

**THE COMPETENCE OF THE EUROPEAN UNION TO LEGISLATE IN
RELATION TO CERTAIN AMENDMENTS ENDORSED BY THE
EUROPEAN PARLIAMENT**

**IN CONNECTION WITH A COMMISSION PROPOSAL FOR AN
IN VITRO DIAGNOSTIC DEVICE REGULATION**

OPINION

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1. Introduction

Lawford Davies Denoon and Axon Lawyers, members of the Alliance of European Life Sciences Law Firms, are instructed by the European Society of Human Genetics (“**ESHG**”) to provide a legal assessment of the competence of the European Union to legislate in connection with certain amendments to the draft *In Vitro Diagnostic Devices Regulation*¹ (the “**IVD Regulation Proposal**”).

These amendments², which were endorsed in the draft report³ of the Committee of the European Parliament with responsibility for the IVD Regulation Proposal, the Committee for Environment, Public Health and Food Safety (“**ENVI**”) and subsequently adopted (with immaterial further amendments) by the European Parliament on 22 October 2013, were proposed by Professor Dr. Michael Schweitzer and Professor Dr. Hans-Georg Kamann of the Centre for European Law at the University of Passau in an opinion (the “**Passau Opinion**”) of January 2013, which was written “on behalf of”⁴ the Group of the European People’s Party (“**EPP**”)⁵. The Passau Opinion was commissioned by the Rapporteur of the European Parliament for the IVD Regulation Proposal, EPP MEP Dr Peter Liese⁶. The amendments based the Passau Opinion set out in the text adopted by the European Parliament upon a partial vote at first reading/single reading (the “**Parliament Text**”) are, accordingly, referred to here as the “**Liese Amendments**”.

2. Executive Summary

The European Union (the “**Union**”) lacks the competence to enact legislation incorporating the Liese Amendments. The Passau Opinion seriously misrepresents this competence.

¹ 2012/0267 (COD).

² Set out in COM(2012) 541 final, 2012/0267 (COD).

³ 3 April 2013.

⁴ Our Opinion is independent of the ESHG and not made on its behalf.

⁵ “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 Devices”, http://www.cep.uni-passau.de/dateien/wissGutachten/HumanGenetics-Opinion_English_7-3-13.pdf. In this Opinion, we refer to the English version.

⁶ By a letter dated 13 September 2012.

It is our opinion that the provisions attributing competence to legislate to the Union do not allow for imposing requirements concerning the practice of medicine in relation to specific medical devices. Even if one were to assume that such competence exists, the principle of subsidiarity dictates that such requirements should not be imposed at EU level but at national level, notably because the European Commission already stated that matters of informed consent are better dealt with at national level. Finally, even if one would assume that the principle of subsidiarity does not prevent this, the arguments raised in the Passau Opinion cannot support such legislation.

3. The Liese Amendments

3.1 This section sets out the Liese Amendments, as set out in the Parliament Text. ENVI Committee's justification, in its draft report, follows each proposal and the Parliament has adopted these in its vote on 22 October 2013.

Recital 59 (the amendments appear in bold text)

“This Regulation respects the fundamental rights and observes the principles recognised 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 European Convention on Human Rights and Biomedicine as well as the Additional Protocol to that Convention concerning Genetic Testing for Health Purposes**. This Regulation should be applied by the Member States in accordance with those rights and principles.”

ENVI Justification

“The principle of free and informed consent is a key point in the Charta [sic], Article 3 and should be mentioned here.”

Article 2, point 12(b)

“‘device for genetic testing’ means an *in vitro* diagnostic medical device the purpose of which is to identify a genetic characteristic of a person which is inherited or acquired during prenatal development;”

ENVI Justification

“The rapporteur introduces specific provisions for genetic tests. That it is why a definition is necessary. The wording is based on the protocol of the Council of Europe.”

Article 4(a)

Genetic information, counselling and informed consent

“1. A device may only be used for the purpose of a genetic test if the indication is given by persons admitted to the medical profession under the applicable national legislation after a personal consultation.

2. A device 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. Information. Before using a device for the purpose of a genetic test the person mentioned in paragraph 1 shall provide the person concerned with appropriate information on the nature, the significance and the implications of the genetic test.

4. Genetic counselling. Appropriate genetic counselling is mandatory before using a device for the purpose of predictive and prenatal testing and after a genetic condition has been diagnosed. It shall include medical, ethical, social, psychological and legal aspects and has to be addressed by physicians or another person qualified under national law in genetic counselling. 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 members of his or her family...

5. 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.”

7. 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 from Article 2(1) and (2) this also applies to products which are not intended to fulfil a specific medical purpose.

8. The provisions of this Article 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 or public order more stringent national legislation in this field.”

ENVI Justification

“See also Explanatory statement. This new chapter refers to long-standing requests of the European Parliament and other international institutions like the Council of Europe and OECD. Genetic Tests should be performed by a medical professional after appropriate genetic counselling. Informed consent is a prerogative of the Charta [sic] of Fundamental Rights and should therefore be introduced in the legislation.”

The “**Explanatory statement**”, which appears on pages 56 to 60 of ENVI’s draft report states:

*“The Commission proposal focuses very much on the quality of the product. Experts and many international organisations, like the Council of Europe, OECD and the European Society for Human Genetics have again and again articulated their position that in many case [sic] **even more important than the quality of the product is the framework in which the product is applied.** Especially in DNA testing it is very important to respect the principle of informed consent. This has also been asked for by the European Parliament several times. A **legal opinion** concludes that it is possible and appropriate to introduce respective wording in the proposal⁷. Therefore the rapporteur proposes amendments on this issue.”*

This last note not only confirms that the supposed legal basis for the Liese Amendments lies solely in the Passau Opinion, but may imply the support of the European Society of Human Genetics in the amendments, as opposed to, say, national frameworks.

3.2 The Liese Amendments have been extensively criticised, notably by EuroGentest⁸. Although we endorse EuroGentest’s concerns about the legal construction of the Liese Amendments, this Opinion is limited to the competence of the Union to legislate in the way suggested in the Passau Opinion and endorsed by the Parliament.

4. The Passau Claims

4.1 Professor Dr. Michael Schweitzer and Professor Dr. Hans-Georg Kamann contend that the Union legislator has, since the coming into force of the Charter of Fundamental Rights of the European Union⁹, enjoyed the competence to produce the following bioethical legislation¹⁰:

- “a directive on the permissibility of DNA analysis in the context of the conclusion of insurance contracts”, insofar as such a directive would now need to take account of the “*fundamental rights to human dignity*”¹¹ and the right to protection of, and access to, personal data and the principle of personal consent;

⁷ Centrum für Europarecht an der Universität Passau: "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".

⁸ “EU Regulation on in-vitro Diagnostic Medical Devices – call for urgent action”: http://www.eurogentest.org/fileadmin/templates/eugt/pdf/Call_for_Urgent_Action.pdf.

⁹ 2010/C 83/02

¹⁰ Passau Opinion, Section 2, VII, page 7.

¹¹ See below.

- “a directive on the permissibility of DNA analysis in the context of the conclusion of employment contracts”, insofar as such a directive would now need to take account, not only of the employee’s “*fundamental right to human dignity*”, right to protection of, and access to, personal data and the principle of personal consent, but also the respect to be accorded to his or her private life;
- “a directive to regulate prenatal genome analyses”, insofar as such a directive would now need to take account of the “*fundamental right to human dignity*”, right to life, “*physical integrity in the particular form of the prohibition of eugenic practices*”, the prohibition of personal data and genetic discrimination;
- “a legal act on the permissibility of research and intra-Union trade in embryos and embryonic stem cells” and “a legal act on the permissibility of trade in embryos and embryonic stem cells with non-EU states”, insofar as such an act would now need to take account of, in particular “*the prohibition of eugenic practices and of financial gain with respect to the use of the human body and the prohibition of reproductive cloning*”.

4.2 On the basis of the following claims, Schweitzer and Kamann further contend that this competence has grown¹², claiming

- that the Treaty of Lisbon has extended the competences of the Union with regard to human genetics and reproductive medicine;
- that the jurisprudence of the Court of Justice of the European Union (“**CJEU**”) has specified and strengthened the competence of the Union to adopt legal acts in the area of human genetics and reproductive medicine;
- that the protection of European fundamental rights has “*strengthened*” the assessment criteria in the area of human genetics and reproductive medicine; and
- that the jurisprudences of the CJEU and of the European Court of Human Rights (“**ECHR**”) has expanded to address important new developments in the fields of human genetics and reproductive medicine.

4.3 Schweitzer and Kamann claim the legitimacy of the Liese Amendments on the basis of these beliefs. However, as this Opinion demonstrates, each one of these claims is fundamentally incorrect¹³.

¹² Passau Opinion, section 3, page 9.

5. Competence

The overall constraints on Union competence are established by Article 5 of the Treaty on the European Union (“TEU”), which provides the following:

5.1 Conferral

Under the principle of conferral, Union competences are restricted to those conferred on it by Member States in the Treaties. Those not so conferred remain with the Member States.

5.2 Subsidiarity and Proportionality

Outside the realm of Union exclusive competence, the principle of proportionality forbids the Union to act unless, and only to the extent that, the objectives of its proposed action cannot be sufficiently achieved by Member States (at central, regional or local levels), but can be better achieved at the Union level by reason of the scale or effects of its proposed action¹⁴.

5.3 Irrespective of its competence, the principle of proportionality forbids the content and form of Union action from exceeding what is necessary to achieve Treaty objectives.

5.4 Union institutions must apply the principles of subsidiarity and proportionality in accordance with the Protocol on the application of the principles of subsidiarity and proportionality (the “**Subsidiarity and Proportionality Protocol**”).

5.5 Paragraph 2 of Article 4 of the Subsidiarity and Proportionality Protocol provides that

“The European Parliament shall forward its draft legislative acts and its amended drafts to national Parliaments.”

5.6 We submit that, insofar as an amendment adds material to a draft legislative act, paragraph 2 implies, not only a level of national Parliamentary scrutiny, but also a breadth of consultation commensurate with that required of the Commission, under Article 2 of the Subsidiarity and Proportionality Protocol, in producing the original draft.

5.7 On the same basis (which we ascribe to the wish of the High Contracting Parties, set out in the opening words of the Subsidiarity and Proportionality Protocol, to “*ensure that decisions are taken as closely as*

¹³ Factual errors render the Passau Opinion unreliable from the start. In the Paragraph 1 of its summary of reasoning (section 2), for example, the reference to the Article 2 of Treaty on the European Union is simply incorrect: Article 2 contains no references to economic activities.

¹⁴ Which seems very unlikely in a matter involving a doctor and his/her patient.

possible to the citizens of the Union”), we submit that, insofar as Parliament’s amended draft comprises additional material to the Commission’s draft legislative act that is of extreme significance¹⁵, it is an “*initiative of the European Parliament*”¹⁶ and thus as susceptible to Article 5 of the Subsidiarity and Proportionality Protocol as the Commission’s original proposal.

5.8 Accordingly, the amendments should in our view be justified with regard to the principles of subsidiarity and proportionality and should include a

*“... detailed statement making it possible to appraise compliance with the principles of subsidiarity and proportionality”*¹⁷.

5.9 In compliance with the Subsidiarity and Proportionality Protocol, the Parliament’s statement should confirm that the objective set out in its amendment is a Union objective and should include reasons, supported by qualitative and, wherever possible, quantitative indicators, for concluding that this objective can, by reason of the scale or effects of its proposed measures, be better achieved at Union level than at a local, regional or central level within individual Member States¹⁸. The Parliament should, furthermore,

“take account of the need for any burden, whether financial or administrative, falling upon the Union, national governments, regional or local authorities, economic operators and citizens” and show how it would be “*minimised and commensurate*” with its lawful objective.

5.10 **Conclusion**

On this basis, we submit that the Council of Ministers should refuse to endorse any output of the European Parliament that fails to secure the rights of Member States. However, if a Regulation were to be enacted incorporating these amendments, then, pursuant to Article 8 of the Subsidiarity and Proportionality Protocol and the fourth paragraph of Article 263 of the Treaty on the Functioning of the European Union (“TFEU”) those directly affected may institute proceedings against it in the CJEU “*on grounds of infringement of the principle of subsidiarity by a legislative act*”.

¹⁵ Including constitutional significance, as the effect of assent would in effect provide a basis for an extension of Union competence beyond that allowed for under the Treaties and Charter.

¹⁶ Article 3, the Subsidiarity and Proportionality Protocol.

¹⁷ Article 5, the Subsidiarity and Proportionality Protocol.

¹⁸ Ibid.

6. **Articles 114 & 168, Treaty on the Functioning of the EU**

- 6.1 Article 114 TFEU sets out the basis upon which the Union may lawfully adopt measures to ensure the functioning of “*an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of the Treaties*” (i.e. the Union’s internal market).
- 6.2 The Passau Opinion argues that Article 114 applies to Regulations as well as to Directives. This contention is made on the basis that Article 114(4) “*does not make a separate national approach subject to a specific form of harmonization measure of the Union, e.g. a directive. It, therefore, also applies if the harmonisation measure is a regulation*”¹⁹.
- 6.3 The Passau Opinion associates its contended applicability of Article 114 with the subject matter of Article 168(4)(c) TFEU.
- 6.3.1 Article 168(4) TFEU states that it is a derogation from Article 2(5), under which the Union has “*competence to carry out actions to support, coordinate or supplement the actions of the Member States, without thereby superseding their competence in these areas*”. Article 2(5) also provides that “*Legally binding acts of the Union adopted on the basis of the provisions of the Treaties relating to these areas shall not entail harmonisation of Member States’ laws or regulations.*” Article 168(4) TFEU is also stated to be a derogation from Article 6(a), under which the Union has “*competence to carry out actions to support, coordinate or supplement the actions of the Member States*” in relation to “*(a) protection and improvement of human health...*”

As an express derogation from these provisions, Article 168(4) tells us that the Union lacks the competence that it would otherwise have enjoyed under Article 2(5) “*to carry out actions to support, coordinate or supplement*” Member States’ measures for protecting and improving human health. Even if, contrary to this interpretation, the power were to remain with the Union, the nature of these actions is inherently subordinate to the actions of Member States. Similarly, although the derogation from the second paragraph of Article 2(5) means that measures intended to protect and improve human health do entail the harmonisation of the laws and regulations of Member States, the Union’s competence remains subservient.

¹⁹ Final paragraph, p28 (English translation).

6.3.2 Article 168(4) TFEU is also stated to accord with Article 4(2)(k) TFEU, which provides that the Member States and Union shall share competence in relation to listed common safety concerns in public health matters, for the aspects defined in the TFEU.

6.3.3 The nature of shared competence is set out in Article 2(2) TFEU. This provides that,

“When the Treaties confer on the Union a competence shared with the Member States in a specific area, the Union and the Member States may legislate and adopt legally binding acts in that area.”

6.3.4 Article 2(2) gives the Member States and Union full discretion to negotiate the extent of this shared responsibility. The role of the Council of Ministers as a bulwark of sovereignty in the ordinary legislative procedure is strongly inferred from the second sentence of Article 2(2), which provides that

“The Member States shall exercise their competence to the extent that the Union has not exercised its competence. The Member States shall again exercise their competence to the extent that the Union has decided to cease exercising its competence.”

6.3.5 Article 4(1) TFEU sets out an important threshold test for shared competence: if the competence relates to areas referred to in Article 3 TFEU (Union exclusive competence) and those relating to Article 6 TFEU (Union competence subordinate to Member State competence), then competence is not shared. Member States will, therefore, enjoy exclusive competence in these circumstances.

6.3.6 For present purposes, the Union’s only exclusive jurisdiction under Article 3 TFEU concerns “*common commercial policy*”. For purposes of Article 6 TFEU, the Union has competence “*to carry out actions to support, coordinate or supplement the actions of the Member States*” in connection with the “*protection and improvement of human health*” “*at European level*²⁰”. Article 2(6) TFEU explains that “*The scope of and arrangements for exercising the Union’s competences shall be determined by the provisions of the Treaties relating to each area.*” It follows that exclusive Member State competence under Article 4(1) TFEU will only be triggered where “*common commercial policy*” coincides with “*European level*” Union actions designed “*to support, coordinate or supplement*” those of Member States for the “*protection and improvement of human health*”.

²⁰ Which itself suggests public, not private, healthcare.

- 6.3.7 A critical distinction arises between “*the protection and improvement of human health*” and its “*public health*” subclass, the purview of which is limited to threats to health based on population health analysis. Article 4(2)(k) TFEU states that this public health subclass is shared. By implication, the remaining and far larger subclass, including personal healthcare, does not fall within a shared competence: not being a matter of exclusive Union competence, it remains a matter in which the competence of Member States is exclusive. Because Article 168(4) TFEU is stated to accord with Article 4(2)(k) TFEU, it follows that Union “*measures setting high standards of quality and safety for medicinal products and devices for medical use*” is also limited to the arena of public health. The individual’s use of such products is emphatically not a public matter.
- 6.3.8 Indeed, the obligation of EU Member States, as members of the Council of Europe, to respect their citizen’s private and family life are particularly pertinent to genetic testing, which is an area in which statutory interference would require the strongest justification as being “*necessary in a democratic society*”. Such a case has not been made out in debate and was not included for consultation in the original draft from the European Commission. As observed elsewhere, the Union is required by the TEU to accede to the European Convention on Human Rights (the “**European Convention**”)²¹: it has no scope to flout human rights law on the threshold of accession. The impact of the Convention and of the Charter of Fundamental Rights on the Passau claims and amendments are discussed in sections 7 to 11).
- 6.3.9 The scope of Article 168(4) does not extend to the delivery of medical or healthcare services, still less to services delivered using “*devices for medical use*”.
- 6.3.10 Article 168(1) confirms that the effect of the derogation (discussed above), under which Union actions are subordinate to those of the Member States, stating that “*Union action... shall complement national policies*” and the public health limitation; and that

“*Union action... shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health.*”²²
- 6.3.11 To avoid any doubt over the matter, Article 168(7) provides that:

²¹ Article 6(2) TEU.

²² As noted elsewhere, the Passau amendments would impede public health by restricting the deployment of essential diagnostic devices.

“Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services.”

- 6.4 On the basis of this analysis, even if (contrary to our view) the Passau Opinion were correct in suggesting that measures under Article 168(4)(c) TFEU may take the form of regulations, the scope of any such regulation would necessarily be confined to public health matters relevant to the safety and performance of medical devices as such, with a view to enabling an internal market for medical devices. This is expressed in Article 168 (4) by means of the wording

*“[the EU] shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet **common safety concerns**:*

[...]

*(c) measures setting high standards of **quality and safety** for medicinal products and devices for medical use.”²³*

- 6.5 Article 168 TFEU, as it currently stands, is evidently meant to only enable the EU in the field of medical devices (which includes IVDs) to adopt quality and safety measures. Measures based on that article can only address quality and safety of the devices themselves, and cannot be prescriptive as to how to practice medicine with medical devices, for example by prescribing mandatory patient counselling that must precede the use of a medical device. Such a regulation can at most be merely supportive of the various policies of Member States in the field of medical practice regarding use of medical devices, but it cannot replace these national policies. The Union has no power to impose subordinate regulations upon Member States in this respect.

- 6.6 It follows very clearly from the explanatory text provided by the Parliament’s Rapporteur that the proposals do not seek to limit themselves to safety and quality of the devices concerned themselves, but intentionally go beyond this scope. The Rapporteur for the IVD Regulation Proposal himself states in the explanatory notes to the ENVI Committee’s proposal to the Parliament that it is his explicit intention to cross this boundary with the proposals concerned:

“The Commission proposal focuses very much on the quality of the product. Experts and many international organisations, like the Council of Europe, OECD and the European Society for Human Genetics have again and again articulated their position that in many case [sic] even more important than the quality of the

²³ Emphasis added.

product is the framework in which the product is applied. Especially in DNA testing it is very important to respect the principle of informed consent. This has also been asked for by the European Parliament several times. A legal opinion concludes that it is possible and appropriate to introduce respective wording in the proposal²⁴. Therefore the rapporteur proposes amendments on this issue. There is consensus that it should not be the intention of the European Union to limit the access of patients to DNA tests but appropriate genetic counselling should be offered in any case to inform about the consequences before a test is performed.’²⁵

- 6.7 From the above it is clear that the Parliament intends harmonisation of the practice of medicine with respect to the devices concerned, by obliging Member States to change practices this if they have not adopted these already, and prescribes a detailed and mandatory process for the practice of medicine involving IVDs for genetic testing.
- 6.8 It follows that the Parliament’s amendment to the draft legislative act is not within the scope of the Union’s legislative competence.
- 6.9 Case law in the field of instruments based on the double legal basis of Article 114 (formerly 95) and 168 (formerly 152 and prior to that 129) and Article 114 (formerly 95) in relation with other provisions (like 133 on social policy) underlines the above arguments.
- 6.10 Earlier case law of the CJEU about the legislative use of the combination of the predecessors of Article 114 and 168(4) TFEU show that the CJEU has ruled that the EU cannot use Article 168 as a legal basis in order to circumvent the express exclusion of harmonisation competence laid down in Article 168(4) TFEU of the TFEU²⁶. In other words, one cannot rely on Article 168(4) TFEU as legal basis to circumvent the limits of harmonisation in the field of medical devices contained in that Article. This was decided in the so-called *1st Tobacco Advertising Directive* case, in which Germany argued that the Tobacco Advertising Directive as drafted at the time did not only pursue an internal market goal, but also encroached on the Member States’ national health policies. The CJEU found that the directive at issue indeed pursued health policy goals that went beyond internal market goals and that “national measures affected are to a large extent inspired by public health policy objectives”, while “[t]he first indent of [then] Article 129(4) of the Treaty excludes any harmonisation of laws and regulations of the Member States designed to protect and improve human health.”²⁷ As has been shown above in paragraph 6.6, public health policy objectives by means of harmonisation

²⁴ This is a reference to the Passau Opinion.

²⁵ DRAFT REPORT on the proposal for a regulation of the European Parliament and of the Council on in vitro diagnostic medical devices (COM(2012)0541 – C7-0317/2012 – 2012/0267(COD)), p. 59-60

²⁶ C-376/98 *Germany v Parliament and Council*, ECR 2000 Page I-8419, points 77-79.

²⁷ C-376/98 *Germany v Parliament and Council*, ECR 2000 Page I-8419, points 76-77.

of regulations of the Member States designed to protect and improve human health are precisely what the Rapporteur envisages with the proposal.

- 6.11 This principle has not changed since then. While the first indent of Article 168(4) TFEU has been altered somewhat by addition of the derogation to Articles 2(5) and 6(a) TFEU, this only underlines the use of Article 168(4) TFEU additional legal basis, as described above. The Lisbon Treaty has not altered the fundamental principle set out in the *Germany v Parliament and Council* case that Article 114 in conjunction with Article 168(4) TFEU does not provide for an unrestricted legal basis to legislate in any health policy matter in the EU internal market. Instead, Article 168(4) is very specific in that Article 168 TFEU can only be relied on as a legal basis for adopting measures to (1) meet common safety concerns and (2) set high standards for quality and safety of medical devices.
- 6.12 In conclusion, the objectives pursued by Article 168(4) TFEU cannot be relied on to circumvent the limitations of attribution of scope provided by it. There is no general competence for the EU to pursue a health policy by legislating in internal market matters.
- 6.13 Even if the scope of Article 168(4) TFEU allowed legislation in the scope of the practice of medicine (which we argue above it does not), the competence of the EU is further limited by the principle of subsidiarity in Article 5 TFEU, because this principle also limits the competence of the EU to legislate in the internal market in areas of shared competence. In this light the CJEU has held in a similar matter (the 2nd *Tobacco Advertising Directive* case²⁸) that it must first be considered whether the objective of the proposed action can be better achieved at Community level, and second, whether the intensity of the action undertaken does not go beyond what is necessary to achieve the objective pursued.
- 6.14 In this case the objective of the measure is to regulate modalities of genetic counselling in the Member States. The difference in genetic counselling practices do however not lead to any barriers to trade that need to be addressed at an EU level. Instead, the Rapporteur argues that the need to legislate in this respect does not have anything to do with the circulation of genetic testing IVDs (e.g. prohibitions to use them in particular Member States) but is purely limited to considerations of health policy. The Member States are perfectly capable to address this at national levels, taking account the differences in the field of practice of medicine between them. Therefore, there are no arguments why it is better to address this at an EU level. The only justification given is that

²⁸ C-491/01 paras 179-184.

“To respect the principle of subsidiarity it should be left to the Members States to regulate the details and member states should have the option to go further than the regulation requires.”²⁹

6.15 The Parliament does not provide any justification to support why this would be better regulated at EU level. Instead, the argument amounts to simply appropriating the competence and then arguing that subsidiarity is respected because Member States are allowed to decide on the details of implementation. This is clearly not how the EU and the Member States intend the principle of subsidiarity to work because this interpretation renders the principle of subsidiarity illusory.

6.16 Subsidiarity in the field of practice of medicine is underlined by the fact that the European Commission considers procedural aspects of informed consent to be an intrinsically national ethical aspect. In its discussion of the new regime for clinical studies with IVDs set out in the IVD Regulation Proposal, which should be dealt with on national level the Commission states that:

“As a consequence, the health and safety-related aspects regarding the device for performance evaluation will be assessed by the Member States concerned under the direction of a coordinating Member State. The assessment of intrinsically national, local and ethical aspects (e.g. liability, suitability of the investigators and clinical performance studies sites, informed consent), will however, need to be carried out at the level of each Member State concerned which will retain the ultimate responsibility for deciding whether the clinical performance study may be conducted on its territory.”³⁰

6.17 The proposal of the Parliament does not provide any justification as to why informed consent cannot be achieved on a national level and it does not in any way refute the Commission’s finding that informed consent is a national matter.

6.18 Furthermore, as second leg of the subsidiarity principle, prescribing the exact procedure for use of a genetic test by regulation clearly goes beyond what is necessary to achieve the purpose of harmonising informed consent to genetic testing. As is clear from other EU instruments that also involve informed consent in healthcare, no other instrument is so prescriptive in the informed consent procedure requirements. It follows that the EU does not need to prescribe informed consent procedures in the level of detail that it does in the IVD Regulation Proposal.

²⁹ Draft Report on the proposal for a regulation of the European Parliament and of the Council on *in vitro* diagnostic medical devices. (COM(2012)0541 – C7-0317/2012 – 2012/0267(COD)), p. 60.

³⁰ Proposal, explanatory memorandum, p. 8 (§ 3.6).

7. Competence to legislate on bioethical matters

7.1 Schweitzer and Kamann express the view that the jurisprudence of the CJEU has expanded, having

“...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.”

Although the cases they refer to did not in fact invoke the Charter, they are correct in stating that the Court undertook

“...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.”³¹

7.2 However, for reasons appearing below, the authority of these “answers” is far less than the authors of the Passau Opinion suggest. For the reasons set out below, the Union’s competence to produce bioethical legislation is restricted in a way that would prevent it from producing legislation of the type proposed in the Passau Opinion (see section 4.1 above) and currently appearing in the Liese Amendments.

7.3 The TEU comprehensively binds all EU Member States. Article 6(1) TEU confirms that Member States are as obliged to respect human rights as the Treaties themselves:

“The Union recognises the rights, freedoms and principles set out in the Charter of Fundamental Rights of the European Union³²... which shall have the same legal value as the Treaties....

The rights, freedoms and principles in the Charter shall be interpreted in accordance with the general provisions in Title VII of the Charter governing its interpretation and application and with due regard to the explanations referred to in the Charter, that set out the sources of those provisions.”

7.4 The subject of Title I of the Charter is “Dignity”. Dignity is the overarching principle under which subsist the rights in Articles 2 (“Right to life”) and 3 (“Right to integrity of the person”) and the freedoms in Articles 4 (“Prohibition of torture and inhuman or degrading treatment or punishment”), and 5 (“Prohibition of slavery and forced labour”). The principle is introduced as follows:

³¹ Section 3, I (4), (b), (3).

³² Charter of Fundamental Rights of the European Union (2010/C 83/02).

“Human dignity is inviolable. It must be respected and protected.”³³

- 7.5 The Passau Opinion makes no reference to the fact that Article 6(1) of the Charter also sets out the rules under which the Union must interpret it. To a considerable extent, this explains the Passau Opinion’s misleadingly liberal reading of the Charter and its potential application.

8. Interpreting the Charter of Fundamental Rights

- 8.1 Title VII of the Charter begins by establishing, in Article 51, its field and, in Article 52, its scope.

- 8.2 Article 51 provides that:

“1. The provisions of this Charter are addressed to the institutions, bodies, offices and agencies of the Union with due regard for the principle of subsidiarity and to the Member States only when they are implementing Union law. They shall therefore respect the rights, observe the principles and promote the application thereof in accordance with their respective powers and respecting the limits of the powers of the Union as conferred on it in the Treaties.

2. The Charter does not extend the field of application of Union law beyond the powers of the Union or establish any new power or task for the Union, or modify powers and tasks as defined in the Treaties.”

- 8.3 This clear limitation by reference to the principle of subsidiarity (discussed above in section 5.2) and the limits of Union power is again ignored in the Passau Opinion.

- 8.4 Article 52 provides more detail of the extent to which Charter rights and freedoms can be limited. Here is its first paragraph:

“(1) Any limitation on the exercise of the rights and freedoms recognised by this Charter must be provided for by law and respect the essence of those rights and freedoms. Subject to the principle of proportionality, limitations may be made only if they are necessary and genuinely meet objectives of general interest recognised by the Union or the need to protect the rights and freedoms of others...”

- 8.5 Paragraph 1 of Article 52, which confirms the pre-eminence of the principle of proportionality (discussed above in section 5.2), is based on case-law of the Court of Justice, holding that restrictions on the exercise of rights are lawful if they “...do not constitute, with regard to the aim pursued, disproportionate and unreasonable interference undermining the very substance of those rights...”³⁴ and either correspond to objectives of general interest pursued by the Community (notably under Article 3 TEU) or “the

³³ Charter, Article 1.

³⁴ Paragraph 45, *Kjell Karlsson & Others* Case C-292/97.

need to protect the rights and freedoms of others” (i.e. non-EU rights and freedoms).

- 8.6 Paragraph 3 of Article 52 then limits the scope of the Charter to the confines of the Convention and its Protocols:

“in so far as this Charter contains rights which correspond to rights guaranteed by the Convention for the Protection of Human Rights and Fundamental Freedoms, the meaning and scope of those rights shall be the same as those laid down by the said Convention. This provision shall not prevent Union law providing more extensive protection.”

- 8.7 The Explanations referred to in Article 6(1) TEU (see section 10.3) make an important qualification:

“The meaning and the scope of the guaranteed rights are determined not only by the text of those instruments, but also by the case-law of the European Court of Human Rights.”

- 8.8 This significantly undermines the view of the Passau Opinion that the Union’s legislature is competent to legislate in ethical matters relating to the life sciences. The ECHR has repeatedly emphasised that it must allow Member States a “margin of appreciation” in applying and interpreting fundamental rights. In its judgment in *Evans v United Kingdom*³⁵, the Court’s Grand Chamber set out its rationale as follows:

“A number of factors must be taken into account when determining the breadth of the margin of appreciation to be enjoyed by the State in any case under Article 8. Where a particularly important facet of an individual’s existence or identity is at stake, the margin allowed to the State will be restricted.... Where, however, there is no consensus within the member States of the Council of Europe, either as to the relative importance of the interest at stake or as to the best means of protecting it, particularly where the case raises sensitive moral or ethical issues, the margin will be wider... There will also usually be a wide margin if the State is required to strike a balance between competing private and public interests or Convention rights.”

- 8.9 The Charter therefore requires the Union to respect that margin of appreciation in the manner prescribed by ECHR case-law.

9. European Convention on Human Rights

- 9.1 Besides the obligations under the Charter, Article 6(2) TEU provides that the European Union shall accede to the European Convention. A draft accession agreement has been drawn up.

³⁵ (Grand Chamber). Application no. 6339/05, 10 April 2007.

- 9.2 Further, in the Brighton Declaration of April 2012, Convention states agreed a Protocol to the European Convention, Protocol 15, which amends it so as to emphasise the principles of subsidiarity and of the margin of appreciation discussed above. As amended, the Preamble to the Convention now includes a recital that states:

“Affirming that the High Contracting Parties, in accordance with the principle of subsidiarity, have the primary responsibility to secure the rights and freedoms defined in this Convention and the Protocols thereto, and that in doing so they enjoy a margin of appreciation, subject to the supervisory jurisdiction of the European Court of Human Rights established by this Convention,”

- 9.3 On 6 February 2013, the ECHR adopted an Opinion on the then draft Protocol 15, which confirmed that:

“The intended meaning can therefore be said to be in line with the relevant terms of the Brighton Declaration (in particular paragraph 12b, read along with paragraphs 10, 11 and 12a)...

The other principle that is referred to in the proposed new paragraph is subsidiarity. This having been a fundamental theme of the reform of the process, the insertion of a reference to it in the Convention is to be welcomed. The wording used in this respect, and in the explanatory report, reflects the Court’s pronouncements on the principle.”

- 9.4 The paragraphs of the Brighton Declaration referred to in the Court’s Opinion state:

“10. The States Parties to the Convention are obliged to secure to everyone within their jurisdiction the rights and freedoms defined in the Convention, and to provide an effective remedy before a national authority for everyone whose rights and freedoms are violated. The Court authoritatively interprets the Convention. It also acts as a safeguard for individuals whose rights and freedoms are not secured at the national level.

11. The jurisprudence of the Court makes clear that the States Parties enjoy a margin of appreciation in how they apply and implement the Convention, depending on the circumstances of the case and the rights and freedoms engaged. This reflects that the Convention system is subsidiary to the safeguarding of human rights at national level and that national authorities are in principle better placed than an international court to evaluate local needs and conditions. The margin of appreciation goes hand in hand with supervision under the Convention system. In this respect, the role of the Court is to review whether decisions taken by national authorities are compatible with the Convention, having due regard to the State’s margin of appreciation.

12. *The Conference therefore:*

a) *Welcomes the development by the Court in its case law of principles such as subsidiarity and the margin of appreciation, and encourages the Court to give great prominence to and apply consistently these principles in its judgments;*"

9.5 On 24 June 2013, Protocol 15 was signed by twenty-one Convention states.

9.6 The Council of Europe's Explanatory Report to Protocol 15 states that this amendment is:

"... intended to enhance the transparency and accessibility of these characteristics of the Convention system and to be consistent with the doctrine of the margin of appreciation as developed by the Court in its case law."

9.7 In particular, the Report states that:

"The jurisprudence of the Court makes clear that the States Parties enjoy a margin of appreciation in how they apply and implement the Convention, depending on the circumstances of the case and the rights and freedoms engaged. This reflects that the Convention system is subsidiary to the safeguarding of human rights at national level and that national authorities are in principle better placed than an international court to evaluate local needs and conditions. The margin of appreciation goes hand in hand with supervision under the Convention system. In this respect, the role of the Court is to review whether decisions taken by national authorities are compatible with the Convention, having due regard to the State's margin of appreciation."

9.8 Just as Article 6(2) TEU and the Charter Explanations emphasise, for purposes of EU law, the pre-eminence of the European Court of Human Rights, (see section 8.7), so the Preamble to Protocol 15 to the European Convention confirms the pre-eminence of the ECHR in protecting human rights in Europe.

"Considering the need to ensure that the European Court of Human Rights (hereinafter referred to as "the Court") can continue to play its pre-eminent role in protecting human rights in Europe,"

9.9 Although the Protocol (and, by extension, the amendments to the Convention) will not enter into force until all Convention states have agreed to be bound, there is no reason to believe that this will not take place. Moreover, on the basis of signatures collected to date, it is clear already that most EU Member States³⁶ support the constitutional principles of subsidiarity and the margin of appreciation. For this reason,

³⁶ Austria, Cyprus, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom.

the “*due regard*” to the Charter Explanations, the decisions of the ECHR and the principles of subsidiarity and margin of appreciation demanded of the EU legislature under Article 6(2) TEU will be considerable.

10. Human dignity is a right of persons

10.1 The authors of the Passau Opinion state that, in certain leading cases, the CJEU had

*“...attached central importance to the fundamental rights to human dignity and integrity of the person, also for prenatal life”*³⁷.

10.2 The word “*also*” is used in a way that suggests that prenatal life has dignity and integrity under the law of the European Union. It does not.

10.3 The “**Explanations**”³⁸ referred to in Article 6(1) TEU and in Charter Article 52(7) state in connection with Charter Article 1 (see section 7.4):

“The dignity of the human person is not only a fundamental right in itself but constitutes the real basis of fundamental rights. The 1948 Universal Declaration of Human Rights enshrined human dignity in its preamble: ‘Whereas recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world.’...”

10.4 This is an important constitutional statement. It confirms that, as with the Convention, the source of Charter Article 1 is the Universal Declaration of Human Rights of 1948 (the “Declaration”), Article 1 of which states:

“All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood.”

10.5 It is therefore clear from the Charter, the Explanations and the Declaration³⁹ that insofar as human dignity is a right under the law of the European Union, it is limited to persons. Birth, reason and conscience are prerequisites of the dignity right. It does not extend to potential persons. This matter is addressed further in section 11 in relation to the jurisprudence of the CJEU.

³⁷ Section 3, I (4), (b), (3).

³⁸ Explanations to the Charter of Fundamental Rights (2007/303/02).

³⁹ As well as the case law of the European Court of Human Rights.

11. **The jurisprudence of the European Court of Justice/Court of Justice of the European Union is constrained by the Charter**

11.1 The Passau Opinion contends that in two cases, *Netherlands v European Parliament*⁴⁰ and *Council and Brüstle v Greenpeace*⁴¹, the CJEU has extended its jurisprudence in the field of genetics and reproductive medicine and, with it, the reach of EU law⁴². In fact, these cases did no more than confirm an existing legal position. As the Explanation to Charter Article 1 puts it:

“In its judgment of 9 October 2001 in Case C-377/98 Netherlands v European Parliament and Council [2001] ECR I-7079, at grounds 70 - 77, the Court of Justice confirmed that a fundamental right to human dignity is part of Union law...”

11.2 In the *Netherlands* case, which, like *Brüstle*, concerned the *Biotechnology Directive*⁴³, the CJEU stated that:

*“As regards respect for human dignity, this is guaranteed in principle by Article 5(1) of the Directive which provides that the human body at the various stages of its formation and development cannot constitute a patentable invention.”*⁴⁴

11.3 It is clear from this that human dignity cannot arise before formation of the human body. The point of bodily formation, a matter of scientific fact, not law, is therefore critical. As the Advocate General in *Brüstle v Greenpeace* stated:

*“... only legal analyses based on objective scientific information can provide a solution which is likely to be accepted by all the Member States”*⁴⁵

11.4 Unfortunately, however, the “*objective scientific information*” upon which *Brüstle* was based was remarkably slender: without expert embryological evidence being adduced on the formation question, the Advocate General was made a scientific determination *ex cathedra*⁴⁶. Unfortunately, his suppositions, which were relied on by the Court, did not coincide with

⁴⁰ Case C-377/98, 9 October 2001 [2001] ECR I-7079.

⁴¹ Case 34/10.

⁴² Passau Opinion, Section 3(4), page 14.

⁴³ Directive 98/44 of the European Parliament and Council of 6 July 1998 on the legal protection of biotechnological inventions.

⁴⁴ *Case C-377/98 Netherlands v European Parliament and Council [2001] ECR I-7079, para 71.* Article 5(1) of the Directive 98/44, to which the judgment refers, does not in fact refer to human dignity. The “dignity” reference in Recital 38 of the Directive is to processes, which are the subject of Article 6, whereas Article 5 concerns products. The CJEU also suggested, *obiter*, that dignity could be a quality of non-persons, but these remarks, made without explanation or justification, cannot not be seen as a statement of law and are incompatible with its statement on Article 5 of the Directive: there can be no person without a body.

⁴⁵ Paragraphs 47 and 48, Case 34/10.

⁴⁶ Paragraphs 72 to 85 highlight his confusion and lack of evidence starkly.

scientific fact. This has cast serious doubt over the jurisprudential value of the case and is now the subject of a further reference to the CJEU⁴⁷.

- 11.5 It suffices to observe that the points at which the body forms, prior to its development, can be identified with great precision as a result of the Nobel Prize winning work of Edward Lewis, Christiane Nüsslein-Volhard and Eric Wieschaus. They identified the genes that are essential to the formation of all bodies, including the formation of its head-to-tail axis, segmentation and the specialization of segments into different organs. These “Hox” genes are shared by all creatures with a body plan, from flies to mice to cod to cardinals⁴⁸ and may be transplanted between very distant species with no effect whatsoever. Until the Hox genes become active, no body can form. Indeed, even without consideration of the Hox genes, it is a basic tenet of embryology that, prior to gastrulation⁴⁹, there is no body. As Anne McLaren, the only scientist member of the Warnock Committee⁵⁰ remarked,

*“If one tries to trace back further than that there is no longer a coherent entity. Instead there is a larger collection of cells, some of which are going to take part in the subsequent development of the embryo and some which aren't.”*⁵¹

- 11.6 The CJEU’s failure to base its legal analysis upon “*objective scientific information*” on this and other scientific issues essential to the proper interpretation of Directive 98/44 has led to the following question being asked of the Court in *International Stem Cell Corporation v Comptroller General of Patents*⁵²:

“Are unfertilised human ova whose division and further development have been stimulated by parthenogenesis, and which, in contrast to fertilised ova, contain only pluripotent cells and are incapable of developing into human beings included in the term “human embryos” in Article 6(2)(c) of Directive 98/44/EC on the Legal Protection of Biotechnological Inventions?”

- 11.7 Because *Brüstle* was not based on the “*objective scientific information*” required by the Court’s own Advocate General, the alleged dignity of pre-

⁴⁷ *International Stem Cell Corporation v Comptroller General of Patents* (Case C-364/13).

⁴⁸ In the 19th century, Von Baer noted that all vertebrate embryos begin with the same plan. The Nobel laureates vindicated the “absurd” contemporary hypothesis of Geoffroy Saint-Hilaire; that vertebrates have an upside-down version of an invertebrate body plan.

⁴⁹ Gastrulation is the event at which invagination of a spherical single layer of cells gives rise to a two-layered sac of ectoderm and endoderm. Lewis Wolpert famously observed that, “*It is not birth, marriage, or death, but gastrulation which is truly the most important time in your life.*”

⁵⁰ The Warnock Committee’s legislative proposals were adopted in the UK’s *Human Fertilisation & Embryology Act 1990*.

⁵¹ A. McLaren, ‘Prelude to Embryogenesis’ in CIBA Foundation’s, *Human Embryo Research: Yes or No?* (1986).

⁵² Case C-364/13: reference made on 28 June 2013.

gastrulation embryos (which not only lack bodies but are not legal persons, should be considered to be doubtful⁵³.

- 11.8 Although the CJEU reached its decision on the basis of an inherent jurisdiction circumscribed by *Netherlands*, it had no competence to extend the reach of dignity beyond that which is permitted under the TEU and the Charter. Its power to create new rights, freedoms and principles was limited to the scope of the Charter. Indeed, Article 6(1) TEU also states:

*“The provisions of the Charter shall not extend in any way the competences of the Union as defined in the Treaties.”*⁵⁴

- 11.9 Member States are accordingly obliged, in implementing *Brüstle v Greenpeace*⁵⁵, to “respect the rights, observe the principles and promote the application [of the Charter] in accordance with their respective powers and respecting the limits of the powers of the Union as conferred on it in the Treaties”⁵⁶. In short, no EU Member State can apply *Brüstle v Greenpeace* further than the Charter permits it to do pursuant to Article 6 TEU.

- 11.10 To allay concerns about the extent of the Charter raised by Poland and the United Kingdom during the negotiation of the Lisbon Treaty, a Protocol was added stating that:

*“The Charter does not extend the ability of the Court of Justice of the European Union, or any court or tribunal of Poland or of the United Kingdom, to find that the laws, regulations or administrative provisions, practices or action of Poland or of the United Kingdom are inconsistent with the fundamental rights, freedoms and principles that it reaffirms.”*⁵⁷

- 11.11 Even if, contrary to this analysis, fertilised ova were to be construed as human persons endowed with a dignity right, such a right could not lawfully prevail over the rights of real legal persons. This is because the Charter does not permit any person, even and especially the Union itself, to curtail existing human rights. As Article 54 states:

“Nothing in this Charter shall be interpreted as implying any right to engage in any activity or to perform any act aimed at the destruction of any of the rights and freedoms recognised in this Charter or at their limitation to a greater extent than is provided for herein.”

⁵³ Although *Brüstle* was decided on the basis of the Court’s inherent jurisdiction under the *Netherlands* case, but the Explanations ensure that the same result would follow if it had been decided on the basis of the Charter.

⁵⁴ Article 51 provides that the Charter “does not extend the field of application of Union law beyond the powers of the Union or establish any new power or task for the Union...”

⁵⁵ Case C-34/10, 10 March 2011.

⁵⁶ Charter, Article 51.

⁵⁷ Protocol on the Application of the Charter of Fundamental Rights of the European Union to Poland and to The United Kingdom; Article 1. See also *Secretary of State for the Home Department v ME and others* (21 December 2011).

- 11.12 As the Explanations to Article 1 of the Charter more particularly state, as a consequence of the considerations set out in section 11.1,

“It results that none of the rights laid down in this Charter may be used to harm the dignity of another person, and that the dignity of the human person is part of the substance of the rights laid down in this Charter. It must therefore be respected, even where a right is restricted.”

- 11.13 EU human rights law therefore seriously undermines the claimed reach of *Brüstle*. Plainly, degenerative disease threatens the dignity and integrity of everyone: in *Brüstle*, the cells in question were intended to restore the bodily integrity of real persons so as to protect their human dignity. The Charter ensures that the dignity and integrity rights of real human persons guaranteed under Charter Articles 1 and 3 outweigh any claimed dignity or integrity rights of *in vitro* blastocysts. Consequently, the case cannot be used to deny their legitimate interest in statutory incentives directed at securing such rights⁵⁸. The judgment can, therefore, only be applied to the extent that it does not harm these interests. Still less may the legislature act to suppress the rights of EU citizens.

12. ***Brüstle* is limited by the World Trade Organisation Agreement**

- 12.1 *Brüstle v Greenpeace* was referred to the CJEU to clarify the meaning of only one clause, Article 6(2)(c), of the *Biotechnology Directive*⁵⁹. The judgment must therefore be read subject to the remaining provisions of the Directive.
- 12.2 The Passau Opinion ignores the overarching provisions determining the Directive’s scope. For the reasons set out below, provisions in the Directive concerning international obligations severely limit the actual extent of the CJEU’s decision in *Brüstle* and of the Union legislature to follow it.
- 12.3 Notable among these obligations are those under the Agreement on Trade-Related Aspects of Intellectual Property Rights (“**TRIPS**”), which appears in Annex 1C to the Agreement Establishing the World Trade Organisation (the “**WTO Agreement**”).
- 12.4 The European Community and its Member States concluded the WTO Agreement, on the basis of joint competence, on 25 April 1994. Following approval by the EU Council on 22 December 1994⁶⁰, TRIPS

⁵⁸ The patent system exists to encourage the free public availability of technologies for human benefit.

⁵⁹ Directive 98/44EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.

⁶⁰ Decision 94/800 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994).

became an integral part of the Community legal order⁶¹. The Court acquired the competence to give preliminary rulings on its interpretation⁶², and has stated that if Union rules exist in a field to which TRIPS applies, then the rule in question

“will have to comply with the rules concerning the availability, scope and use of intellectual property rights in the TRIPS Agreement”⁶³.

12.5 As the Advocate General put it in *Monsanto Technology LLC v Cefetra BV*,

“It is clear that, in these circumstances, the most effective interpretative method, if conflicts between Directive 98/44 and the TRIPS Agreement are to be avoided, is to interpret the directive as far as possible in a manner consistent with the provisions of the TRIPS Agreement.”⁶⁴

12.6 Turning to the *Biotechnology Directive*, Article 1 states:

“This Directive shall be without prejudice to the obligations of Member States pursuant to international agreements, in particular the TRIPS Agreement...”

12.7 Commenting in *Monsanto Technology LLC v Cefetra BV*, the Advocate General stated:

“Article 1 of Directive 98/44 expressly provides that the provisions of the directive are without prejudice to the obligations imposed on Member States under the TRIPS Agreement. This means that the legislature took the view that there was nothing in Directive 98/44 which was incompatible with the international treaty in question: in any event, it follows from the express safeguard clause laid down in Article 1 of the directive that a Member State can never be accused of infringing Directive 98/44 where, by its conduct, that Member State is seeking to comply with its obligations under the TRIPS Agreement.”⁶⁵

12.8 *Brüstle’s* reading of Article 6(2)(c) of the *Biotechnology Directive* is therefore severely constrained by TRIPS obligations that the same directive seeks to secure in its opening provision. If Union institutions or Member States fail to respect these limitations on the effect of the judgment, they will not only be susceptible to dispute resolution proceedings under Annex 2 of the WTO Agreement⁶⁶, with the risk of trade tariffs being raised by

⁶¹ See, inter alia, *IATA & ELFAA* (Case C-344/04) para 36, and *Commission v Ireland* (Case C-459/03), paragraph 82).

⁶² Para 31, *Merck Genéricos - Produtos Farmacêuticos Lda v Merck & Co. Inc., Merck Sharp & Dohme Lda*, (Case C-431/05) 11 September 2007.

⁶³ Para 67, *Daiichi Sankyo v Sanofi-Aventis Deutschland* (C-414/11), 18 July 2013.

⁶⁴ Paras 71 & 72, *Monsanto Technology LLC v Cefetra BV, Cefetra Feed Service BV, Cefetra Futures BV, Alfred C. Toepfer International GmbH*, (Case C-428/08), Opinion of 9 March 2010.

⁶⁵ Paras 71 & 72, *Monsanto Technology LLC v Cefetra BV, Cefetra Feed Service BV, Cefetra Futures BV, Alfred C. Toepfer International GmbH*, (Case C-428/08), Opinion of 9 March 2010.

⁶⁶ Understanding on rules and procedures governing the settlement of disputes; Joseph Straus, *GRURInt* 2011, p. 148, 149.

objecting states, but will breach Article 1 of the Directive itself. Although individuals cannot rely directly upon Community law to enforce rights under TRIPS⁶⁷, they are entitled to redress for loss and damage for rights assured by a Directive but denied by a Member State.⁶⁸

- 12.9 The weakness of the decision is yet more apparent given that Article 24(1) TEU provides that the CJEU has no jurisdiction with respect to common foreign policy. For these reasons, the decision must be read subject to international obligations and it will be “*necessary, as far as may be possible, to supply an interpretation in keeping with the TRIPS Agreement*”⁶⁹. As will be shown below, this severely restricts the actual impact of *Brüstle*.

Article 27 of TRIPS

- 12.10 Under “Section 5: Patents”, Article 27(1) of TRIPS states:

*“... patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. [P]atents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.”*⁷⁰

- 12.11 On this basis, WTO Member States have a clear obligation to offer patent protection to human embryo derived inventions that meet the fundamental criteria of novelty, inventiveness and industrial applicability. However, the words above are “*Subject to the provisions of paragraphs 2 and 3...*”. If these apply, WTO Member States would *not* be obliged to offer such patents. Paragraph 3 sets no obstacle, but paragraph 2 of Article 27 states:

“Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.”

- 12.12 As the opening words make clear, this exception cannot apply unless the WTO member exercises its option to do so. The European Union does so under Article 6(1) of the Directive, which states:

⁶⁷ Para 44 of joined cases, *Christian Dior SA v Tuk Consultancy BV (C-300/98)* and *Assco Gerüste GmbH, Rob van Dijk v Wilhelm Layher GmbH & Co.KG, Layher BV (C-392/98)*, 14 December 2000.

⁶⁸ Paras 38-46, *Francovich & Others v Italian State (Cases C-6/90 and C-9/90)*,

⁶⁹ Para 72, *Monsanto Technology LLC v Cefetra BV, Cefetra Feed Service BV, Alfred C. Toepfer International GmbH, (Case C-428/08)* 6 July 2010. Para 35, *Merck Genéricos - Produtos Farmacéuticos Lda v Merck & Co. Inc., Merck Sharp & Dohme Lda, (Case C-431/05)* 11 September 2007.

⁷⁰ Article 27(3) concerns exclusions from patentability that are not relevant here.

“Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.”

12.13 Article 6(2) then particularises “uses of human embryos for industrial or commercial purposes” as being unpatentable on this basis.

12.14 As the CJEU itself in *Daiichi Sankyo v Sanofi-Aventis Deutschland* states, Article 27(2) TRIPS allows WTO members

“to exclude from patentability inventions the prevention of whose commercial exploitation is necessary for overriding reasons of the public interest”.⁷¹

12.15 In the midst of the translation from Article 27(2) of TRIPS to Article 6(1) of the Biotechnology Directive, the precondition of necessity was discarded. However, because Article 6(1) is in a field to which TRIPS applies⁷², a court must “as far as may be possible... supply an interpretation in keeping with the TRIPS Agreement”⁷³. Unless the invisible necessity criterion is read into Article 6, the European Union will be in breach of its obligations under the World Trade Organisation Agreement.

12.16 This leaves a simple test of any decision under Article 6 concerning the uses of “human embryos”; namely, “is it necessary to prevent the commercial exploitation of inventions relating to uses of human embryos for industrial or commercial purposes?”

Lack of necessity

12.17 As a matter of fact, it is *not* necessary to prevent the commercial exploitation of human embryo derived inventions in any EU Member State, whether to protect *ordre public*, morality or anything else. Even if commercialisation of hESC products were to be criminalised in a particular EU Member State, any patent exemption would still require proof that it was contrary to *ordre public* or morality in that territory: mere illegality is insufficient under Article 27 (2) of TRIPS⁷⁴.

12.18 It is also a matter of fact that EU law expressly allows for, and encourages, the commercialisation of such products. Indeed, it endows hESC products with exclusive rights that are very much more powerful and effective than any patent. As one commentator has observed,

⁷¹ Para 67, *Daiichi Sankyo v Sanofi-Aventis Deutschland* (C-414/11), 18 July 2013.

⁷² Para 47 of joined cases, *Christian Dior SA v Tuk Consultancy BV* (C-300/98) and *Assco Gerüste GmbH, Rob van Dijk v Wilhelm Layher GmbH & Co.KG, Layher BV* (C-392/98), 14 December 2000

⁷³ Para 35, *Merck Genéricos - Produtos Farmacéuticos Lda v Merck & Co. Inc., Merck Sharp & Dohme Lda*, (Case C-431/05) 11 September 2007.

⁷⁴ And Article 6(1) of the Biotechnology Directive.

“Not only does EU law outside patent law not prohibit activities involving uses of human embryos including their destruction, but EU law specifically envisages and regulates the use of human embryonic tissues in the industrial production of therapeutic products, as well their marketing and commercialisation in Europe. In general, hESC-based products may be made on an industrial scale and commercialized in Europe irrespective of whether the activities involved destruction of human embryos.”⁷⁵

- 12.19 Any claim that it is “*necessary*” to ban hESC patents in order to uphold *ordre public* or morality is immediately punctured by the *EU Directives on Human Tissue and Cells* (“EUTCD”), which since 2004 have provided a clear legislative framework for the clinical use of human embryo derived products in the EU⁷⁶.
- 12.20 The claim, inferred in the Passau Opinion’s reading of *Brüstle*, that a clinical use sanctioned by Europe’s highest legislature is immoral is, therefore, ludicrous. In principle, such clinical use could be wholly non-commercial, in which case a patent ban would be prohibited even if such use did happen to be immoral⁷⁷.
- 12.21 However, a further piece of legislation actively encourages the commercialisation of hESC related products across the EU. The Advanced Therapy Medicinal Products Regulation⁷⁸ (“ATMP Regulation”) reprograms the Union’s Medicinal Products Directive⁷⁹ and Medicinal Products Regulation⁸⁰ so as to bring hESC-derived products into the EU regime for licensing medicinal products. The Directive now specifically applies to hESC-derived

*“... medicinal products for human use intended to be placed on the market in Member States and either prepared industrially or manufactured by a method involving an industrial process”.*⁸¹

⁷⁵ Towards Systemic Legal Conflict: Article 6(2) of the EU Directive on Biotechnological Inventions, Aurora Plomer; page 180, *Embryonic Stem Cell Patents: European Patent Law and Ethics*, OUP 2009.

⁷⁶ The EUTCD comprise three directives: Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells [2004] OJ L102, and two technical directives; Directive 2006/17/EC and Directive 2006/86/EC. See Directive 2004/23; Recital 7 of the Directive 2004/23 states “This Directive should apply to ... embryonic stem cells”.

⁷⁷ Because the potential exclusion under Article 27(2) is limited to commercial uses. The CJEU held research purposes involving research and clinical use to be commercial if they are covered by a patent, i.e. even if non-commercial clinical use is allowed, patentability could be excluded. However, where there is *no* patent over such use, the practice is not prohibited and may be part of a fee-for-service arrangement. Consequently, it cannot be “*necessary*” to prevent it.

⁷⁸ Regulation 1394/2007 of the European Parliament and Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83 and Regulation (EC) No 726/2004.

⁷⁹ Directive 2001/83 EC of the European Parliament and Council of 6 November 2001 on the Community code relating to medicinal products for human use.

⁸⁰ Regulation (EC) No 726/2004.

⁸¹ Article 2(1), Directive 2001/83.

- 12.22 The inclusion of hESC-derived products within a regime for marketing medicinal products is not an accident. During the passage of the ATMP Regulation, the Parliamentary Committee for Legal Affairs tried to exclude human embryonic cells from the scope of the Regulation. Had the Committee succeeded, the ATMP Regulation would have included this restriction:

“This Regulation shall not apply to advanced therapy medicinal products that contain or are derived from human embryonic or foetal cells, primordial germ cells or cells derived from those cells.”⁸²

- 12.23 The European Parliament roundly defeated this proposal. However, recognising, as the CJEU in *Brüstle v Greenpeace* would later fail to do, the “margin of appreciation” (see section 8.8 et seq.) of EU Member States, the Parliament and Council allowed objecting Member States to opt out of the Regulation as regards hESCs in their part of the EU:

“The regulation of advanced therapy medicinal products at Community level should not interfere with decisions made by Member States on whether to allow the use of any specific type of human cells, such as embryonic stem cells. It should also not affect the application of national legislation prohibiting or restricting the sale, supply or use of medicinal products containing, consisting of or derived from these cells.”⁸³

- 12.24 Manifestly, given that the EU has expressly encouraged the commercial therapeutic use of stem cells, it is not “necessary” to prevent it on the grounds of *ordre public*, morality or anything else, except perhaps in those states⁸⁴ where it is not only illegal but either immoral or could lead to problems of public order. Of course, the ATMP regulation only applies to therapeutic uses. In principle, commercialisation of hESC-derived products for non-therapeutic purposes (for example, in drug testing) remains exposed to a ban, although it would be hard to justify such a distinction: how could a use that is moral for direct clinical use (cell therapy) be deemed immoral for an indirect one? Given that the legislator decided to promote therapeutic purposes, it can hardly have meant to declare non-therapeutic purposes as immoral.

Non-patent rights

- 12.25 The fact that a ban on patenting is unnecessary, and therefore in breach of TRIPS, is made with particular force when it is understood that EU law provides an alternative vehicle for commercialising medicines that are derived from human embryonic cells that is not susceptible to

⁸² Ironically, if this proposed Amendment 17 had succeeded, such products could have been commercialised even more easily, as they would have been unregulated.

⁸³ Recital 7, ATMP Regulation.

⁸⁴ Should they exist.

objection on moral grounds. These non-patent rights are more valuable than patents and supplementary protection certificates. Their existence undermines the prohibition itself.

12.26 The exclusive rights in question arise as an incident of Article 10 of the *Medicinal Products Directive*⁸⁵, which provides that an applicant for an authorisation to market a hESC-derived medicinal product:

*“shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the medicinal product is a generic of a reference product which is or has been authorised under Article 6 for not less than eight years in a Member State or in the Community”*⁸⁶.

12.27 Eight years of data exclusivity on therapeutic cell lines is just the beginning. Article 10(1) adds a further two years of market exclusivity, with a further year if, during the first eight year period, the owner of the marketing authorisation for the reference medicinal product obtains one or more new therapeutic indications.

12.28 From this alone, it is clear that, irrespective of any patent or supplementary protection certificate in respect of the underlying invention, the holder of a marketing authorisation for a hESC-derived product has a substantial, guaranteed period of exclusivity over would-be generic products.

12.29 In fact, the period of exclusivity is far greater than the eleven years suggested by Article 10(1). While it is relatively easy to “*demonstrate that the medicinal product is a generic of a reference product*” when the reference product is a small molecule such as aspirin (180 Daltons), it becomes progressively harder to demonstrate bioequivalence as complexity (as indicated by molecular weight) increases, most obviously in the case of “biosimilars” of market-authorised biological medicinal products. Satisfying a regulator that a molecule is a generic of insulin (5,700 Daltons) is immensely expensive; a molecule of the scale of erythropoetin (34,000 Daltons) is even worse; and by the time molecular weight has reached that of a monoclonal antibody (about 150,000 Daltons), regulators are rejecting a significant proportion of applications on the basis of an inability to establish “bioequivalence” with the reference product. The requirement to provide data on pre-clinical tests and clinical trials, which applies when the raw materials or manufacturing processes of an aspiring generic differ from those of the reference product, presents a colossal obstacle to any aspiring biosimilar business. It is greater still in the case of cell therapies and other advanced therapy medicinal products, where “raw materials” will simply not be the same

⁸⁵ Directive 2001/83.

⁸⁶ Article 10(1).

and even trivial departures from the (unknown) manufacturing process lead to disproportionate product variances. In the case of cells, the size and complexity of the reference product is so vast (the molecular weight of a cell is of the order of 2,000,000,000,000,000 Daltons) that the likelihood of proving that one cell is the generic of another is effectively nil. With no incentive for a competitor to seek to incur the cost of proving bioequivalence, the monopoly enjoyed by the marketing authorisation holder for a cell line may effectively be unlimited. Of course, this would not prevent a competitor seeking to develop its own innovative ATMP with all of the attendant risks and costs. Furthermore, should anyone seek to put a product on the market without authorisation (obviously, they won't) the state would bear the legal costs of enforcement: a far cheaper and less risky option than attempting to enforce a patent.

- 12.30 In these circumstances, it is plainly untenable to suggest that it is “*necessary*” to ban limited monopolies in order to protect morality, but not unlimited ones.
- 12.31 Even if it were “*necessary*” to ban hESC products for industrial or commercial purposes, we can be certain that the European Parliament and Council did not intend the prohibition to extend to the patenting of products *derived from* the use of human embryos. As the United Kingdom observed in its Amicus Curiae Submission to the Enlarged Board of Appeal of the European Patent Office in *WARF*⁸⁷, the consensus between Member States extended only as far as preventing the patenting of uses of human embryos for industrial or commercial purposes.
- 12.32 This consensus, more limited in scope than has been subsequently represented, was achieved at a meeting of the Council of Ministers on 27 November 1997. It is well captured by the words of the Rapporteur to the European Parliament in the debate on the Biotechnology Directive, following which the Parliament voted in support of the Council's position:

“In relation to the use of embryos, the Council has set some limitations: they are not to be used for industrial or commercial purposes. But I would only ask you to remember that this was done with the United Kingdom in mind. We cannot as European legislators decree that something which does not contravene the underlying legal principles of all Member States is a contravention of public order, and we cannot brand something that we do not jointly regard as abhorrent as a

⁸⁷ Case G2/06, Wisconsin Alumni Research Foundation, paragraph 19.

*contravention of common decency. That is not acceptable!*⁸⁸

12.33 Lest there were any doubt over the matter, the European Parliament and Council voted to fund research using pre-gastrula human embryos under the EU's "Framework Seven" Programme, which aims to secure economic returns on European taxpayer investment⁸⁹. Finally, by permitting contracts to be made within Europe to grant licences over hESC patents granted outside Europe, the EU enables commercial exploitation, inside Europe, of inventions derived from human embryos.

12.34 Given that the Council of Ministers and European Parliament have passed laws to facilitate and encourage the development and commercial exploitation of human embryo derived inventions in Europe, it is plainly impossible to maintain that it is "necessary" for the European Union and its Member States to *prevent* it, whether the supposed purpose is that of protecting *ordre public*, morality or satisfying religious or environmental pressure groups.

In summary, the only legitimate basis for a prohibition on hESC patenting under Article 27(2) of TRIPS is where a particular EU Member State has blocked every opportunity to commercialise hESC-derived inventions in its territory on grounds of *ordre public* or morality. EU law⁹⁰ cannot therefore oblige Member States to breach Article 27(1) of TRIPS by requiring them to respect a gratuitous ban. Indeed, because *Brüstle v Greenpeace* can only be effective within the premises of TRIPS, those Member States whose courts and patent offices apply it more broadly may be liable to individuals and organisations whose TRIPS rights under Article 1 of the Biotechnology Directive have been denied to them. More seriously, they will be exposed to dispute settlement proceedings, brought by other WTO Member States, for breach of their obligations under Article 27(1) of TRIPS. Were a complaint by another WTO Member to be upheld, it could use it as a legitimate basis for raising trade tariffs on EU goods.

⁸⁸ <http://www.europarl.eu.int/debats/debats?FILE=98-0511&LANGUE=EN&LEVEL=DOC&GCSELECTCHAP=4&GCSELECTPERS=27>; quoted at paragraph 20 of the UK Amicus Brief, which adds, "See also to similar effect the comments by the Rapporteur to the Parliament's Committee on Legal Affairs and Citizens' Rights on the legal framework provided by the TRIPS Agreement within which the proposed Biotech Directive was being debated - A4-0222/97 – "*an invention whose industrial application is permitted can never be excluded from patentability*".

⁸⁹ In a draft Opinion to the European Parliament, its Legal Affairs Committee ("JURI") argued that funding under the next framework agreement ("Horizon 2020") should be stopped on the basis that *Brüstle* had deprived EU taxpayers of the possibility of an economic return. By the time of JURI's final Opinion, this argument had been airbrushed away, the Committee justifying its prejudice on the dubious basis that *Brüstle* had introduced a pan-European ethico-legal rule.

⁹⁰ Or the European Patent Office.

13. Other International Conventions

Although the Passau Opinion, upon which the Liese Amendments are founded, ignores TRIPS, its authors lay particular emphasis on the authority of three other international conventions and guidelines:

- The Council of Europe *Additional Protocol to the Convention on Human Rights and Biomedicine*, concerning Genetic Testing for Health Purposes done at Strasbourg on 27 November 2008⁹¹ (the “**Genetic Testing Protocol**”).
 - The *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine*, to which the Genetic Testing Protocol applies, was completed at Oviedo on 4 April 1997 (the “**Bioethics Convention**”).
- UN *Convention on the Rights of Persons with Disabilities*, adopted by a resolution of the General Assembly of the United Nations on 13 December 2006 (the “**Disabilities Convention**”).
- OECD *Guidelines for Quality Assurance for Molecular Genetic Testing* of 2007 (the “**OECD Guidelines**”).

13.1 Genetic Testing Protocol

The Passau Opinion concedes that the Union has not signed the Bioethics Convention (let alone any protocol to it), pointing merely to the fact that there are “*open for signature and ratification by the European Union*”. The Union was not alone. On 1 February 2008⁹², the Bioethics Convention remained unsigned by Austria, Belgium, Germany, Ireland, Liechtenstein, Malta, and the United Kingdom; of the few EU states that had signed it, Finland, France, Italy, Latvia, Luxembourg, the Netherlands, Poland and Sweden had not ratified it.

- 13.2 Despite the lack of legitimacy in the Union of the Bioethics Convention and Genetic Testing Protocol, Schweitzer and Kamann nevertheless contend in the Passau Opinion that the Bioethics Convention and Genetic Testing Protocol “*constitute important assessment criteria for the Union legislator*”. There is no legal basis for this view.

⁹¹ Not, as the Passau Opinion states, 2011.

⁹² The latest date published by the Council of Europe:
<http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=164&CM=8&DF=1/2/2008&CL=ENG>

13.3 **Disabilities Convention**

Schweitzer and Kamann refer to five articles of the Disabilities Convention: Article 1 (purpose); Article 3 (general principles) Article 5 (equality and non-discrimination); Article 10 (right to life) Article 17 (protecting the integrity of the person). They correctly note that these rights refer to “persons”. Without explaining which persons, with or without disabilities, Schweitzer and Kamann felt to be relevant, they proposed to extend Recital 59 so as to make the Regulation to reflect the principles of the Disabilities Convention. Notably, the Liese Amendments omit this pointless suggestion.

13.4 **OECD Guidelines**

The Passau Opinion again concedes that the Union is not in any way bound by the authority relied upon, treating it more as a sort of touchstone. However, the three general principles of best practice for molecular testing that Schweitzer and Kamann highlight undermine their case for EU intervention in clinical matters. In particular, the principle relating to genetic counselling states:

“A.5 Pre and post test counselling should be available. It should be proportionate and appropriate to the characteristics of the test, the test limitations, the potential for harm, and the relevance of test results to individuals and their relatives.”

The inflexible compulsion of Schweitzer and Kamann’s proposal supplants the OECD requirement of proportionality and appropriateness. In effect, it removes the clinical discretion that the OECD Guidelines seek to inform, replacing best practice with an EU-level intervention. The reference to the next principle underscores the irony of their proposal:

“A.6 Personal genetic information should be subject to privacy protection and security in accordance with applicable law.”

14. **The Liese Amendments interfere with private and family life**

14.1 Plainly, the applicable law on privacy includes Article 8 of the European Convention, which states:

1. *Everyone has the right to respect for his private and family life, his home and his correspondence.*
2. *There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or*

the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.”

- 14.2 There is no more significant aspect of a person’s private and family life than the genes that enable it. Genetic information is inherently private and familial and demands the highest possible respect under Article 8. The provision therefore protects a person’s right to that information from interference by a public authority, subject to the rights of family members and the “necessary” exceptions. Because Member States are bound to respect Article 8, they have no power to subject that person’s access to such information to the discretion of a particular person or class of person to whom such information must be disclosed for inspection.
- 14.3 The only legitimate circumstance under which a Member State (and, by extension, the Union) may interfere with a person’s right to respect for his private and family life is where it *“is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.”*
- 14.4 The proposed condition, requiring a person’s private and family information to be disclosed to a third party gatekeeper for assessment before that person can access it, is plainly not necessary for any of these purposes in a democratic society, although of potential value to non-democratic ones.⁹³ It is, moreover, in conflict with the fundamental principle of consent, as citizens of the Union will be unable to consent to the disclosure, to their medical practitioner, of their private and familial genetic information. The Liese Amendments would remove the citizen’s discretion and impede his or her access to that information. This is in direct conflict with Article 8 of the Charter, which requires all personal data to be

“processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified....”

- 14.5 Member States have no authority to limit the rights of their citizens under the European Convention for the benefit of the European Union or any other legal person, which is anyway constrained by the Charter. Indeed, the Union is itself obliged to accede to the European Convention⁹⁴.

⁹³ This is not to say that citizens might wish to receive expert counselling from an expert in clinical genetics (for whom the requirement of medical qualification is no guarantee of expertise) or that clinical best practice will not dictate the manner in which this is done.

⁹⁴ Article 6(2) TEU.

Consequently, the Union has no greater right: once again, it is incompetent to legislate as proposed.

- 14.6 In summary, Schweitzer and Kamann singularly failed to present the significance of Article 8 to the Group of the European People's Party in their Passau Opinion.

Conclusion

It is regrettable that the European Parliament is misled as to the Union's competence to legislate in the way proposed by the Liese Amendments. As a matter of procedure, it now falls to the Council of the European Union to consider the proposals in the light of its true competence

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