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**«THE ADVANTAGES OF OBSCURITY».  
LANGUAGE, POLICY AND ETHICAL CHALLENGES  
IN EU HARMONIZATION PROCESS**

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*Abstract:* Eu law tends to reach an independent notion of «public morality», which should be autonomous at both conceptual and terminological levels; this attempt leads away from the «general clauses» used in the domestic law of the Member States, highly informed by their domestic cultural background. This process displays some significant problems in legal translation and its political consequences. The interconnection between culture, language and translation, and the consequences that Eu law harmonization provokes on these issues for the legislations of Member States, are of utmost importance in the relationship between biotechnologies and law. The Eu centralizing effort by means of a language «revolution» seems to neutralize the content of these concepts, which have moral and social connotations linked to the cultural and legal background of the different Member States.

*Keywords:* Eu Policy – Harmonization – Patentability – Moral Limits – Biotechnologies.

### ***Introduction***

Biotechnology covers a wide range of techniques that make use of living organisms. Today biotechnology makes significant promises. To cite just a few: to feed the world, cure the sick, support motherhood through assisted reproductive technologies, all in order to improve the quality of life and the environment. Genetic diagnosis, gene therapy, plant-derived vaccines and biopharmaceuticals derive from genetic and biological manipulations and make it possible to tailor health treatment to individual needs<sup>1</sup>.

It is acknowledged that biotechnology has become a key technology for many

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\* Giulia Terlizzi,

<sup>1</sup> O. Mills, 2010, 8-9.

industrial sectors, and that it represents one of the most rapidly developing technologies in the European market of products.

This impressive economic improvement runs parallel with a wide-ranging debate on the ethics and limits of biotechnological research and developments. Arguments for and against biotechnology are, essentially, polarised into a debate about economics and ethics.

It is not surprising, therefore, that Directive EC 98/ 44 on the legal protection of biotechnologies has been one of the most crucial pieces of legislation in Europe, and that over the last decade «patenting has been forced into the public spotlight by general ethical concerns about biotechnology»<sup>2</sup>.

In this context, the effort made by European Union law is to delineate a European and independent notion of public morality, autonomous at both conceptual and terminological levels, which should represent a limit to the patentability of biotechnologies for the Member States. This is the creeping message emerging from the text of the Directive on biotechnology.

If this search for uniformity is desirable, it evidently represents a risk. First, it implies a relevant problem of legal translation of the «general clauses» used in the domestic law of the Member States (the German *gute Sitten*, the French *bonnes moeurs* and *ordre public*, the Italian *buon costume*), which do not always have the same content and scope. There is, in fact, evidence that the uncertainty and confusion surrounding biotechnology patenting lead to different national solutions, and consequently, to differences between decisions of national courts and the European Patent Office (Epo).

In this scenario the intertwining of ethics, geopolitics and translation becomes decisive when one focuses on legal perception of general principles, such as the *morality* clause and *ordre public* clause in Eu law, compared to the content and enforcement of such principles by Member States in their domestic jurisdictions.

The recourse to a new morality clause in Eu law is an urgent matter when at stake there are bioethical challenges to be regulated in a pluralistic and multilingual scenario, such as the European Union. This phenomenon highlights how language has a primary task in the normative dimension and the attempt by Eu law to create a shared but autonomous notion of a general clause able to regulate issues with moral and ethical implications at a European level. In this way, language may be used as a tool to regulate a highly debated legal issue. The paper aims to investigate the terminological and political use of these general principles in the Eu harmonization policy, particularly focusing on the challenges of bioethics in our pluralistic society.

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<sup>2</sup> G. Kamstra *et. al.*, 2002, 1.

### ***I. Multilingual Challenges in Eu Law Harmonization Process***

The harmonization process of the European Union in the biotechnological patent field is taking place in a multilingual context which involves problems that should not be underestimated. As well known, EU policy of linguistic equality requires that EU law is enacted in multiple languages (24); these various versions have equal weight in judicial interpretation. In such a context it is common to find that Eu legal terms, even when they correspond to their counterparts in domestic jurisdictions, refer to legal concepts that are totally or partially different<sup>3</sup>.

This lack of correspondence is rooted in the strong link between the law and culture of a society. It is therefore normal to find, for example, that legal concepts in Sweden and Finland are very close, since Finland was part of the Kingdom of Sweden for over six centuries<sup>4</sup>. Civil law and common law legal systems however are still built around very different legal concepts, precisely because of differences in their historical traditional cultures.

In this perspective, the Eu legal system immediately shows its peculiarity due to its multicultural components which have given it significant inputs from various directions. According to Mattila, «it can rightly be described as a sort of hybrid, mixed law, in which the legal traditions of Europe increasingly intertwine»<sup>5</sup>, including the convergence of civil law and common law.

Problems of terminology deriving from these multilingual and multilegal contexts are frequently reflected in the different language versions of the Eu law: Treaties, Regulations and Directives.

The «general clauses» differ from one Member State to another in both content and terminology. How can the French term *ordre public* be translated in English? The English term public policy is commonly used, but the sense of this notion greatly differs from that of public order used in traditional civil law systems.

Another example is the German *gute Sitten*, often translated with the English good morals, but it is important to highlight that the first has a wider content because *gute Sitten* in Germany also covers aspects of *ordre public*. In the opposite way, the English term «public policy» includes good morals and does not coincide in meaning with the notion of *ordre public*.

As a result, European legislative texts and European Conventions which make use of «general clauses» are often somewhat ambiguous. This is well illustrated by the comparison of the different official versions of the 1957 EC Treaty and of the European Charters and Conventions<sup>6</sup>.

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<sup>3</sup> P. Rossi, 2013, 80.

<sup>4</sup> H. Mattila, 2013, 139.

<sup>5</sup> Ivi, 140.

<sup>6</sup> Article 30 of the French text of the 1957 EC Treaty refers to the French term *ordre public*. The English text of the Convention for the Protection of Human Rights and Fundamental Freedoms refers in Article 2 to the

The European Court of Justice is aware of the difficulties of harmonized interpretation and enforcement of the Union's new legal concepts in the legal orders of Member States.

In Case 49/71, the Court held that «terms used in Community law must be uniformly interpreted and implemented throughout the Community, except when an express or implied reference is made to national law»<sup>7</sup>.

In addition to the problems of interpretation of the meaning of a concept in the EU dimension by the Member States, problems of translation of the same concept in different language emerge. As stated in Case 283/81<sup>8</sup>, since the Community legislation is drafted in several languages, the different language versions are all equally authentic. Therefore, «an interpretation of a provision of Community law thus involves a comparison of the different language versions»<sup>9</sup>. After comparison of the parallel texts, the Court stressed that «even where the different language versions are entirely in accord with one another, (...) Community law uses terminology which is peculiar to it. Furthermore, it must be emphasized that legal concepts do not necessarily have the same meaning in Community law and in the law of the various Member States»<sup>10</sup>.

It is clear, therefore, that in the harmonization process, on the one hand there is a need for terminological unity between the various languages to avoid problems of ambiguity, while on the other hand it is evident that the terms created have to be adapted to the peculiarities of each language<sup>11</sup>. It is worth noting that comparison of the wording of the language versions (as mentioned above) often reveals differences, so that it is normal for the Court to leave aside the analysis of the differences observed, to take directly into account the contextual, systemic and teleological arguments<sup>12</sup>.

This was precisely the conclusion upheld by the Court in the Cilfit case: «Every provision of Community law must be placed in its context and interpreted in the light of the provisions of Community law as a whole, regard being had to the objectives thereof and to its state of evolution at the date on which the provision in question is to be

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French term *ordre public*, but in Article 6 the terms «morals and public order» are used. Article 53(a) of the European Patent Convention in its English version uses the French term *ordre public* in quotation marks. The French term is also used in the English version of Article 6(1) of Directive 98/44/EC.

<sup>7</sup> Case 49/ 71, Judgment of the Court of 1 February 1972, Hagen OGH v Einfuhr- und Vorratsstelle für Getreide und Futtermittel. Reference for a preliminary ruling: Hessischer Verwaltungsgerichtshof - Germany. Marketing centres, regarding the term «offer».

<sup>8</sup> Case 283/81 CILFIT [1982] European Court Reports 1982 -03415, para 18 and para. 19-20 (on the autonomy of the EU notions with respect to those used in the Members States), available at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A61981CJ0283>.

<sup>9</sup> Case 283/81 CILFIT [1982] European Court Reports 1982 -03415, see n above.

<sup>10</sup> *Ibidem*.

<sup>11</sup> See, for example, the decision held in Case 49/ 71, Judgment of the Court of 1 February 1972, Hagen OGH v Einfuhr- und Vorratsstelle für Getreide und Futtermittel. Reference for a preliminary ruling: Hessischer Verwaltungsgerichtshof - Germany. Marketing centres, regarding the term «offer»: «Terms used in Community law must be uniformly interpreted and implemented throughout the Community, except when an express or implied reference is made to national law».

<sup>12</sup> E. Paunio, 2013, 35.

applied»<sup>13</sup>. This aspect of the temporal context is particularly important because the values and general clauses have to be interpreted in light of the dynamic and continuously evolving character of Eu law and have to be applied in the dynamic and continuously evolving field of biotechnological inventions<sup>14</sup>.

As affirmed, the authentic value of all linguistic versions of Eu law (Regulation 1 of 1958), means that there is no longer a single text to interpret, but a combination of various texts, in which even the deviation occurring in one version could be relevant. The consequence is that interpretation starts inevitably from a sort of meta-text, in which the teleological approach is evidently emphasized: in case of doubt, the legislator's proposal should be awarded<sup>15</sup>. This is why there is an abundance of Recitals in the Eu Directives and Regulations. In fact, the number of Recitals has continued to grow, even though these Recitals are not always reflected in the Articles of the Directive.

This practice obviously opens huge problems of interpretation. The only imaginable alternative could be to draft highly precise and detailed text to explain every situation, even the most peculiar. But everybody knows that this is simply impossible, because the ambiguities that occur may also regard one single word or even conjunction<sup>16</sup>.

Faced with this problem, it is evident that even identifying the aim of a Directive or Regulation is not at all easy. As ironically observed, the difficulty deals with what may be called «the advantages of obscurity» of Eu drafting style in judgements and legislation<sup>17</sup>.

As stated by Sir Konrad Schiemann, former judge of the European Court of Justice, it often happens that Eu judges use evasive techniques when they must challenge themselves with issues not completely solved by Eu legislation. Sometimes, judges don't look at the premises of the case, focusing only on the litigation and leaving the task of clarifying the implications linked to that case to the future (usually because of disagreement due to lack of consensus among the Eu legislators). A paramount example of this scenario is the term «embryo», which is linked to a specific legislation characterized by a scientific basis. In the absence of an agreed and shared definition, judges refer to a vague common core, without entering into the debate.

Since the *Cilfit* case, the European Court of Justice has always been consistent in stating first that the «Community legislation is drafted in several languages and that the different language versions are all equally authentic»<sup>18</sup>. Second, that «an interpretation of a provision of Community law thus involves a comparison of the different language

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<sup>13</sup> Case 283/81 CILFIT [1982] European Court Reports 1982-03415, para 20, available at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A61981CJ0283>, n 8 above.

<sup>14</sup> E. Paunio, 2013, 27.

<sup>15</sup> Eu Regulation 1/1958.

<sup>16</sup> See, among others, S Šarčević, 2001, 248; A. Gambaro, 2006. More recently, see E. Ioriatti, 137 ff.

<sup>17</sup> Words pronounced by Sir Konrad Schiemann, in a conference speech devoted to the drafting of Eu legislation and judgements; IALS, 7 October 2013, <https://ial-online.org/recording-the-advantages-of-obscurity-the-drafting-of-eu-legislation-and-judgments/>

<sup>18</sup> Case 283/81 CILFIT [1982] European Court Reports 1982-03415, para 20, available at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A61981CJ0283>, n 8 above.

versions»<sup>19</sup>. And third, «that even where the different language versions are entirely in accord with one another, that Community law uses terminology which is peculiar to it»<sup>20</sup>. Furthermore, as the Court stresses, «it must be emphasized that legal concepts do not necessarily have the same meaning in Community law and in the law of the various Member States». In addition, «every provision of Community law must be placed in its context and interpreted in the light of the provisions of Community law as a whole, regard being had to the objectives thereof and to its state of evolution at the date on which the provision in question is to be applied»<sup>21</sup>. Given all that, it is now interesting to investigate how the Directive on Biotechnologies shall be enacted and enforced by the Member States without incurring a threat of legal certainty.

## ***II. Directive 98/44 CE and its impact on translation, ethical and geopolitical issues***

Directive 98/44 on the legal protection of biotechnologies and its drafting history clearly show the impact and importance of the interconnection between law, translation, and ethical issues of the Member States in Eu law harmonization policy <sup>22</sup>. As already observed, the Directive aims to limit the uncertainty regarding the protection of biotechnological and certain microbiological inventions, through harmonization of European legal systems. Since the adoption in 1988 of the original proposal, the purpose was to harmonise the laws and practices of the different Member States, clarifying the law and providing greater certainty in the Member States. The core issue is that differences could create barriers to trade and hence impede the proper functioning of the internal market.

The Directive is also aware of the risk of national Courts interpreting patenting legislation differently, causing an uncoordinated development of national laws on the legal protection of biotechnological inventions in the Community.

At the core of the Directive is the introduction of a more emphatic ethical dimension into patent law through recourse to an evaluative criterion to grant or refuse patentability. In fact, as observed, «the development of biotechnology has led to a broad debate on the conformity of biotechnological inventions to public order and morality, forcing different patent offices to respond to the legality of the patenting of such inventions»<sup>23</sup>.

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<sup>19</sup> *Ibidem*.

<sup>20</sup> *Ibidem*.

<sup>21</sup> *Ibidem*.

<sup>22</sup> Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ L 213, 30.7.1998, p. 13-21; available at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31998L0044>.

<sup>23</sup> A. Stazi, 2015, 31.

It is worth recalling that the first European Commission proposal of 1988, which was essentially technical and legal in nature, was the first text ever rejected by the Parliament under the conciliation procedure in 1995. As observed, «this was basically because of different interpretations of ethical problems, in particularly the questions of the patentability of parts of the human body and the genetic manipulation of the human body»<sup>24</sup>. Biotechnology raises moral questions particularly because it affects living matter, and it is therefore explicitly stated in the motivation in the Preparatory Acts<sup>25</sup> to the Biotechnology Directive that it is necessary to implement, in a suitable way, the ethical dimension in the Directive.

It is worth noting that on this particular aspect the Directive does not explicitly identify the limits to patenting biotechnological products and their content. This increases uncertainties and differences between decisions of the various national Courts and the European Patent Office (Epo), creating not only legal and ethical problems, but geopolitical consequences regarding free movement of biotechnology-based products within the European market, and the investments in research and development.

The most relevant exclusions concern patents whose «commercial exploitation would be contrary to *ordre public* or morality». The concept refers mainly to the respect of human dignity, which is at the root of human rights, and is mentioned in Article 1 of the Charter of Fundamental Rights. The European Patent Convention (Epc) refers to *ordre public* and morality in Article 53(a) and the Biotech Directive in Article 6. The Biotech Directive has also specified some exclusions in Article 6(2) to provide national courts and patent offices with a general guide to interpreting the reference to *ordre public* and morality, even though they cannot be presumed as exhaustive<sup>26</sup>. This list of moral exclusions contained in Article 6 of the Biotech Directive has also been transposed into Rules 23(d)a-d of the Epc.

Although the Epc of 1978 included a morality exception to patentability by Article 53 (a) (which represented the first attempt of legal systems to grant or deny patentability on biotechnologies on moral and *ordre public* grounds), EPO case law made clear that the application of Article 53 (a) EPC is likely to result in inconsistencies among the EPC States. The evaluation criteria concerning *ordre public* and morality offered by the European Patent Office revealed their incapacity to offer sufficient guidelines to prevent the lack of uniformity among States. In 1994 the European Commission fixed the second fundamental goal of the Directive, «over and above harmonization of patent practice»: the introduction of an ethical dimension in patent law.

In this perspective, with the enactment of the Directive in 1998, the exceptions based on morality and *ordre public* limits became more concrete and therefore of paramount importance. It is now clear that morality and *ordre public* criteria are a matter for

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<sup>24</sup> OJ C 295, 7.10. 1996, at 12.

<sup>25</sup> COM/97/446.

<sup>26</sup> See Recital 38 Directive 98/44/EC.



European institutions<sup>27</sup>.

### **III. Legal uncertainty in the Biotechnology Directive**

Directive 98/44 on the legal protection of biotechnologies raises critical issues at various levels.

At a first stage, there is a problem of ambiguity in terminology, which creates confusion about the precise meaning and scope of these general principles evoked. Serious consequences follow, such as infringement of legal certainty and the resulting risk of discrepancies in the application of this *ordre public* clause by the Member States.

The threat to legal certainty derives from the presence of an incoherent terminology among Recitals and Articles of the same Directive text. In several Recitals and in Article 6 there are different formulations of this morality criterion. Article 6 of the Directive refers to *ordre public* and morality, while Recital 38 refers to «ethical or moral principles», provoking significant difficulties in determining the content of such principles. The situation is made worse when one compares the different official versions of the same text.

The comparison exemplifies the importance of translation as an integral part of the Eu law-making process and shows how translation can create further uncertainty with regard to the meaning of final texts adopted in over 20 languages. It is not, therefore, uncommon «for the same text to point towards different textual interpretations depending on which language version we are looking at»<sup>28</sup>.

This problem leads us to the importance of national legal jargon. It is worth noting that unlike the English text of the European Patent Convention, the drafters of the UK implementing legislation (Patents Regulation 2000, n. 2037) translated *ordre public* as public policy<sup>29</sup>.

At this point, we move towards the second level of criticism, and the question is: are these concepts sufficiently clear?

In Decision T356/ 93 the Board of Appeal of the European Patent Office defined the concepts of *ordre public* and morality under Article 53 (a) of EPC as follows:

«The concept of *ordre public* covers the protection of public security and the physical integrity of individuals as part of society»<sup>30</sup>. In this concept, also the protection of the environment is involved. Moreover, according to Article 53(a) of the EPC, «inventions the exploitation of which is likely to breach public peace or social order (for example, through acts of terrorism) or to seriously prejudice the environment are to be excluded from

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<sup>27</sup> O. Mills, 2010, 79-80.

<sup>28</sup> E. Paunio, 2013, 49

<sup>29</sup> G. Kamstra and others, 2002, 26-27.

<sup>30</sup> EPO, Case T 0356/93 (Plant cells) of 21.2.1995, available at <https://www.epo.org/law-practice/case-law-appeals/recent/t930356ex1.html>.

patentability as being contrary to *ordre public*».

As to morality, it was defined as a concept «related to the belief that some behaviour is right and acceptable whereas other behaviour is wrong». Morality is therefore «founded on the totality of the accepted norms which are deeply rooted in a particular culture». In any case, it is important to note that, «for the purposes of the EPC, the culture in question is the culture inherent in European society and civilisation. Accordingly, under Article 53 (a) EPC, inventions the exploitation of which is not in conformity with the conventionally accepted standards of conduct pertaining to this culture are to be excluded from patentability as being contrary to morality»<sup>31</sup>.

Apart from the enigmatic content of this statement concerning the standard of morality and *ordre public* clauses, one cannot deny that the content of these notions has changed a lot over time.

According to Recital 39 of the Directive: «*ordre public* and morality correspond in particular to ethical or moral principles recognised in a Member State, respect for which is particularly important in the field of biotechnology». In this way, «Such ethical or moral principles shall supplement the standard legal examination under patent law regardless of the technical field of invention».

This can be seen as a sign of the importance given to the moral questions in the Biotech Directive.

Furthermore, Article 7 of the Biotech Directive refers all ethical evaluation to the Commission's European Group on Ethics in Science and New Technology. The group can also be consulted when biotechnology is to be evaluated at the level of basic ethical principles on patent law.

#### ***IV. Ethics, Law and Language in the case law: an overview***

With regard to the meaning and scope of Article 6 of the Directive, it is worth citing Case C-377/98 Kingdom of the Netherlands v. European Parliament and Council of Europe, of 9th October 2001<sup>32</sup>. The case involved the question of whether a process to produce chimeras from germ cells or totipotent cells of humans and animals is patentable or not. The Netherlands' complaint was focused on the argument that patentability of

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<sup>31</sup> It should be noted that EPC Working Party recognised that «there was no European definition of morality», and therefore, the «interpretation of the concept of morality should be a matter for European institutions», see document IV/2767/61-E, 7.

<sup>32</sup> C-377/98 - Netherlands v Parliament and Council, Judgment of the Court of 9 October 2001, Kingdom of the Netherlands v European Parliament and Council of the European Union. Annulment - Directive 98/44/EC - Legal protection of biotechnological inventions - Legal basis - Article 100a of the EC Treaty (now, after amendment, Article 95 EC), Article 235 of the EC Treaty (now Article 308 EC) or Articles 130 and 130f of the EC Treaty (now Articles 157 EC and 163 EC) - Subsidiarity - Legal certainty - Obligations of Member States under international law - Fundamental rights - Human dignity - Principle of collegiality for draft legislation of the Commission.

isolated parts of the human body (Article 5 (2) of the Directive) reduces living matter to a means to an end, offending human dignity. The Netherlands (supported by Italy and Norway) asked for the annulment of the Directive on biotechnologies and put forward four arguments to the effect that Article 6 infringes the principle of legal certainty «because, rather than helping to remove the legal ambiguities described in the Recitals, the Directive tends to exacerbate them, thus breaching the principle of legal certainty»<sup>33</sup>, giving national authorities discretion «in applying concepts expressed in general and ambiguous terms, such as *ordre public* and morality which appear in Article 6»<sup>34</sup>.

Advocate General Jacobs argued against the claim, concluding that the concept of *ordre public* and morality are sufficiently clear concepts in European law. Interpretation of these terms may differ between the national courts of the Member States, but it will always be subject to the control of Ecj, which clarifies their scope. Lastly, having regard to the plaintiff's statement that public morality may be determined in accordance with a Member State's own scale of values or with regard to a common standard, the Advocate General replied that, although this principle remains true, a degree of harmonization by Eu law is not precluded, adding that Eu acts give guidelines for applying the concepts at issue<sup>35</sup>.

The case in question shows that in the end, the final word on the content of *ordre public* and morality pertains to Ecj discretion. The risk involved is apparent. Unlike other judicial bodies such as national courts, the European Court of Justice has a variable structure with regard to composition and duration of judges' terms in office. These elements can easily foster uncertainties having regard to the interpretation of general clauses.

The opinion of Advocate Jacobs in Case C-377/98 offers good evidence of a shift also in view of the meaning of these notions. We can see the changes when, as observed by the claimant's arguments, we compare these new Eu concepts with each Member State's individual scale of values and common standards. It is recognized by now that «the Directive attributes the joint concepts of *ordre public* and morality with a dimension wider than what states intended originally»<sup>36</sup>.

It is worth noting that if in 1995, according to the Technical Board of Appeal 3.3.4 of the European Patent Office the concept of morality was «founded on the totality of the accepted norms, which are deeply rooted in a particular culture and tradition»<sup>37</sup>. In the following decisions, such as in Case C-377/98, it has been stressed that «for the purposes of the EPC, the culture in question is the culture inherent in European society and civilisation. The fact that some ethical issues may be more appropriately evaluated in the context of the culture of a particular Member State and others are susceptible to a

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<sup>33</sup> C-377/98 - Netherlands v Parliament and Council, n above.

<sup>34</sup> Case C-377/98, Netherlands v Parliament and Council, n 32 above.

<sup>35</sup> Case C-377/98, n 26 above, Opinion of Advocate General Jacobs.

<sup>36</sup> O. Mills, 2010, 138.

<sup>37</sup> T 0356/93 (Plant cells) of 21.2.1995, OJ 1995, 545.

common standard does not however in my view preclude - either here or elsewhere - a degree of harmonization»<sup>38</sup>. Moreover, in another case, the board found that in the assessment of an Art. 53(a) EPC 1973 objection, «no single definition of morality based on e.g. economic or religious principles represents an accepted standard in European culture»<sup>39</sup>.

In this sense, the words of Advocate General Jacobs in Case C-377/98 don't leave any doubt about the fact that a change occurred. Citing his own words, «The application by national authorities of the concepts of *ordre public* and morality, however, will always be subject to review by the Court». Therefore, «Member States do not have an unlimited discretion to determine their scope». In the case involved, the Court decided that «recourse by a national authority to the concept of *public policy* presupposes, in any event, the existence, in addition to the perturbation of the social order which any infringement of the law involves, of a genuine and sufficiently serious threat to the requirements of *public policy* affecting one of the fundamental interests of society».

In Case C- 34/10 EC Oliver Brüstle v. Greenpeace eV., recourse to fundamental principles and human dignity is emphasised, as mentioned in the Preamble of the Directive and Recital 16 of the Directive.

The Court affirmed: «the preamble to the Directive states that although it seeks to promote investment in the field of biotechnology, use of biological material originating from humans must be consistent with regard for fundamental rights and, in particular, the dignity of the person»<sup>40</sup>. Evoking again Recital no.16 in the preamble to the Directive the Court emphasises that «patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person»<sup>41</sup>.

In Case C-364/13, the recourse to fundamental principles and human dignity is central<sup>42</sup>. The protection of human dignity seems to become of paramount importance when granting or denying patents in this field. The Court stated in fact that «according to the referring court, to exclude parthenotes<sup>43</sup> from patentability does not strike a balance at all between, on one hand, research in the field of biotechnology which is to be encouraged by means of patent law and, on the other hand, respect for the fundamental

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<sup>38</sup> Case C-377/98, see n 24 above.

<sup>39</sup> T 0315/03 (Transgenic animals/HARVARD) of 6.7.2004.

<sup>40</sup> Case C- 34/10 EC Oliver Brüstle v. Greenpeace eV., European Court Reports 2011 I-09821, available at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62010CJ0034>.

<sup>41</sup> Case C- 34/10 EC Oliver Brüstle v. Greenpeace eV., n above.

<sup>42</sup> Case C-364/13, Judgment of the Court (Grand Chamber), 18 December 2014. *International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks*. Request for a preliminary ruling from the High Court of Justice (England & Wales), Chancery Division (Patents Court). Reference for a preliminary ruling — Directive 98/44/EC — Article 6(2)(c) — Legal protection of biotechnological inventions — Parthenogenetic activation of oocytes — Production of human embryonic stem cells — Patentability — Exclusion of 'uses of human embryos for industrial or commercial purposes' — Concepts of 'human embryo' and 'organism capable of commencing the process of development of a human being', available at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62013CJ0364>.

<sup>43</sup> Parthenotes are stem cells derived from parthenogenesis, a reproductive mechanism that is common in lower organisms and produces a live birth from an oocyte activated in the absence of sperm.

principles safeguarding the dignity and integrity of the person (see Recitals 2 and 16 in the preamble to Directive 98/44)»<sup>44</sup>.

The Court states that «from the context and aim of Directive 98/44, the Eu legislature intended to exclude any possibility of patentability where respect for human dignity could thereby be affected»<sup>45</sup>. It follows that «the concept of ‘human embryo’ within the meaning of Article 6(2)(c) of that Directive must be understood in a wide sense»<sup>46</sup>.

These passages are useful to better understand that, since the list of what is contrary to *ordre public* and morality established by Article 6 of the Directive is not exhaustive, all processes which offend human dignity are also excluded from patentability. This means that albeit in a subtle way, the content of the traditional notions of *ordre public* and morality are also undergoing a real transformation. It has been observed that «from a review of past cases assessing the morality of biotechnological inventions the EPO has felt pressure to declare such inventions morally acceptable. Of the four inventions opposed on moral grounds, none has ultimately been denied patent protection on this basis»<sup>47</sup>.

This brief excursus on Directive 98/44 CE and the case law therein involved, leads us to the conclusion that we are witnessing increased implementation of the principle of «Dignity» and «Fundamental Principles» in Eu law, and a progressive decline for the traditional general clauses of *ordre public* and good morals.

Case law shows how the search for harmonization of Eu law may lead to a «neutralization» of the general principles used by Member States in their domestic jurisdictions, which is in open contrast with the spirit of the harmonization process proclaimed by the same Directive and the power of discretion recognized to the Member States. In addition, as the passages mentioned reveal, the lack of uniformity in the legal language of the ECJ patently shows its confusion between the use in the same text of *ordre public* and public policy, leading to a threat of legal certainty for the Member States who adopt the Directive.

At a deeper stage in the analyses, we can observe that the evolution of the case-law connected with the Directive shows some evident changes in terminology clearly directed towards an instrumentality of moral values in Eu law. At the sheer level of form, we observe an undeniable evolutionary trend in the use of different expressions when referring to either moral or political values. We find terms such as «morality», «public

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<sup>44</sup> Case C-364/13, Judgment of the Court (Grand Chamber), 18 December 2014. *International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks*. Request for a preliminary ruling from the High Court of Justice (England & Wales), Chancery Division (Patents Court). Reference for a preliminary ruling — Directive 98/44/EC — Article 6(2)(c) — Legal protection of biotechnological inventions — Parthenogenetic activation of oocytes — Production of human embryonic stem cells — Patentability — Exclusion of ‘uses of human embryos for industrial or commercial purposes’ — Concepts of ‘human embryo’ and ‘organism capable of commencing the process of development of a human being’, available at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62013CJ0364>.

<sup>45</sup> Case C-364/13, see n 29 above, para 24.

<sup>46</sup> *Ibidem*.

<sup>47</sup> D.M. Gitter, 2001, 41

morality», or «human dignity», instead of the traditional use of «good morals' and *ordre public*».

### **V. The Unadvertised Shift from Morality to «Dignity» and «Fundamental Principles».**

The Eu's increasing recourse to values such as «Fundamental Principles and Dignity» is obvious: the «fundamental rights arguments continue to grow in importance in the Court's reasoning»<sup>48</sup>. The traditional formulations linked to the Member States' cultural contexts are increasingly left aside. This is in favour of notions that are more linked to values recognised in charters and international treaties well exemplified by the constant recourse to the notion of Dignity<sup>49</sup>.

As established by Recital 16, patent law must be applied so as to safeguard the *dignity and integrity of the person*. In addition, Recital 38 of the Directive reinforces Article 6 of the Directive and establishes that:

«Whereas the operative part of this Directive should also include an illustrative list of inventions excluded from patentability so as to provide national courts and patent offices with a general guide to interpreting the reference to *ordre public* and morality; whereas this list obviously cannot presume to be exhaustive; whereas processes, the use of which offend against human dignity, (...), are obviously also excluded from patentability»<sup>50</sup>.

It is therefore arguable that «since invocation of the Recitals is required in the interpretation of the Directive, and because the Recitals are drafted in broad terms, this suggests that the meaning attributed to *ordre public* and morality be extended accordingly»<sup>51</sup>. Lastly, one cannot ignore that the European Convention on Human Rights (Echr) forms part of the general principles of Community law. Therefore, the Directive has to be interpreted following the moral criteria of Echr.

This is well described by the evolutionary case law involved in the subject disciplined by the Directive. All these cases faced the question of whether processes for cloning human beings, processes for modifying the germ line genetic identity of human beings and uses of human embryos for industrial or commercial purposes should be excluded or not from patentability.

Probably in this process the transformation described in these pages does not just involve the language of the law (and consequently the translation of these legal terms in

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<sup>48</sup> E. Paunio, 2013, 30.

<sup>49</sup> See Art.1 of the Charter of Fundamental Rights of the European Union, OJ C 83, 30.3.2010, at 389-403.

<sup>50</sup> See Recital 38, Directive 98/44 CE, available at <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:31998L0044&from=FR>

<sup>51</sup> O. Mills, 2010, 141.

a multilingual context); it also underlines a policy choice, with a deeper symbolic value. This choice favours the use of concepts and principles which are more apt to be easily accepted into a pluralistic society and are safer than others, which seem old, *démodé* and not uniform. Dignity and Fundamental Principles are already quoted in international charters and treaties.

As stated in the Directive itself at Recital 3, «ensuring effective and harmonized protection in all Member States is essential in order to maintain and promote investment in biotechnology».

However, it is the same Directive that considers it unnecessary to create a specific right to replace the national patent law. According to its wording, «national Patent law remains the fundamental reference to the legal protection of biotechnological inventions». However, after the general recognition of Member States' autonomous regulation of the matter, the Directive lays down the first limit to patentability as set out in Recital 1, that of dignity: «patent law must be exercised in compliance with the fundamental principles that guarantee the dignity and integrity of man». Only at Recital 38, the Directive mentions public policy and good morals as limiting the patentability of biotechnological inventions but reiterates that to provide national courts and national patents with broad guidelines for the interpretation of public order and good morals, all patents must be excluded from «the proceedings whose application is prejudicial to human dignity».

In practice, Recital 38 of the Directive provides Member States with a criterion for correctly interpreting their public order and good morals, excluding from patentability all those proceedings whose application is prejudicial to human dignity. From this initial reading of the text of the Directive clearly emerges the fact that human dignity is the fundamental principle to which bioethical activities must be oriented and represents «the fundamental parameter for the assessment of the legality of medical-scientific activities interfering with the sphere of the person in its physical and informational components». As noted by an authoritative legal theory, «the proliferation of references to human dignity in the contemporary Bio-law is widely recognized and is not so surprising if we think that human dignity constitutes, as it is written, the only “absolute value” in an informed context of relativism of values»<sup>52</sup>.

In this sense, the use of the principle of dignity is becoming more and more frequent, as a fundamental principle to which Bio-law activities should be directed, and as a precept capable of carrying out an important regulatory function and governing social complexity in a secularized society.

While, on one hand, the Directive leaves to Member States the regulation of the patentability of biotechnological inventions, through their domestic limits of public order and good morals, on the other hand, it addresses them with a twofold definition to be taken into account in the discipline.

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<sup>52</sup> G. Resta, 2010, 260-261.

The word dignity «is being given a European Union meaning that encompasses the common constitutional traditions of these Member States»<sup>53</sup>. In this way the Eu concept of dignity «has a substantive meaning recognized as a fundamental right, part of Eu Law and applied by the CJEU»<sup>54</sup>.

## VI. Final remarks

The European harmonising effort has already revealed some evident shifts in terminology. On the terminological side, we observe an evolutionary trend from moral to social and political values.

As shown before, in the same Directive text we find the traditional formulas of good morals and *ordre public*, as well as the increasing use of the «Dignity» principle and «Fundamental Principles» recognized in Eu Charters and Member States' Constitutions, because of the intimate relationship between fundamental rights and values underlying every legal system. This trend may suggest a policy choice undertaken by Eu legislators signalling the fear to give a meaning to these notions by inspiring to moral and cultural values recognized in one or different Member States. The Eu legal system prefers to «ensure respect for human dignity and emphasizes protection of fundamental rights on a general level so as to accommodate different national sensibilities»<sup>55</sup>. The problem of legal certainty still remains, however, given that we move from the vagueness of general clauses to the vagueness of the concept of «Dignity» and of the «Fundamental Principles».

If it is true that «vague texts allow for flexibility and development», and that «ambiguous texts can serve as a way of allowing the wheels to keep turning»<sup>56</sup>, it is not comprehensible why Eu law is moving towards notions which are as vague and general as the former traditional clauses of *ordre public* and morality.

Moreover, this change does not seem to foster the harmonization goal of the European Union, except in words, but not at all in the content, which remains different for each Member State.

As argued, «in terms of protection, harmonization under the Directive can be achieved only when Member States either reach a consensus as to the meaning of *ordre public* and morality within the context of patentability or reject it altogether»<sup>57</sup>. This is a hard task, but not an impossible one. Reaching a consensus in a pluralistic and multilingual context does not mean reaching an abstract neutrality. This won't be a

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<sup>53</sup> J. Jones, 2012, 291.

<sup>54</sup> *Ibidem*.

<sup>55</sup> E. Paunio, 2013, 165.

<sup>56</sup> Sir Konrad Schiemann, *The advantages of obscurity: the drafting of EU legislation and judgments*, Conference, Lecture organised jointly by the IALS and Clarity International, held in June 2013 at IALS.

<sup>57</sup> O. Mills, 2010, 153.



concrete solution in reality. As we will see, the same problems occur time after time. Moreover, this attempt has never been a solution either for legislators or for judges. If the legislator prefers to not express the content of a notion (because he is afraid to express it explicitly or because he has not reached a clear opinion on the issue regulated) interpreters have to do what they always do with legislative acts: they have to interpret them. They have to find a good solution with the help of the general principles they are familiar with, by means of the general principles that correspond to those values accepted by society. Jurists should work for a reasonable solution, balancing costs and benefits of the operation. Jurists should work for a solution which would not break abruptly with the traditions respected over the years. Basically, jurists and interpreters will act as they always act, looking for a reasonable and just interpretation. This is the task, whether with multilingual or monolingual texts<sup>58</sup>.

Eu policy, translation and cultural tradition need to look at each other, and work hard together, to really find a shared common core not just in its exterior shape but in its real dimension.

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<sup>58</sup> Of this opinion, R. Sacco, 2002, 238.

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