.

2. According to the jurisprudence of the European Court of Justice the possibility to adopt legal acts in the area of human genetics and reproductive medicine based on the internal market competences has been further specified and strengthened.

3. The substantive assessment criteria for Union legislation in the area of human genetics and reproductive medicine, in particular the protection of European fundamental rights, have further developed. According to Article 6(1) TEU introduced by the Treaty of Lisbon, the Charter of Fundamental Rights has gained binding force within the Union legal order. The validity of the fundamental freedoms laid down in the ECHR as general principles of Union Law has been strengthened, too. Accordingly, indications of an intensification of the protection of fundamental rights can be found in the jurisprudence of the ECJ, also seeking coherence with the jurisprudence of the European Court of Human Rights.

4. Finally, important changes have taken place particularly in the fields of human genetics and reproductive medicine.

   a) Both the ECJ and the European Court for Human Rights developed in their jurisprudence first important, even though merely rudimentary requirements of primary law for Union legislation in the field of human genetics and reproductive medicine.

      – The ECJ has for the first time assessed Union legal acts in the field of human genetics by taking account of the fundamental rights to human dignity and integrity of the person, as they are now provided by Article 1 and Article 3(1) of the Charter of Fundamental Rights. At the same time it has undertaken to give legally binding answers to genetic questions, that are morally and ethically very sensitive and controversial in the Member States (e.g. the question of the definition of a human embryo), in the light of the fundamental rights that have to be guaranteed. Herewith it attached central importance to the fundamental rights to human dignity and integrity of the person, also for prenatal life.

      – The European Court of Human Rights has also further developed the protection of fundamental rights in the fields of human genetics and reproductive medicine. At the same time, it attached great importance to the basic right of parents to private and family life according to Article 8 ECHR, which is reflected in Article 9 of the Charter of Fundamental Rights, which has significant relevance for the Union legislator.

   b) On the international level, important international treaties have been concluded. This includes the UN Convention on the Rights of Persons with Disabilities as well as the Additional Protocol to the Bioethics Convention on genetic testing for health purposes of the Council of Europe, which directly or indirectly constitute an assessment criterion for the Union legislator. This factually applies also to the OECD Guidelines for quality assurance for molecular genetic tests.

II. Based on the so-called Damião-report, the European Parliament, in its Resolution of 21 November 2002, called on the Commission to draft a regulation for the introduction of a standard for genetic tests as well as EC-provisions on DNA-testing. The European Parliament requested among others that genetic testing and analysis must be conducted within the frame of competent, independent and personal counselling which must cover medical, ethical, social, psychological and legal aspects, that genetic testing analysis and diagnosis data must remain confidential and should be used only for the benefit of the person requiring such tests and that determination of sex in connection with prenatal diagnosis should be permitted only – if at all – if there is a risk of serious gender specific hereditary diseases.

The Union legislator could address and implement these requests on the basis of the internal market competences, complemented by the health competence pursuant to Article 168(4)(c) TFEU.

1. Should the Union legislator want to regulate questions of counselling prior to a genetic test or the reservation of genetic testing to the medical profession of and of prenatal diagnosis in a separate legal act (similar to how e.g. Germany has done in its Genetic Diagnostics Act), it can do so on the basis of the internal market competence for services according to Article 53(1) in conjunction with Article 62 TFEU. In this case the Union legislator could only act in the form of a directive.

2. Should the Union legislator intend to amend the planned IVD-Regulation, which mainly concerns the placing on the market and the making available of in vitro diagnostics devices, in order to include more specific requirements for genetic counselling prior to the use of genetic tests and the reservation of genetic testing to the medical profession as well as requirements for prenatal diagnosis, it could also do so on the basis of the general internal market competence according to Article 114 TFEU, complemented by the health competence pursuant to Article 168(4)(c) TFEU. For this the Union legislator would not have to apply in addition the special internal market competence for services according to Article 53(1) in conjunction with Article 62 TFEU.

III. It appears possible to address and implement the requests of the Resolution 21 November 2002 within the framework of the planned IVD-Regulation in accordance with the applicable substantive requirements of Union law, in particular with the general objectives of the TFEU as well as the fundamental rights of the persons concerned according to the Charter of Fundamental Rights and the ECHR and with the principle of proportionality.

1. The requests for obligatory genetic counselling, the requests concerning gender choice, as well as the requests for the reservation of genetic testing to the medical profession affect numerous objectives, fundamental rights and interests under the Charter of Fundamental Rights:
   - the objectives (and the fundamental right) of a high level of health protection (Article 35 sentences 1 and 2), as well as a high level of consumer protection (Article 38)
   - the fundamental right to respect of human dignity (Article 1) and protection of life (Article 2)
   - the fundamental right to physical integrity (Article 3(1)), as well as the obligations contained in Article 3(2) in the field of medicine and biology, which constitute substantive assessment criteria for the Union organs when the legislation applies to private persons:

- requirement of free and informed consent of the person concerned (first indent);
- the prohibition of eugenic practices (second indent);
- the prohibition on making the human body and its parts as such a source of financial gain (third indent) as well as
- the prohibition of the reproductive cloning of human beings (fourth indent).

– the prohibition of genetic discrimination (Article 21).
– the fundamental right of parents to respect for his or her private and family life (Article 7)
– the fundamental right to the protection of personal data (Article 8) and
– the fundamental right to freedom to conduct a business of the concerned producers, traders and professional users of in vitro diagnostic devices, as well as of service providers who provide pre-diagnostic services (Article 16).

2. In addition the UN Convention on the Rights of Persons with Disabilities and the Bioethics Convention as well as the Additional Protocol to the Bioethics Convention on genetic testing for health purposes of the Council of Europe become directly or at least indirectly, as well as the OCED guidelines factually, the legal yardstick for the Union legislator.

3. It is the task of the Union legislator to balance the fundamental rights of the persons concerned as well as public and private objectives and interests in a proportional manner. According to these principles provisions intending to implement the requests of the Resolution of 21 November 2002 do not appear manifestly disproportionate.

4. It is systematically possible to include in the planned IVD-Regulation provisions on the use of in vitro diagnostic devices for the purpose of genetic tests and prenatal diagnosis that implement the requests raised by the European Parliament. It is not excluded that the Union legislator adopts these provisions not only by way of full harmonization, but also by way of minimum harmonization which entitles the Member States to maintain or introduce more stringent health-protection provisions.

Passau and Frankfurt, January 2013

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