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THE "COMPASSIONATE EXEMPTION" IN SPAIN: NOT ASKING FOR COMPASSION*

by

Francisco Miguel Bombillar Sáenz ♦

Abstract:

The Royal Decree 1015/2009, June 19th 2009 (RDDMSE) aims to facilitate the access to drugs –the drug in question should be subject to a marketing authorisation application or must be undergoing clinical trials– before approval, in Spain, in patients with a chronical or severely debilitating disease or one considered life threatening and who cannot be treated satisfactorily by an authorised product (*compassionate use*); as well as the access to drugs approved in countries other than Spain, when they do not comply with the definition of compassionate use of investigational drugs (*foreign drugs use*) and, finally, the access to drugs in conditions other than those stated in the authorised data sheet (*off-label use*). Traditionally, in Spain, the first and third cases were known as "compassionate use" –an unfortunate name, as it is not compassion that is sought–, being legally regulated in the same way.

The RDDMSE seeks to eliminate formal steps and speed up procedures, strengthening, in turn, guarantees of safety in these special applications, without neglecting the information and transparency that should prevail in this area. Among the innovations stated in the RDDMSE, we must highlight the fact that the access to drugs that are in research or unauthorised in Spain can be managed telematically for each patient, as well as through a temporary authorisation issued by the AEMPS (the Spanish Medicines Agency), in coordination with other European agencies, for a group of patients. In relation with the off-label use, this Decree eliminates the need to obtain an individual authorisation from the AEMPS, focusing liability on doctors.

* This article is part of the result of my PhD thesis, defended at the University of Granada (Intervención administrativa y régimen jurídico del medicamento en la Unión Europea) and the University of Bologna (Regime giuridico del farmaco negli ordinamenti italiano e spagnolo: la trasposizione del diritto farmaceutico europeo) and it has been made within the research project financed by the Andalusian Government SEJ-03266 «El derecho a la salud y al medio ambiente en la sociedad del riesgo y la innovación», lead by Professor Rafael Barranco Vela, Head of Department of Administrative Law at the University of Granada, the master of my entire university research career. In other way, we would like to remark that the quotes collected in this article have been unofficially translated from Spanish to English, whit the help of the lawyer Patricia Gil.

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Key words: Availability of drugs in specific situations. Compassionate use. Foreign drugs. Off-label. Clinical trials. Authorisation. Temporary authorisation. Telematic application. Spanish Medicines Agency. Patient. Risk. Pharmacovigilance.

Availability Of Drugs In Specific Situations: Cases

Drugs are designed as an instrument of health policy in the States through which, the right to health protection[1] becomes effective, as they help prevent, cure or relieve diseases and correct or repair the damage caused by these. Thanks to the medicine, mankind has been able to effectively fight against the diseases which have plagued us in recent years. Medicine saves lives, eases pain, provides a better quality of life, and is a hope for the future[2]. Access to these is, therefore, an integral part of the right to health protection[3], this being the reason why our legal system «recognises the right of all citizens to obtain medication under equal terms» (art. 88 LGURMPS[4]).

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[1] See PEMÁN GAVÍN, J.: *Derecho de la salud y Administración Sanitaria*, Publicaciones del Real Colegio de España, Bolonia, 1989; APARICIO TOVAR, J.: «El derecho a la protección de la salud. El derecho a la protección sanitaria», in MONEREO PÉREZ, J. L.: *Comentario a la constitución socio-económica de España*, Comares, Granada, 2002, pp. 1553-1566; ESCRIBANO COLLADO, P.: *El derecho a la salud*, Instituto García Oviedo de la Universidad de Sevilla, Sevilla, 1976; or RIVERO LAMAS, J.: *Protección de la salud y Estado social de Derecho. Discurso leído en el acto de su recepción académica el día 30 de noviembre de 2000*, Real Academia de Medicina, Zaragoza, 2000.

[2] In this regard, in Spain, the Explanatory Memorandum to the Medicines Act 1990 [Ley 25/1990 of December 20th, 1990 (*BOE* n. 306 of December 22th, 1990)] stated the following: «*The drugs have achieved, in the past eighty years, memorable successes in the prevention of and fight against pain and disease. Old scourges afflicting humanity such as smallpox have been wiped off the face of the earth, not to mention more than one example to which many others could be added. In fact many of the acts and medical or surgical procedures include drug treatment. The benefits of drugs are not only expressed in terms of lives saved and suffering avoided, but also in terms of disease and hospitalization shortened, and major economic savings due to the replacing role they play in relation with prior less effective therapies*».

[3] The Spanish Constitution recognises, in article 43, section one, «*the right to health protection*», and compels, in section two, «*the public powers to organise and guarantee public health through preventive measures and the necessary provisions and services*». This right is connected, in this as well as to other constitutional rules, with the respect to the person stated in articles 1.1. and 10 CE, and with the fundamental right to life and to physical and moral integrity stated in article 15 CE. See DE LA CUEVA ALEU, I.:

Several months ago, the Government adopted a significant regulatory standard to control the availability of the drugs in specific situations: the Royal Decree 1015/2009, June 19th 2009 (hereinafter RDDMSE[5]), as regulatory development of provisions stated in article 24 LGURMPS[6]. The mentioned Decree aims to facilitate the access to drugs in the clinical research stage for patients who do not have a satisfactory therapeutic alternative, suffering from diseases severely debilitating, endangering their lives, even without being part of a clinical trial (compassionate use[7]). Also, the Decree regulates access to drugs approved in other countries but not in Spain, for patients who are not in research and whose use is essential for these (foreign drugs[8]). Third, it controls access to drugs used in conditions other than those provided in their data sheet (off-label[9]). Traditionally, in Spain, the first and third cases are known as "compassionate use"[10], being legally regulated in the same way. However, this is an unfortunate name, as it is not compassion that is sought.

This rule seeks to eliminate formal steps and speed up procedures, strengthening, in turn, guarantees of safety in these special applications, without neglecting the information and transparency that should prevail in this area. Among the innovations stated in the RDDMSE (innovations that will be considered in this work), we must highlight the fact that the access to drugs that are in research or unauthorised in

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«El Derecho constitucional a la protección de la salud: Jurisprudencia constitucional», *Cuadernos de derecho judicial*, n. 5 (2004), *Salud pública y Derecho administrativo*, pp. 13-80.

Specially, in relation to the field of drugs, in Argentina, for instance, the Supreme Court of Justice of the Nation has recognised on several occasions that the protection of health is a consequence of the right to life and, hence, the State has the obligation to provide the population with the necessary drugs (among other issues, *vid Asociación Benghalensis y otros vs Estado Nacional*, June 1st 2000; *Campodónico de Beviacqua, Ana vs Estado Nacional*, October 24 th, 2000 or *Asociación de Esclerosis Múltiple vs M.S.A.S.N.*, December 18 th, 2003).

4 Law regarding Guarantees and Rational Use of Medicines and Health Products (*Ley 29/2006, de 26 de julio, de Garantías y Uso Racional de los Medicamentos y Productos Sanitarios*. Hereinafter, LGURMPS). *BOE* n. 178 of July 27th, 2006.

5 In Spanish, *Real Decreto 1015/2009, de 19 de junio, por el que se regula la disponibilidad de medicamentos en situaciones especiales*. *BOE*, n. 174 of July 20th, 2009, pp. 60904 *et seq*.

6 Provision which contemplates how, in exceptional circumstances, the Spanish Agency for Medicines and Medical Devices (hereinafter, AEMPS) may grant a permit subject to the requirement for the applicant to meet certain annually reviewable conditions, –concerning, particularly, the safety of the drug, the information given to the competent authorities referred to any incident related to its use, and the measures to be taken. The RDDMSE is responsible, under this protection, to establish the criteria for granting such authorisations. Specifically, those related to prescription and implementation of unapproved drugs for patients not included in a clinical trial, in order to, by compassionate use, treat the special needs of individual patients; as well as the conditions for prescribed approved drugs when used under conditions other than those authorised, being, in any case, exceptional. The LGURMPS also empowers the AEMPS to authorise the importation of drugs not approved in Spain, provided that they are legally marketed in other States, when such importation is necessary for prevention, diagnosis or treatment of specific diseases, being no other proper alternative in Spain, or due to shortage situations.

7 The RDDMSE understands the compassionate use of drugs in research as follows: *«the use of a drug before approval, in Spain, in patients with a chronical or severely debilitating disease or one considered life threatening and who cannot be treated satisfactorily by an authorised product. The drug in question should be subject to a marketing authorisation application, or must be undergoing clinical trials*» (article 2.1 RDDMSE).

8 Under the provisions of article 2.3 RDDMSE, the access to unapproved drugs in Spain is defined as *«the use of drugs approved in countries other than Spain, when they do not comply with the definition of compassionate use of investigational drugs*».

9 Finally, article 2.2 RDDMSE, establishes the following definition for drugs used in conditions other than those authorised: *«the use of drugs in conditions other than those stated in the authorised data sheet»* (article 2.2 RDDMSE).

10 To know the regulation of the compassionate exemption in the United States, see: MATHIEU, M.: «Accessibility programs for the desperately ill», in *New drug development: a regulatory overview* (Ed. M. MATHIEU), Columbia, Parexel International Corporation, 1987, pp. 257-274.

Spain can be managed telematically for each patient, as well as through a temporary authorisation issued by the AEMPS, the Spanish Medicines Agency (hereinafter, AEMPS)[11], in coordination with other European agencies, for a group of patients.

The use of the temporary authorisations mentioned above will bring forward administrative procedures, as patients who meet the requirements stated in the protocols issued by the Administration will have direct access to compassionate use without resorting to an individual authorisation. Regarding the problem of access to drugs that are used for conditions other than those authorised in Spain, and included in its data sheet, the RDDMSE establishes a specific authorisation procedure different to the one provided for compassionate use. The new regulation eliminates the need to obtain an individual authorisation prior to the AEMPS. The responsibility in this area is assumed by the doctor, who will address the recommendations issued by the AEMPS in this respect.

Compassionate Use And Rddmse: A Before And After?

A. TRADITIONAL LEGAL CONCEPT OF COMPASSIVE USE OF MEDICINE.

In connection with the specific authorisation procedures, we must consider, first of all, what is legally knowned as *compassionate use of drug*, being this term being the result of a poor translation –as it does not require compassion– from the English *compassionate exemption*[12]. We are not referring here to an altruistic treatment, palliative, or placebo; but to the use, in individual patients not related to clinical trials, of drugs in research or drugs for indications other than those authorised. To NÚÑEZ LOZANO, compassionate use would entail «the use of a drug in a special way, different to general use, because it is not yet approved, or because it is being authorised, it is prescribed for practices other than those for which they were authorised»[13]. This would be the explanation of its special authorisation regulation.

In order to authorise the compassionate use of a drug, the following requirements must be met: patient's informed consent, doctor's report and compliance from the director of the centre where the drug will be obtained. The fact that our legal system has not granted an active role to those concerned – the patients[14]– is striking. The legal system's fundamental criterion for dispensing the drug is the

[11] Its Statutes have been approved by the Royal Decree 520/1999, March 26th, 1999 (*BOE*, n. 77, March 31st, 1999). See AEMPS homepage: http://www.agemed.es/

[12] See OLALLA, R. & TERCERO, M. J.: «Uso compasivo de medicamentos. Marco legal, tramitación y suministro», *OFFARM*, vol. 26, n. 8 (September, 2007), pp. 94-98.

[13] See NÚÑEZ LOZANO, C.: «Régimen jurídico del uso compasivo de los medicamentos», *REDA*, n. 130 (2006), pp. 327 *et seq.*, specially, p. 328.

[14] As DOMENECH expressively states, *«AEMPS' assessment prevails over the patient's, although only the interests of the patient are at stake; the citizen considers that it is worth taking some risks to save his life, but the public authorities deprive him the possibility of salvation, trying to protect him against his freely formed will, as they consider that they know better than him what he needs, that the risks exceed the expected benefits».* See DOMENECH PASCUAL, G.: *Régimen jurídico de la farmacovigilancia*, Thomson-Civitas, Madrid, Cizur Menor (Navarra), 2009, p. 173.

indispensable quality of its use at the doctor's discernment. It does not state specifically under what criteria.

Although our legal system does not mention exactly what drugs may benefit from this procedure, it is understood that the compassionate use applies basically to those who suffer from diseases which are considered serious (cancer, HIV, rare diseases...) and improves the quality of life of those suffering, especially in areas of paediatric, oncology and psychiatry.

B. ITS DIFFERENCES WITH THE LEGAL REGULATION APPLICABLE TO CLINICAL TRIAL

The legal regulation applicable to the compassionate use of drugs differs from the corresponding regulation to clinical trials. Although in both cases the patient makes use of medicines in research -that *«pharmaceutical form of an active substance or placebo that is being tested or used as a reference in a clinical trial, including products which have marketing authorisation when used or combined (in formulation or packaging) in a different way from that authorised, or when used as treatment for an unauthorised indication, or for obtaining further information regarding an authorised use»*[15]- these are assumptions that are not in the same class. Although it repeatedly seems that, *de facto*, this is not so. The Health Administration keeps demanding requirements for the compassionate use that are not adequate for this[16].

Therefore, the compassionate use takes place, according to its definition, on the fringes of a clinical trial with an individual (see, i.e. the Judgment of Tribunal Superior de Justicia de Catalonia, Sala de lo Social, n. 2700, 1st April 2008). Unlike in clinical research, in which it applies to a group[17]. While in a clinical trial multiple interests meet (those of the sponsor, the investigator, the individuals of the trial and also the society as a whole)[18] –as it is to determine the safety and/or effectiveness of a drug subject to

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[15] Article *2.d)* of Royal Decree 223/2004, of February 6th, which regulates clinical trials with drugs. On this regard, see ANTÚNEZ ESTÉVEZ, F.: «Los ensayos clínicos», RIVAS VALLEJO, P. & GARCÍA VALVERDE, Mª D. (dirs.): *Derecho y Medicina. Cuestiones jurídicas para profesionales de la salud*, Thomson-Aranzadi, Cizur Menor (Navarra), 2009, pp. 619-668.

[16] In this sense, the words of Mª A. MONEDERO MATEO, Head of the Pharmaceutical Assistance Service to the Department of Pharmacy and Health Products in Madrid, are illustrative, stating that «the compassionate use of a drug should be based on ethical assumptions and evidence of effectiveness as strong as those required for approval of a clinical trial»; «the absence of "something better" does not justify the use in clinical practice of uncontrasted emerging technologies». See MONEDERO MATEO, Mª A. «Uso compasivo», *Formación continuada para farmacéuticos de hospital 2.5*, pp. 114 and 115; searchable online at: www.ub.es/legmh/capitols/monedero.pdf

[17] In Andalusia, we can mention the prohibition, by the Andalusian Health Service (*Servicio Andaluz de Salud*, SAS), in May 2010, of the prescrition of *aprepitant* as antitumor. The drug, used to alleviate nausea and vomiting from chemotherapy, was administered in the *Virgen del Rocio* Hospital, in Seville, to some patients as a last attempt to stop the cancer. The Andalusian Ombudsman's complaint of an alleged preferential treatment for drug use, administered only to those patients who were relatives of hospital doctors, uncovered inappropriate and unsafe use of the compassionate procedure. Indeed, in a context of utter arbitrariness and total lack of methodological rigor, rashly and in haste, patients were used as "guinea pigs" in order to test the anticancer drug effect, resulting high mortality (seven of ten patients died). In fact, what was carried out was a clinical trial, transgressing basic ethical principles that should be observed in the field of medical and health care.

[18] The regulation and practice of the Administration in this field leaves a lot to be desired: it links the authorisation of the treatment to the risks that it entails. In the words of the chemists OLALLA and TERCERO: «The main advantage of compassionate use is that it allows certain patients, due to the type of disease they have or the seriousness of their condition,

research– here, the only possible remedy existing for a patient who has no other therapy is being sought. This is why there are no specific rules for those cases in which the patients that will benefit from the compassionate use are minors or disabled adults, such as occurs in the field of clinical trials. No specific precautions are contemplated because, by definition, compassionate use seeks the benefit of the patient, therapeutic benefit[19].

The authorisation procedure for compassionate use has been considered in the Spanish legal system – until the arrival of RDDMSE– as a procedure planned for exceptional cases, under the sole responsibility of the doctor who suggests and justifies its need, having the informed and express consent of the individual patient who accepts it, with the agreement of the director of the centre where the treatment is to be administered[20], and after administrative approval of AEMPS, through its Directorate General for Medicinal Products for Human Use. Once the compassionate use has been authorised, the specific drug will only be administered to the individual patient and used to treat the disease approved for. Now, however, there will be certain cases where access to the drug will be allowed for compassionate use without prior individual authorisation.

Without any doubt, the Spanish legislation in this area is now more advanced than, for example, the Italian one. The D.M. May 8th, 2003[21], regulates compassionate use in Italy, addressing the legal regime of «*uso terapeutico di medicinale sottoposto a sperimentazione clinica*». In that country, compassionate use will always require a prior individual authorisation, not contemplating the possibility of collective ones, as it happens in Spain.

C. THE PATIENT AS A MINOR PLAYER IN THE PROCESS

to benefit from the latest drug developments, even before passing all necessary administrative procedures for marketing, whenever there is scientific proof that supports its efficacy and safety for the indication for use that is requested. However, the compassionate use should be limited only to patients, for which clinical benefit can be obtained, not fulfilling the inclusion criteria of the clinical trial. It is not recommended to use this as an alternative to clinical trials, as the compassionate use is not a means for evaluating a drug, does not provide data on its effectiveness». See OLALLA, R. & TERCERO, M. J.: «Uso compasivo de medicamentos…», *op. cit.*, p. 97.

[19] See NÚÑEZ LOZANO, C.: «Régimen jurídico del uso compasivo de los medicamentos», *op. cit.*; specially, p. 333.

[20] In Extremadura, the Compassionate Use Committee deals with this approval, regulated in Order of February 13th 2006, as a collegiate body, attached to the Directorate General of Health Care of the Health Service of Extremadura. In the case of granting its assent, the Directorate General of Health Service of Extremadura will transfer the proceedings to the AEMPS, which will authorise the use of drugs under the conditions for compassionate use. The Commission must verify the existence of informed consent, as well as study the clinical report in which the doctor justifies the need for treatment, granting or denying such approval for compassionate use of the drug in question.

[21] *GU* n. 173, July 28th, 2003. In relation to article 25 of D. Lgs. n. 178, May 29th, 1991, *Norme di recepimento delle direttive della comunità economica europea in materia di specialità di medicinali per uso umano*, D.L. n. 536, October 21st, 1996, *Misure per il contenimento della spesa farmaceutica e la rideterminazione del tetto di spesa per l'anno 1996* (trasformed into Law by art. 1 Law n. 648, December 23rd, 1996), D.L. n. 23, February 17th, 1998, *Disposizioni urgenti in materia di sperimentazioni cliniche in campo oncologico e altre misure in materia sanitaria* (trasformed into Law with modifications by art. 1.1 Law n. 94, April 8th, 1998); D.M. February 11th, 1997, *Modalità di importazione di specialità medicinali registrate all'estero*, and D.M. March 18th, 1998, *Modalità per l'esenzione dagli accertamenti sui medicinali utilizzati nelle sperimentazioni cliniche*. See SILANO, V. & SILANO, M.: *Medicinali di uso umano. II Edizione. Aspetti amministrativi, economici, legislativi, normativi e tecnici connessi alla sperimentazione, alla produzione, al commercio, ai prezzi e all'uso dei medicinali industriali e galenici e delle relative materie prime*, Tecniche Nuove, Milano, 2001, pp. 272 and 273.

The traditional regulation of compassionate use in Spain has pushed the role of the patient into the background, as we have previously said. Everything is subject to the doctor's opinion, which opens or closes the doors to compassionate use. Worse than this, although the doctor's opinion is "vital" in this procedure, there have not existed –nor exist today, until, perhaps, the future approval of "protocols" and "recommendations" of the AEMPS– clear evaluation parameters which would function as a reference in order to examine their performance when analyzing the feasibility of the treatment that the patient intends to benefit from[22]. Moreover, it is presumed that the patient has a lack of knowledge to declare about the subject, even when what is at stake is his/her own life. Thus, the doctor's refusal to meet the patient's request of compassionate use leaves the patient an only solution, which is to trek around other hospitals looking for another doctor –perhaps in private practice– who is willing to undertake the patient's request.

This is despite the fact that the patient consenting to the treatment is the one taking the risk[23], not the doctor who evaluates its viability. The doctor will be as liable for the above as for ordinary prescriptions. It is not required to sign any specific document to assume liability, nor have to address the potential risks of the treatment with a financial guarantee (such as an insurance policy, established for clinical trials). As a general rule, it will be enough for the doctor to practice according to *lex artis*. He/she does not take, therefore, greater responsibility than the one incurred when drugs are prescribed and used as usual. The doctor will be liable, however, when prescribing a drug for an indication not approved by our health authorities without being under the protection of a compassionate use (case *Iloprost*)[24].

Therefore, the fact that the only role that the patient has historically played in this process is, of course, giving informed consent to the treatment on the terms contemplated in the patient's autonomy regulation, is very striking. The Centre Director must also consent to the treatment. This

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22 The author of these lines is unaware of any pronouncement in this regard from the Spanish Constitutional Court, nor in relation, due to obvious temporary reasons, to RDDMSE, nor to the previous rules contained in Royal Decree 223/2004, February 6th.

23 See RECUERDA GIRELA, M. A.: «Dangerous Interpretations of the Precautionary Principle and the Foundational Values of European Union Food Law: Risk versus Risk», *Journal of Food Law & Policy*, vol. 4 (2008), pp. 1 to 43.

24 In this case, a patient diagnosed with primary pulmonary hypertension died as a result of her doctor changing her treatment. The doctor replaced the *Flolan*, *postaciclina* medication, whit intravenous *Iloprost*, *prostaglandin*, the use of intravenous *Iloprost* not being authorised in this disease, only approved by inhalation, as there was not enough clinical experience or doctrinal or scientific studies to substantiate its safety. Therefore, this patient was administered a drug that was not authorised for her disease. Moreover, on account of its vasodilator effect, it was damaging to the patient due to the congestive heart failure that she suffered. This treatment could only have been justified if the procedure for compassionate use of the former article 28 RD 223/2004 had been correctly followed.
The Court Juzgado de lo Contencioso n. 1 in Seville (Judgement of February 6th, 2006) understood, however, that a case for compassionate use could not be argued here. Firstly, because the change of medication was not seeking the absolute necessity of a cure, instead it was expecting an improvement in the quality of life of the patient and a development of scientific research in this field, and, secondly, because the authorisation of the Directorate General of Pharmacies was subsequent to the initiation of the treatment, and the patient's consent was provided when the drug had been already changed. See ABELLÁN, F. & SÁNCHEZ-CARO, J.: *Responsabilidad médica por la información del medicamento*, Comares, Granada, 2007, pp. 55 and 56.

does not mean that the compassionate use can only take place within a health facility with regard to hospitalized patients or those who depend on their treatment, but also the obligation to access these drugs through pharmacy services in health centres. Although the regulation does not clarify what evidence is to be considered by the Centre Director in order to provide compliance or not, NÚÑEZ LOZANO supports the idea that «what is expected from the Director is a control of the rational use of the drug, this is, a decision valuing the cost that the drug prescription may entail, on the basis of the effectiveness expected from the treatment», a positive assessment of the economic aspect[25]. Do not let yourself be deceived: this is the great "Trojan horse" from which all objections that are made regarding to compassionate use derive.

After this, the AEMPS always intervene, being competent to approve or refuse the compassionate use for each case. This is a new step in this obstacle race against the clock, fighting against administrative bureaucracy; at stake, a person's life. To this mentioned author (and time has proved her right) it was a mistake that the AEMPS had to deal with evaluating, case by case, the benefit/risk connection of a given treatment; and, further, that the access to compassionate use had to be subject to the existing scientific evidence, refusing to subject patients to "unnecessary" risks[26]. Here we can deal with some logical bioethical issues that may emerge in some tragic choices, as the one of the recent judgment of Tribunal Supremo –Sala Tercera de lo Contencioso-Administrativo– 7th July 2009[27].

It is contradictory to base this relationship on the denial of authorisation, as the prevailing approach in order to undertake the decision cannot be other than the patient's will, who wants healing, who wants the improvement of quality of life and, in many cases, just to live. Unless the AEMPS has available data supporting the uselessness of compassionate use (in connection with the provisions of article 3.4 RD 223/2004 with regard to clinical trials: *«In order to ensure optimal protection of the health and rights of individuals, obsolete or repetitive research may not be conducted»*), it should not be refused on the basis of possible existing risks to the patient.

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[25] See NÚÑEZ LOZANO, C.: «Régimen jurídico del uso compasivo de los medicamentos», *op. cit.*, pp. 327 *et seq., passim*; specially, p. 337.

[26] Written reply of the Ministry of Health to a parliamentary question based on the therapy against cancer suggested by Dr. Brú (*BOCG*, Chamber of Deputies, Serie D, n. 371 of April 17th, 2006, p . 261). The Government refused to accept the compassionate use in this case, arguing that there was no data that would justify the extensive use of this treatment proposed by the physicist-mathematician, not considering «appropriate to subject patients to risks from the use of drugs, of which there is no evidence to suggest a potential efficacy».

[27] In the application of thrombolytic therapy, consisting of installation of a pharmaceutical agent in order to dissolve the existing clot or thrombus inside the artery, the Court recognises that this therapy is not exempt from complications, mainly bleeding, being the worse cerebral haemorrhage. For this reason, the Court understood that: «it cannot be said that [⋯] it was possible to apply the abovementioned therapy, or that the same could have prevented or lessened the effects (suffered by the patient), given the nature and complications presented by the application of the therapy [⋯] due to the risk and special characteristics of the therapy (intraarterial thrombolysis), the family would have to be informed as of a "heroic" treatment [⋯]».

The patient has already considered and accepted these, giving his/her informed consent and, therefore, the treatment can be interrupted or ceased only by the patient's own will.[28] The refusal of authorisation cannot be based on the absence of scientific certainty, as, not in vain, it is on precisely this uncertainty that the factual element of the regime is founded[29]. Unfortunately, as we shall see below, not now (with both RDDMSE and LGURMPS regulations) nor during our recent past (with RD 223/2004), the legal system of compassionate use has established the substantive parameters on which doctors and AEMPS take their decisions; nor has been regulated the proceedings in view of the suspension, revocation or modification of any authorisations issued in this field.

D. RDDMS GESTATION. BACKGROUND TO THE ANDALUSIAN REGIONAL MINISTRY OF HEALTH RESOLUTION, FEBRUARY 2008

The slowness of a process fraught with red tape –mostly unknown to health professionals- and the Centre Directors' reluctance to give their approval to these treatments (not wanting to pay the high costs that these directly generate in their budgets) are just some of the main problems that historically the patients who wanted access to this medication in the specific situations outlined above had to deal with[30]. A few years ago, and in order to address these and other identified problems, the Government raised a reform of the legal framework of compassionate use. In the struggle for this reform, associations of patients affected by rare diseases (BARRANCO[31]) integrating into FEDER spoke on several occasions[32].

Consequently, it is in the area of rare diseases where there is a greater number of applications for compassionate use. Most of these requests are for drugs used in cancer diseases, or neurological, ophthalmologist and dermatological cases. In Spain, the access to these drugs in specific situations, in year 2008, according to the Ministry of Health, lead to the processing of 60,000 applications before the

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[28] See NÚÑEZ LOZANO, C.: «Régimen jurídico del uso compasivo de los medicamentos», *op. cit.*, pp. 327 *et seq.*, *passim*; specially, p. 343.

[29] For the journalist A. MURO, we can see the absurdity of protecting forests, animals or coastlines with more eagerness than human beings. Not surprisingly, the Rio Declaration of year 1992 states that *«When the threat of serious or irreversible damage exists, the lack of definitive scientific evidence should not be used to justify measures directed to prevent environmental degradation and to protect ecosystems»*. In this sense, MURO wonders: «Is there further environmental degradation for a human being than to helplessly contemplate how cancer is going to consume his health? Is there any other ecosystem to be protected by our administrators understood more delicate than human life?». See MURO, A.: «Caso Bio-Bac: el principio de precaución y el uso compasivo», *Dsalud*, *on line* at: http://www.dsalud.com/numero47_3.htm

[30] Conclusions drawn by Dr. MONTERO COROMINAS, Coordinator of Compassionate Medicinal products Area for the AEMPS, within the framework of the *V Conference on Rare Diseases of Andalusia,* Granada, November 14th and 15th, 2008.

[31] See BARRANCO VELA, R.: «El estatuto jurídico de los medicamentos huérfanos en la Unión Europea: el derecho a la salud de los pacientes con enfermedades raras», in *El acceso al medicamento. Retos jurídicos actuales, intervención pública y su vinculación al derecho a la salud* (dir. R. BARRANCO VELA; coord. F. M. BOMBILLAR SÁENZ), Comares, Granada, 2009.

[32] The Spanish Federation for Rare Diseases (FEDER), established in Seville in year 1999, brings together more than 170 associations and non-profit organizations that deal, in Spain, with the care of diseases of low incidence. Website: http://www.enfermedadesraras.org

AEMPS (50% related to foreign drugs, 35% related to drugs in conditions other than those stated in its data sheet and 15% related to drugs in research).

After the LGURMPS come into effect, the Government proceeded to repeal (via RD1345/2007) the regulatory source that previously dealt with this issue: article 28[33] of the mentioned RD223/2004, regarding clinical trials[34]. This allowed the Government to continue with a new regulation for compassionate use, adapted to the demands of society, aiming for a reduction in waiting times for patients. In order to achieve this significant goal, considered the Decree's guiding cross, a "temporary authorisation for use" has been created and the administrative procedures so far available have been speeded up. Specifically, we must mention the unification of applications and the use of new information technologies, establishing telematic procedures.

The momentary and apparent regulatory gap that occurred between the repeal of the regulation and the approval of the new Decree 1015/2009, was seized with striking precipitation by the Andalusian Administration, approving a Resolution in February of 2008[35] (clearly invading the exclusive area of competence reserved for the Spanish Government according to article 149.1.16º Spanish Constitution: legislation on drug products[36]) regulating the administrative procedure to be followed by the Andalusian Health Service staff in order to use a drug under conditions other than those specified in its data sheet;

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[33] Article 28 of Royal Decree 223/2004 of February 6th, defines compassionate use as *«the use in individual patients and outside a clinical trial, of investigational drugs, including medicinal products for indications other than those authorised, when the doctor on his own responsibility considers its use essential»* (Section one), requiring for this *«informed consent from the patient or his legal representative, a clinical report in which the doctor justifies the need for such treatment, the compliance of the director of the centre where the treatment is to be implemented, and the approval of the Spanish Agency for Medicines and Health Products»* (Section two), adding that *«the doctor will inform the Spanish Agency for Medicines and Health Products about the treatment's results, as well as any suspected adverse reactions which may be due to it»* (Section three).

[34] Previously, this issue had been addressed in article 23 of Royal Decree 561/1993 of April 16th, which laid down the requirements for conducting clinical trials with drugs, in force until May 1st, 2004. article 23 stated, as would occur later, that: *«The use of a drug under compassionate use conditions will require written informed consent from the patient or his legal representative, a clinical report in which the doctor justifies the need of such treatment, the agreement of the Director of the centre where it is to be implemented, and the approval of the Department of Pharmacy and Health Products for each particular case».*

[35] Resolution of the Ministry of Health of Andalusia (*Consejería de Salud de Andalucía*), February 21st, 2008, on Harmonisation of criteria for use of drugs in the Andalusian Health Service (SAS). See SUÁREZ, J.: «Resolución del Servicio Andaluz de Salud y uso compasivo», *Cuadernos de Derecho Farmacéutico*, n. 25 (2008), pp. 6-12. Also in Andalusia, we should bear in mind the mentioned prohibition of the drug *aprepitant* as antitumor in the footnote n. 17.

[36] In observance to Community guidelines, the Spanish Government has exclusive power of legislation on pharmaceutical products, allowing the establishment of «plans of drugs as "substances" whose manufacture and marketing is under [⋯] the control of public authorities, in order to guarantee the rights of patients and users who use them» (see SSTC 98/2004, of May 25th, FJ 5, and 152/2003 of July 17th, FJ 7). Together with mentioned art. 149.1.16º CE, the Spanish Government also asserts here other evidence of exclusive jurisdiction stated in our Constitution: basis and general coordination of health (art. 149.1.1 and 16 CE), economic regulation of Social Security (art. 149.1 17 CE), Procedure law (art. 149.1.6 CE), General Taxation (art. 149.1.14 CE) or industrial property (art. 149.1.9 CE). See GARRIDO CUENCA, N. M.: «Sanidad, salud y farmacia», in Reformas estatutarias y distribución de competencias [F. BALAGUER CALLEJÓN (dir.); L. ORTEGA ÁLVAREZ, G. CÁMARA VILLAR & J. A. MONTILLA MARTOS (coords.)], Instituto Andaluz de Administración Pública, Sevilla, 2007, pp. 549 *et seq*.; and VIDA FERNÁNDEZ, J.: «La redistribución de competencias entre el Estado y las Comunidades Autónomas en materia de medicamentos», *Revista Española de Derecho Administrativo*, n. 117 (2003), pp. 67 *et seq*.

in clear disagreement with the objective criteria on the matter at a Community and National level, without observing the exceptionality[37] quality or the protective rules of our legal system.

In particular, a request for authorisation would be submitted to the SAS General Secretary. This management centre would make the final decision after advisement from a committee set up for this purpose, consisting primarily of medical specialists that belong to the SAS. This administrative body manifestly incompetent, as the Law 22/2007 of Pharmacy in Andalusia[38], as it could not be otherwise, did not give any powers to the mentioned Regional Ministry to perform this task. The Autonomous Communities have competence in the area of pharmacy, not in the world of medicine[39]. This administrative Ministry could not authorise the use of drugs under conditions other than those approved. No medication can be made available to the public without the authorisation of the relevant health authorities of the Member States (in Spain, the AEMPS) or, at a European Community level, the European Commission, following the scientific opinion of the European Medicines Agency (EMEA), in compliance with the established procedures.

Apart from the relevant patient's informed consent, this Order –nowadays repealed- stated that, in order to request authorisation from the Ministry of Health of Andalusia, the doctors would issue, without any other requirements, a report which would specify the reason for the request and would support, with bibliographical documentation, the drug's usefulness[40], along with the proposal to this effect of the Multidisciplinary Committee for the Rational Use of Drugs of the referred Hospital[41]. It

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[37] Moreover, if we take into account the fact that this Resolution was focused on medicines registered in the past five years – more innovative and, therefore, more expensive from the perspective of its funding- it was said by some professionals of this field that we might find ourselves before a unique use of this mechanism due to purely economic criteria. See SUÁREZ, J.: «Resolución del Servicio Andaluz de Salud y uso compasivo», *op. cit.*, p. 9.

[38] Law 22/2007 of December 18th, of Pharmacy in Andalusia, regulates the planning and management of pharmaceutical services in this Community, trying to ensure quality access to the drug and greater transparency in the allocation of the pharmaceutical offices. The rule includes a policy of rational use of the drug that has been carried out in Andalusia for many years, such as prescription by active principle, and reinforces the role of the pharmacist as a health agent. See GÁLVEZ PÉREZ, J.F.: «El futuro de la ordenación farmacéutica en Andalucía», *Revista Andaluza de Administración Pública*, n. extra 2 (2003), pp. 495-534.

[39] In Spain, the Autonomous Communities have competence to develop and implement health issues, meeting general basis and coordination in this regard established by the Spanish Government, but it is the Spanish Government, as noted, who is exclusively responsible of the configuration and development of those measures addressed to ensure the security and safety of drugs, being the CCAA competent to implement. The State Government has taken into consideration the demands of the principle *market unity*, stated in article 139.2 of the Constitution: well above the territorial scope of an autonomous community of the phenomenon under competition, the Spanish Government has argued that public activity exerted on it is not susceptible of division, requiring an amount of homogeneity that can only be ensured through the assignment of executive powers to a single authority, the Spanish Government itself (STC 243/1994 of July 21st, FJ 6). On the other hand no one misses, as evidenced by DOMÉNECH, that leaving to the Autonomous Communities the decision to grant or deny a permit could cause an irrational fragmentation of the market, raising the costs supported by pharmaceutical companies. See DOMÉNECH PASCUAL, G.: *Régimen jurídico de la farmacovigilancia*, *op. cit.*, *passim*, specially, pp. 125 to 130.

[40] It is worth recalling that, if a doctor, outside both a clinical trial and the established legal procedure, prescribes a drug for a different indication (based, for instance, on scientific publications), the potential adverse effects that might occur to the patient will have no legal coverage and, therefore, the doctor himself will be responsible for these.

[41] Each of these Committees, based on scientific evidence criteria, evaluates the efficacy, safety and efficiency of new drugs, in comparison with the available therapeutic alternatives, deciding whether the drug is included or not in the Hospital's Pharmaceutical Guide in question and, if so, under which use conditions. About the economic evaluation of drugs, should bear in mind the important role, in the United Kingdom, of the NICE (National Institute for Health and Clinical Excellence), The recommendations of this independent organisation, can help the NHS to save millions of pounds, whilst

was enough if the doctor understood necessary off-label uses of the drug, in the event that the drug's usefulness was justified. Therefore, other objective conditions related to the patient's situation and especially the fact of not having any other drugs approved for the treatment of disease were dispensed. In any case, the Andalusian Regional Government led the way and, shortly after, the Spanish Government would follow, adopting the RDDMSE in year 2009.

In this sense, the Director of any SAS hospital was able to directly authorise a request similar to another one which the Government had already provided a positive response, whenever the clinical circumstances described in both cases would meet; extending, thus, automatically the SAS authorisation of other "similar" situations, without the supervision of an independent administrative entity. As stated above, the RDDMSE does not include the need for an application and authorisation individualized for each patient. Access to drugs in research or that are unauthorised in Spain may be managed through a *temporary authorisation* issued by the AEMPS, in coordination with other European agencies, for a group of patients.

Related to this issue, we must mention that the request of some Autonomous Regions, such as Madrid, to participate in the decision of authorising these drugs, was left out of the oral hearing stage. They had a strong interest in participating in such proceedings, due to the drug being a very high cost product, and they would then have to pay through the integrated hospitals in their Health Services. For them, the application of such a rule was especially concerning in a period of economic recession, taking into consideration the pharmaceutical spending bill growing exponentially year after year[42]. An economic impact that we cannot rule out, although what it stands for is precisely the rationalisation of these types of procedures –which, in any case, would be justified by the fact that these procedures seek only to reach patients with seriously debilitating or life threatening diseases, possibly meaning their salvation.

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maintaining or improving the quality of care. See: http://www.nice.org.uk/ and the report written by J. ESPÍN & J. ROVIRA: «Analysis of differences and commonalities in pricing and reimbursement systems in Europe», EASP Final Report, June 2007.

[42] In order to avoid the "discrepancies" produced in recent years among the various doctors within the Andalusian Public Health System when prescribing drugs having a special health, social and, of course, economic impact, Resolution of the Andalusian Health, August 7th, 2009, entrusts the SAS Head Management, at the new Advisory Commission's proposal for harmonisation of standards for the use of such drugs, and in view of reports of the Andalusian Sanitary Technologies Evaluation Agency, to decide, based on these criteria, which drugs will be included in the Hospital's Pharmaceutical Guide in the SAS organisation. Moreover, a unified procedure for prior authorisation for prescribing and dispensing drugs with prescriptions subjected to control is established. It is used when, exceptionally, due to lack of therapeutic alternatives, it is necessary to conduct an off-label use of these drugs. Such authorisation may be requested only by doctors assigned to a hospital. This will be accompanied by a doctor's report stating the non existence of alternative therapies, as well as providing scientific documentation. This will be referred to the relevant Branch, who will seek, from the Advisory Commission, a report harmonising the criteria for use of drugs in different conditions to those stated in its data sheet, containing the proposed terms of use in order to grant permission or the reasons for its refusal. The above without losing sight of the recommendations issued by the AEMPS in this regard. In case of disagreement among the members of this Commission, the procedure for high-impact medication will be attended. In this case, provided that the application is invoked the circumstances of urgency of treatment, SAS Branch may propose to the Head Management to issue an interim decision applicable only to the individual case concerned. In other cases that do not have such complications, the head Management will make a decision, extended to all patients who attend the same circumstances.

E. A NEW REGULATION FOR AUTHORISATIONS

The AEMPS may allow the compassionate drugs used for investigational drugs. For this purpose, there are two available procedures: individual access authorisation and temporary use permits. It is no longer necessary, as it was before, the express permission of the AEMPS for each case. Patients who meet the requirements set out in the corresponding protocol, approved by the AEMPS, shall have access to compassionate use without resorting to an individual authorisation issued by the mentioned authority.

In the first case, referred to in article 8 RDDMSE, the hospital in question will submit a request to the AEMPS for access to investigational drugs on an individual basis[43], subject to approval by Centre Management. In its application, the Centre will enclose a clinical report issued by the corresponding doctor stating, on the one hand, the need for medication for that specific patient, including dosage and expected duration; on the other, the reason that justifies that the patient is not able to be treated by a drug that has already been approved in our country[44]; also proof and data supporting its use in the patient; and, finally, the explanation of this why drug is not appropriate to be included in a clinical trial. Although the patient's consent (or his/her representative's) –previously informed of the drug's relevance, implications and risks of treatment– will be essential prior to the administration of the drug, this will not be part of the authorisation application before the AEMPS. This Spanish Agency will enable a formal system so as to facilitate access of the Autonomous Communities' Competent Authorities to the individual authorisations.

Second, we must pay special attention, as already pointed out, to the temporary authorisation to use investigational drugs outside a clinical trial[45] (article 9 RDDMSE). Such authorisations, considered a great innovation of the Decree 1015/2009, may be issued *«in cases of drugs that are at an advanced stage of clinical research designed to support a marketing authorisation, whenever it is planned to be used on a significant group of patients»*. The resolution, which will include the requirements and conditions under which the drug may be used out of clinical trial, will exonerate the centres from the need to apply for authorisation to individualised access for each patient.

In the European Union, the Regulation (EC) 726/2004[46] contemplates –*acquis communautaire* which is now embraced by our internal rules[47]– a query procedure before the Committee for Medicinal Products

[43] Obviously, prior to this fact, the sponsor of the clinical trial or the applicant for marketing authorisation must state their willingness to provide that product to the AEMPS (article 7.1, second paragraph, RDDMSE).

[44] In the case of patients with rare diseases, it is difficult to find an alternative treatment available. Therefore, it is among this group of diseases where the largest numbers of requests for compassionate use are submitted.

[45] The AEMPS will encourage and facilitate the inclusion of these patients in clinical trials, promoted in relation to investigational medicinal products for which the compassionate use was applied for.

[46] Regulation (EC) n. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

for Human Use (CHMV) in EMEA towards the development of protocols for use with the objective of ensuring equity in the access to compassionate use drugs[48]. These protocols are called, by the RDDMSE, *temporary use permits*. These tools streamline administrative procedures, this being something to treasure in a field in which human lives are at stake.

The AEMPS will develop and give these temporary authorisations, and will amend, suspend or revoke them when new scientific evidence indicates so, for the sake of the patient's safety and the proper use of the product. In order to do so, work teams will be formed, according to different pathologies, composed by physicians, pharmacists, pharmaceutical companies, research groups, scientific societies, patient associations and the AEMPS itself. They will set the criteria to be reflected in those protocols. Protocols or temporary use permits that which we believe will fit into the category of plurality or general administrative acts, as will be discussed later.

The AEMPS will also notify such temporary use authorisations to the EMEA[49] and report them, as well as the security problems detected in relation to them, to the competent authorities of the Autonomous Communities (Spain it is an extraordinarily decentralised country) and the clinical trial sponsor or the applicants for the marketing authorisation. The applicants will also be informed within 15 days from notification, of suspected serious adverse reactions. Obviously, the doctor should also notify the AEMPS immediately of the severe reactions suspected according to his knowledge, as well as any other information related to the requested treatment. The sponsor of clinical trials or the applicant for marketing authorisation will cooperate with the AEMPS, in order to lay down the requirements of its use, and will notify the AEMPS at once of any significant information in relation to product's safety. Each and every one of these agents is involved in the activity of pharmacovigilance, having the obligation to continuously provide the best possible information on drug safety.

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[47] As in the 33rd initial consideration it has been said: «*In order to meet, in particular, the legitimate expectations of patients and to take account of the increasingly rapid progress of science and therapies, accelerated assessment procedures should be set up, reserved for medicinal products of major therapeutic interest, and procedures for obtaining temporary authorisations subject to certain annually reviewable conditions. In the field of medicinal products for human use, a common approach should also be followed, whenever possible, regarding the criteria and conditions for the compassionate use of new medicinal products under Member States' legislation*».

[48] Article 83.2 Regulation (EC) 726/2004 provides the following definition of compassionate use «*to give, for compassionate reasons, a drug belonging to the categories mentioned in paragraphs 1 and 2 of Article 3, to a group of patients suffering from chronic or serious debilitating illnesses, or considered to be life threatening and cannot be satisfactorily treated by an authorised drug. This drug should be subject to an application for marketing authorisation pursuant to Article 6, or to clinical trials*». The drugs in question should be those subject to a centralized procedure (orphans, biotechnology, paediatric...), along with others which contain a new active substance not authorised in the Community on the date the regulation coming into force, those which constitute a significant innovation from a therapeutic, scientific or technical point of view, and those whose consent would present a concern for patients at a community level.

[49] Art. 83 Regulation (EC) 726/2004 states that, when a Member State grants an authorisation for compassionate use, the Agency shall be notified. The Committee for Medicinal Products for Human Use, after consulting the manufacturer or the applicant, may adopt opinions on conditions of use, distribution conditions and the patient's necessity of the above. These opinions will be updated regularly, published on the website of the Agency, and will be taken into consideration by Member States. In any case, these opinions will not affect the civil or criminal liability of the manufacturer or the applicant for marketing authorisation.

Concerning the Hospital Management, after approving the implementation of such authorisation in its centre it will ensure, that the patients who are proposed to use these drugs meet the conditions set out in temporary permits, and that they have given their written informed consent to the medicine administration.

The Use Of Drugs In Different Conditions To The Approved

The RDDMSE also raises the problem of access to drugs used in conditions other than those authorised in Spain and included in its data sheet[50]. The RDDMSE states a separate authorisation procedure for such cases, differing from the established procedure for compassionate use. This particular situation occurs when there is clinical data on a particular therapeutic use, but it does not appear on the drug's data sheet (or on the product's characteristics summary). This sometimes happens in therapeutic areas in which research activity is very intense –not allowing the existing scientific knowledge at a given time to incorporate such uses in the data sheet– on drugs that are used with a specific population (such as paediatrics), as well as on "classic" drugs, that can have established conditions of its use in clinical practice, but not mentioned in the authorisation, as it is not economically viable to undertake the necessary studies to obtain its approval.

The RDDMSE leaves no doubt: this is an exceptional use of the drug, limited to those situations in which there are no authorised therapeutic alternatives. It is framed within a clinical practice area and subjected to a special procedure before the AEMPS, differing from the corresponding procedure for compassionate use. This new procedure focuses liability on doctors[51]. These must justify the need for using drugs in different conditions from those provided in the data sheet, and properly inform the patient of all the details related to this practice, obtaining the patient's consent after explaining risks and benefits of this use. A different question would be the patient having to know how to act against doctors who do not approve the access to medication in different conditions than those stated in the data sheet, if these are protected by *lex artis*. This question is left unanswered by the RDDMSE.

Although the new legislation eliminates the need to obtain an individual permit from the AEMPS, it keeps its ability to issue such use recommendations as it deems appropriate in the following cases listed in article 13 RDDMSE, namely: when a health risk due to a drug used in conditions other than those

[50] For instance, the use of antidepressants to treat obesity problems. See OLALLA, R. & TERCERO, M. J.: «Uso compasivo de medicamentos…», *op. cit.*, p. 95.

[51] The prescription is a document that ensures the establishment of a treatment with drugs under the instructions of a doctor, a dental surgeon or a chiropodist. Now, after the reform of article 77 LGURMPS on December 2009, nurses can also to prescribe certain drugs, through a dispensing order from the hospital.

authorised can be reasonably foreseen, in the case of drugs subject to restricted medical prescription[52], or finally when the use of a drug in such conditions *«entails a significant health care impact»,* meaning, substantially increases public pharmaceutical expenditure[53] (i.e. the Judgment of Tribunal Superior de Justicia of Madrid, Sala de lo Contencioso Administrativo, n. 1810/2009, September 30th, 2009[54]). These recommendations are to be considered by health care facilities when developing the appropriate treatment protocols replacing individual permits. The AEMPS will share this information with the competent authorities of the Autonomous Communities.

These recommendations for use prepared by the AEMPS will be revised, depending on the efficacy and safety data available. The AEMPS may request information not only from the authorisation holder – who will be informed of these recommendations as well as notified of the suspected adverse reactions– but will also have its own group of experts. The holder of the marketing authorisation is obliged to notify, in turn, the possible adverse reactions of his knowledge, not to advertise[55] the use of the drug in different conditions to those approved, and to provide the AEMPS with all the information concerning the product in question that could affect it. The treating doctor will also notify the AEMPS of the adverse reactions he suspects according to his knowledge, and also inform the patient, in a comprehensive way, of the treatment, of its implications and of its risks.

Use Of Foreign Drugs

In relation to foreign drugs, the regulation updates the procedure towards its acquisition, allowing patients to access to them through an individual application in accordance with a protocol supported by the AEMPS, provided that these drugs have been legally authorised in other countries and are essential to the prevention, diagnosis or treatment of specific diseases, there being, in our country, no other

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[52] The drugs subject to treatments that can only be followed in the hospital (due to their pharmacological properties, novelty or reasons of public health); those used for the treatment of diseases which must be diagnosed in a hospital or an other appropriate centre, although the administration and monitoring can be carried out outside this centre; and those intended for outpatients, whose action can produce very serious adverse reactions, shall be subject to the subcategory of medicinal products reserved to restricted prescription, requiring such documents as issued by a specialist and a specific monitoring during the treatment. In the Spanish legal system, Title II, Chapter II, LGURMPS, the Order of May 13th, 1985, on medicinal products under special medical supervision in its prescription and use, or the Royal Decree 618/2007 of May 11th, which regulates the procedure for the establishment, by a specific permission (*visado*), of a unique procedure for prescribing and dispensing drugs.

[53] The resources that the States have are limited, being the right to health shaped by *economic considerations*. The State must not only preserve the health of the citizens, but also of public funds, which must face many other needs of its population. Although limited to the Italian context, a particular referenced work on this issue is the doctrinal article developed by Profs. CASSESE, S.; PARDOLESI, R. & CARAVITA DI TORITO, B.: «La disciplina dei prezzi dei farmaci», *Il Foro amministrativo T.A.R.*, 2003, pp. 3117 *et seq*.

[54] In this judgment the Court understood that a patient had no right to receive the medical assistance consisting of infiltration of BOTOX, in order to treat chronic headache and cervical dystonia, under ASISA insurance company, together with ISFAS (Social Institute of Armed Forces), as such treatment had not taken place in a hospital stay regime.

[55] See DE LA QUADRA SALCEDO, T.: «La regulación de la publicidad de los medicamentos de uso humano», in *Derecho de la sanidad y los medicamentos: seis estudios*, Ministerio de Sanidad y Consumo, Madrid, 1999, pp. 15 to 61; or SUÑÉ ARBUSSÁ, J. M. y BEL PRIETO, E.: «El Real Decreto 1416/1994, por el que se regula la publicidad de los medicamentos de uso humano», *Cuadernos de Derecho Europeo Farmacéutico*, n. 3 (1996), pp. 57-91.

suitable alternative approved for this indication, or in a situation of shortages. Logically, we will only be in the presence of this alleged case when the definition of compassionate use of investigational drugs is not being observed.

Given the above, two requirements are, therefore, included in the RDMSE in order to allow, in exceptional circumstances, access to unapproved drugs in Spain: that there is no other drug with the same composition already authorised in our country –or being so, it must be in a pharmaceutical form that does not allow the patient's treatment– or, second, that there is no other licensed drug in our country as an alternative to it. As in the field of compassionate use, here there are also two established procedures for authorising public access to such drugs: individual access and collective access through a protocol of use.

As for individual access, the corresponding request will be submitted to the AEMPS through the Health Ministries of the Autonomous Communities (or specific departments designated by them) or through the Hospital Management. The application must be attached to a medical prescription and a clinical report which justifies the need of such treatment, its duration and the number of containers required, as well as scientific data that can justify the use of such medication for the specific therapeutic indication when, exceptionally, it differs from that mentioned in the data sheet of the country of origin (also, and if required, the laboratory's consent will be attached) It will not be necessary to enclose the mentioned documents, if the AEMPS understands so, when the product in question is necessary in our country as a result of shortages of the alternative approved drug in Spain. The patient's informed consent will not be part of the application for authorisation, although it will be essential in order to administrate the drug.

Secondly, access to these drugs is provided through a protocol of use, which makes it unnecessary to request an individual permit. The AEMPS, via these protocols -which may be nominated by the competent authorities of the Autonomous Communities- will set the conditions for the use of a "foreign drug" when its need is foreseen for a significant subset of patients. The AEMPS will review these protocols when necessary, based on scientific data or new drug approvals of its knowledge, informing the owner of the drug. The AEMPS will also inform the competent authorities of the Autonomous Communities about these protocols –as individual licenses– in order to then spread the documents among the health centres located in their own region. According to these protocols of use, the ministries of health (or centres designated by them), or the management of health facilities will request the needed amount of drug from the AEMPS, provided that the patient in question complies with the protocol of use established by the AEMPS.

The treating doctor will prescribe the drug and draft a medical report justifying the need for the specific treatment, he will then notify the suspected adverse reactions of his knowledge informing the patient of all the details related to the treatment, in order to obtain his/her informed consent. At the same time he

will ensure that the patients meet the conditions required in the approved use protocols. As for the holder of the marketing authorisation, he is subject to a number of obligations, namely: he must provide the documentation requested by the AEMPS, he must notify all suspected adverse reactions to the AEMPS or confirm the availability of the drug and to ensure its supply. Given the exceptional nature of the procedure that we are addressing, the holder of the authorisation for the foreign drug has the obligation not to promote the use of the drug and ensure that it will be used solely and exclusively by the applicant institutions.

Along with the aforementioned unauthorised access to drugs in Spain and the drugs intended to be used in our country, referred to in article 4.24 LGURMPS and regulated in Chapter IV of RDDMSE, we must mention a special case in which, provided that there is a health emergency, the legal system includes an exception in terms of import and export of drugs. In this sense, article 24.5 LGURMPS, along with article 5 D2001/83[56] empowers the AEMPS to *«temporarily allow distribution of unauthorised drugs in response to the suspected or confirmed spread of a pathogen or a chemical toxin, or nuclear radiation capable of causing harm»*. Such a permit is temporary. During this period of time, lasting as long as the health emergency, the holder of the authorisation and health professionals are exempt from civil liability for the use of the referred drug or the unauthorised signs[57].

Administrative Simplification And Use Of Icts

The RDDMSE seeks that all requests under its coverage are submitted to the AEMPS, except in specific cases, such as telematic uses (GAMERO)[58], as provided in article 27.6 of Law 11/2007, June 22nd, regarding electronic access of citizens to Public Services[59], stating that *«the Civil Service may make it compulsory to communicate with them via electronic means only, when persons concerned are legal persons or groups of individuals who, due to economic or technical capacity, professional dedication or other accredited reasons, have guaranteed*

[56] Directive 2001/83/EC of the European Parliament and Council of November 6th 2001, which establishes a Community Code on Medicinal Products for Human Use; subject to several reforms up to the current date, one of the most important being that operated by Directive 2004/27/EC.

[57] See OLIVERA MASSÓ, P.: «Fabricación, distribución, importación y exportación de medicamentos en el marco de la Ley 29/2006, de garantías y uso racional de los medicamentos», *Noticias de la Unión Europea*, n. 288 (2009), pp. 33-45; specially, p. 45.

[58] In connection with telematic notifications, we must mention the work of GAMERO CASADO. Among others, the following monographs: *Los medios de notificación en el procedimiento administrativo común*, Instituto Andaluz de Administración Pública, 2001; y *Notificaciones telemáticas y otros medios de notificación administrativa en el procedimiento común*, Bosch, 2005.

[59] All this in connection with the guarantees of transparency stated in article 3 RDDMSE: the AEMPS *«will ensure access to its decisions and recommendations in this Royal Decree to health facilities, to the competent authorities of the autonomous communities, to the holder of the marketing authorisation of the drug or his representative, to the applicant of the marketing authorisation or the sponsor of the investigational product»;* and under the provisions of Organic Law 15/1999, of December 13th, on Protection of Personal Data; in Law 41/2002 of November 14th, regulating the patient's autonomy and rights and obligations regarding information and clinical documentation; and, of course, the Law 30/1992 of November 26th, on the Legal Regime of Public Administration and Common Administrative Procedure (LRJAP).

access and availability of precise technological means». The above is related to the *Plan for the Reduction of Administrative Burdens and Regulation Improvement*, i.e., administrative simplification work (CIERCO)[60].

Moreover, the transitory disposition of RDDMSE anticipates that, during the period of one year from coming into effect the mentioned regulation, it will be possible to submit the applications here given by any of the means listed in article 38.4 LRJAP[61]. However, after such period, the applications must be submitted by telematic means. In our opinion, the patient would not be helpless due to this new rule. The citizen himself is not who directly processes the compassionate use request to the AEMPS[62]. A hospital (a legal person to which it is guaranteed access and availability of precise technological means) will do so meaning that the application would not be here exempted under article 27.1 of Law 11/2007[63].

Under this new legal framework, it is expected that a telematic application will be installed in the AEMPS site, now running as a pilot project, allowing the hospital pharmacy teams send requests for compassionate use from their own terminals, leaving behind years of long and cumbersome administrative processes used under the previous regulation. Thus, it is expected that practitioners have more time to invest fully in the monitoring of patients and the safety of drugs. Not surprisingly, more than 60,000 applications processed through the AEMPS in year 2008 entailed between two hours and a month's work per request. Therefore, the Health Ministry and the AEMPS have a special interest in the RDDMSE beginning to deploy its effects as soon as possible. In any case, until the summer of 2010, the AEMPS will continue processing requests via paper format.

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[60] In compliance with First Additional Provision of Law 4/1999 of January 13th, ammending Law 30/92, the Royal Decree 670/1999 of April 23rd was approved, creating the Interministerial Commission of Administrative Simplification. In this respect, the thoughts of César CIERCO, included in his articles, are very interesting: «Algunas reflexiones sobre la simplificación de los procedimientos administrativos a la luz de los avances de la Administración electrónica», *Revista General de Derecho Administrativo*, n. 19 (2008); «Simplificación administrativa y principio de precaución: ¿Objetivos incompatibles? (Reflexiones a propósito del asunto Monsanto, STJCE de 9 de septiembre de 2003)», *Revista española de derecho europeo*, n. 13 (2005), pp. 111-155; «La tramitación integrada de los procedimientos administrativos conexos», *Revista Vasca de Administración Pública*, n. 65, 1, 2003, pp. 11-50; or «La reducción de la carga de presentación de documentos ante la Administración Pública», *Revista Andaluza de Administración Pública*, n. 48 (2002), pp. 389-436.

[61] Under this provision of the LRJAP, the requests directed by the citizens to the bodies of the Public Administration may be submitted: in the Registers of the Administrative centres where they are addressed, in the Registers of any Administrative centre belonging to the government (in the case of entities of the Local Government, only if they have signed the appropriate agreement), in post offices or diplomatic or consular offices of Spain abroad. Specific cooperation agreements signed between the different public administrations will establish intercommunication systems and coordination of registries to ensure their technological compatibility, as well as the data transmission of registration entries and requests.

[62] See TEDESCO, M. R.: *L'integrazione europea e l'influenza delle nuove tecnologie sui diritti di partecipazione ai processi decisionali delle Istituzioni*, PhD thesis, defended at the Seconda Università degli Studi di Napoli, 2009.

[63] In the mentioned article, it is stated that: *«The citizens may choose at any time how to communicate with the Administrations, by electronic means or not, except in those cases where a legal regulation establishes the use of a non-electronic means. The option to communicate by different means is not binding for the citizen, who may, at any time, may choose a mean other than the one initially appointed».*

Challenge Of The Denial Of Approval

Due to the legal problems that this issue may raise, we want to highlight in its own chapter the procedures provided to challenge the denial of approval by the AEMPS of the procedures for access to drugs in special situations. The variety of cases in which the patient can request access to the drug in special situations –from those involving a deadly serious risk to the applicants ("situations of eviction") to those which "only" affect certain conditions of the enjoyment of their lives– results in a broad *technical discretion*[64]. Discretion meaning that, in the case of refusal by the Administration to accept such use, the patient will not have effective feedback mechanisms. In any case, to NÚÑEZ LOZANO, the criterion understood here should not be purely technical, it will be necessary to weigh the different interests at stake[65]. To do otherwise would, once again, wrongly attribute compassionate use requirements that are characteristic of clinical trials.

The RDDMSE provides in articles 8 and 18, in both cases in paragraphs 3 and 4, the procedure to follow in order to challenge the authorisation of individual access to compassionate use of drugs to be authorised and of unauthorised drugs in Spain, respectively.

If the application does not meet the requirements stated in our existing legal regulation, in the opinion of the AEMPS, it will be required that the applicant corrects the deficiencies within 10 days. If this is not done correctly, it will be understood that the applicant will withdraw its application. Similarly, if the AEMPS considers that individual access to the drug in question cannot be allowed, the applicant will be informed and will have a period of 10 days for allegations and to provide the documentation deemed appropriate. The problem is that neither LGURMPS nor RDDMSE expressly establish the substantive parameters under which the AEMPS shall grant or refuse such approval.

The denial of approval is a final administrative act, that is capable of challenging the appropriate appeal for reversal (*recurso de reposición*) or judicial review *(recurso contencioso-administrativo*). The authorised person who has the right to bring forward the action is the patient, who is considered to be "the interested party" in the procedure, although he cannot initiate it, as the application is processed through the hospital. Even conceiving the authorisation as a singular administrative act, in this case the subjective element of the authorisation is the patient himself, as an authorised individual to use the drug in a

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[64] Regarding legal authority and administrative discretion, SÁNCHEZ MORÓN, M.: *Derecho Administrativo. Parte General*, Tecnos, Madrid, 2008 (4th Edition), pp. 87-98; specially pp. 90 and 91. According to this author, this would be a case of technical discretion «when the legal system states in favour of managers, an area of their own decision to issue an argument based on purely technical assessments or characteristics of a professional knowledge». The decision has an objective basis, being able to contrast and, if necessary, withdraw, citing contradictory evidence or technical analysis to show the "error" of the Administration. See also IGARTUA SALAVERRÍA, J.: *Discrecionalidad técnica, motivación y control jurisdiccional*, Civitas, Madrid, 1998.

[65] According to this author, this technical discretion «cannot ignore the interest of the patient; and the decision taken on the request for compassionate use must be sufficiently motivated, with appropriate consideration between what the current state of Science dictates the doctor, the potential profit that could be obtained by compassionate use and the risk that the patient –not the doctor- is willing to take». See NÚÑEZ LOZANO, C.: «Régimen jurídico del uso compasivo de los medicamentos», *op. cit.*, specially, p. 337.

special situation[66]. Obviously, in such cases, the logical response would be to request a discrecionary appeal and immediately ask for, as a precautionary measure, the suspension of the denial, which would mean precautionary receiving authorisation for the drug[67]. This measure would have its full meaning, as the dismissal of the petition could have irreparable consequences for the patient's health or life.

But is there any way to challenge the decisions of temporary authorisation of use of investigational drugs, apart from a clinical trial, or protocols developed by the AEMPS stating the conditions for access to unapproved drugs in Spain? Moreover, what legal status do these "protocols" developed by the Administration have? There are many questions which the RDDMSE gives no answer to.

We understand that these protocols could be considered administrative acts, described by doctrine as plural or general (THOMA[68]): those with a general subjective scope, presenting a plural or indefinite receiver (MARTÍN-RETORTILLO[69]). This act relates Administration, hospitals and doctors –in short, the National Health System– and, of course, patients themselves who demand access to these drugs through compassionate use. Citizens that would be entitled to challenge such "protocols" –first, through an administrative appeal and then, if necessary, before the administrative courts– would be covered by their *legitimate interest* in this regard. A qualified interest, not just an objective interest in the enforcement of the law or a hypothetical interest, i.e., an interest resulting from an administrative action that leads to a particular subject (own, real, actual or potential).

Although these citizens will not be able to object to the protocol claiming an their own right, a subjective right of substantive nature, they may, however, claim that the decision of the Administration (the protocol) is taken by the competent authority, following the established procedure, without arbitrariness, meeting all requirements and conditions stated in the legal system. In order to do so, they have a reactional right to defend their interests and rights of participation in the procedure dealing with that decision (article 31.2 LJCA[70]). The challenge will be precisely identifying and specifying the requirements and conditions on the basis of which these citizens could claim the annulment of the

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66 See LAGUNA DE PAZ, J. C.: *La autorización administrativa*, Civitas, Madrid, 2006, p. 196.

67 Although this measure is rarely taken, we can find an exception to this rule in the Judgment of the Sala de lo Contencioso-Administrativo of Seville, TSJA, of October 19th, 2004.

68 From a doctrinal point of view, the concept of "*allgemeine Verfügung*" was thought of by the German author THOMA, being the first to notice the existence of general orders, focused on a plurality of persons which were lacking legal status so they should be considered as administrative acts. Several examples can be mentioned: the determination of the date of an exam, the announcement of an official examination. See THOMA: *Der Polizeibefehl im Badischen Recht*, I, Tübigen, 1906, pp. 63 *et seq*.

69 See GARCÍA DE ENTERRÍA, E.: «Recurso contencioso directo contra disposiciones reglamentarias y recurso previo de reposición», *RAP*, n. 29 (1959), pp. 161 *et seq*; MARTÍN-RETORTILLO BAQUER, L.: «Actos administrativos generales y reglamentos», *Revista de administración pública*, n. 40 (1963), pp. 225-250; or LEGUINA, J.: «Legitimación, actos administrativos generales y reglamentos», *RAP*, n. 49 (1966), pp. 193-224.

70 Law 29/1998 of July 13th, regulating the Administrative Procedure (in Spanish, *Jurisdicción Contencioso Administrativa*), its article 31.2, states that the claimant *«may claim the recognition of a particular legal situation and the adoption of appropriate measures for the full restoration of the same, including compensation for damages, when appropriate».*

decision taken in breach of law. It would be more difficult, given the field in which we are, to see compensation for "damages" suffered as a result of that action[71].

These citizens could also act through groups of patients or persons affected by a particular disease, as our legal system also considers it worth protecting the *collective interests* –interests that do not affect, or at least not exclusively– a person individually, but a group or category of people (i.e., those affected by the *brittle bone* disease*,* grouped within the association AHUCE). This is a collective interest that goes beyond mere compliance with law. Thus, these kinds of associations are given the right of their holders to intervene in administrative proceedings (article 31 LRJAP), to be party in judicial proceedings (article 7.4 LOPJ) and, in short, to defend through these their rights as a collective.

Not much more can be said until we have knowledge of the effects that this Decree RDDMSE will have. In any case, it is a promising standard for the millions of patients who have been struggling for years against their own disease and against a procedure that is slow, cumbersome and bureaucratic in the extreme. An obstacle race against time to reach a drug that allows them to save or considerably improve their greatest asset: life. We hope for that.

[71] See SÁNCHEZ MORÓN, M.: *Derecho Administrativo. Parte General*, Tecnos, Madrid, 2008 (4th Edition), pp. 87-98.

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Paper n. 2

DISCRIMINATION AND REASONABLE ACCOMMODATION: "INSIGHTS" FOR A (NON) ZERO SUM GAME

by

Giovanni Comandé

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DISCRIMINATION AND REASONABLE ACCOMMODATION: INSIGHTS FOR A (NON) ZERO SUM GAME[1]

by

Giovanni Comandé ♦

"In any society the rights of one will inevitably come into conflict with the rights of others. It is obvious then that all rights must be limited in the interest of preserving a social structure in which each right may receive protection without undue interference with others."[2]

Abstract:

Modern societies are becoming increasingly multicultural due to intensive migration as well as free internal circulation of people in specific regional areas such as the EU. This circulation of people from different cultural and legal backgrounds is both reviving old legal issues and raising new ones, thereby calling for a better understanding of the interplay between individual and group protections in light of fundamental rights and non discrimination principles. Indeed, no matter the characteristics of the group (e.g. gender, ethnicity, health…) there is always the risk that, while attempting to protect it from external discrimination, the measures serve to perpetuate individual discrimination within it. Usually these issues are mainly targeted from a mere public law perspective. In this article the author lays down the grounds for more extensive research aiming to study the impact that the circulation/migration of individuals is having on private law adjudication, and the techniques through which it occurs in modern times. In order to set the boundaries of the research the author selects examples of impact from the areas of family, property and contract law and uses the Canadian approach as a litmus test for spotting the relevant legal problems. Further, the selection of Canada as a target of study, with a closer focus on Québec and Ontario, sets the basic elements for further investigating eventual variances in approaches among civil and common law systems.

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[2] *Ont. Human Rights Comm. v. Simpsons-Sears*, [1985] 2 S.C.R. 536, at para 22.

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Key words:

Introduction

Globalization stirs both old and new issues. Modern societies are becoming increasingly multicultural due to intensive migration as well as free internal circulation of people in specific regional areas such as the EU. This circulation of people from different cultural and legal backgrounds is both reviving old legal issues and raising new ones, thereby calling for a better understanding of the interplay between individual and group protections in light of fundamental rights and non discrimination principles. Indeed, no matter the characteristics of the group (e.g. gender, ethnicity, health…) there is always the risk that, while attempting to protect it from external discrimination, the measures serve to perpetuate individual discrimination within it. Usually these issues are mainly targeted from a mere public law perspective. In this article the author lays down the grounds for more extensive research aiming to study the impact that the circulation/migration of individuals is having on private law adjudication, and the techniques through which it occurs in modern times. In order to set the boundaries of the research the author selects examples of impact from the areas of family, property and contract law and uses the Canadian approach as a litmus test for spotting the relevant legal problems. Further, the selection of

Canada as a target of study, with a closer focus on Québec and Ontario, sets the basic elements for further investigating eventual variances in approaches among civil and common law systems.

The physical circulation of people is an increasing occurrence concerning several countries. Furthermore, motivations for migration have altered, shifting States' concerns on the flows of circulation of people. For example, in Italy which until recently was more affected by the phenomenon in the form of tourism than by the presence of large numbers of non-citizens permanently residing on their territory,[3] concerns regarding the coexistence of different cultures are rather recent.

The permanent presence of non-citizens on national soil is a complex issue when the enjoyment of civic rights is considered, particularly in relation to the risk of discrimination.

Clearly enough then, discrimination and the actual application of the equality principle are also at stake when non-citizens are involved.

In European Union private law evolutionary trends, the non-discrimination principle is fully present both in the Principles of the Existing EC Contract Law, so called Acquis Principles, whose Chapter 3, is entirely devoted to "Non-discrimination", obviously with express reference to the language of directive 2000/43/EC, and in the Draft Common Frame of Reference which, after ample recalling in the introductory remarks, dedicates Book II Chapter 2 to non-discrimination with useful proxies regarding the relevance of the principle of non-discrimination with reference to the principle of equal treatment[4].

Last but not least, as emphasized by the ECJ[5], Articles 52 and 59 of the Treaty prohibit any restrictions on the freedom of establishment and the freedom to provide services. Any measures which prohibit, hinder or makes less attractive the exercise of these liberties must be considered as restrictions to them[6].

In this process of continuous innovation a pivotal role has been afforded to judicial decision-making which, while primarily aiming to coordinate different jurisdictional levels (national vs. European mainly), has rendered any unreasonable discrimination increasingly difficult, often by reference to fundamental freedoms protection. In Europe, this willingness to protect the fundamental rights of

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[3]For instance, according to official data (available on www.istat.it) in Italy there are to date about 4 millions of resident foreigners. See ISTAT: Rilevazione sulla "Popolazione residente comunale straniera per sesso ed anno di nascita". More than half a million of them were born in Italy. Foreign citizens come from about 254 areas in the world with communities of different dimension varying form 1 individual (Tuvalu, Kiribati) to more than 796.477 (for instance Rumenian).umenian). See also OECD Statistical Profile for Italy, available at: http://stats.oecd.org/Index.aspx?DatasetCode=CSP2009

[4] O. LANDO and H. BEALE (eds.), *Principles of European Contract Law Parts I and II*. Prepared by the Commission on European Contract Law (The Hague 1999); Ole Lando, Eric Clive, André Prüm and Reinhard Zimmermann (eds.), *Principles of European Contract Law Part III* (The Hague, London and Boston 2003). Outline Edition of DCFR available online at https://portal.law-net.eu/home/start.php?art=3902&showart=3902&gruppe=4

[5] See Judgment of the ECJ (Grand Chamber) of 16 December 2008, *Heinz Huber v Bundesrepublik Deutschland*, Case C-524/06, ECR 2008 I-09705 and Judgment of the ECJ (Second Chamber) of 5 June 2008 *James Wood v Fonds de garantie des victimes*, Case C-164/07, ECR 2008 I-04143

[6] See Judgment of the ECJ (Sixth Chamber) of 30 March 1993, *Christos Konstantinidis v Stadt Altensteig* Case C-168/91 ECR 1993 I-01191 at 15, and Judgment of the ECJ of 20 February 2001, *Asociación Profesional de Empresas Navieras de Líneas Regulares (Analir) and Others v Administración General del Estado*. Case C-205/99, ECR 2001 Page I-01271 at 21.

individuals from unlawful discrimination has also been bolstered by reference to common constitutional traditions and indeed the case law of the European Court of Human Rights in Strasbourg[7]. Often, from judicial arguments, both at national and international level, one can even identify patterns of indirect impact of fundamental rights protection, embedded in national constitutions and binding international conventions, on private relations[8].

All of the processes referred to above are incorporated by legal systems according to both the protections afforded and limits imposed by fundamental rights protection in private law rules. In other words, fundamental rights protection is at the heart of the extension of the civil rights enjoyed by citizens, while also going to the core of their limitation and the possible (to some extent even legitimate) discrimination by legislators amongst citizens and between citizens and non-citizens..

Canadian multiculturalisms and the crossroads of private law: reasons of (European) interest

As anticipated, the increased circulations of people and recent migration trends have rendered the situation more complex, as we have just summarized.

Sometimes cultural, religious, ethnic, and disparate behaviours in our societies generate new phenomena which require either the incorporation of new legal institutions and norms, known or unknown to our systems, or their consideration as part of the process of accommodating different interests.

Occasionally they necessitate the tackling of old issues from a different angle, as in the so called Wood case heard before the ECJ[9] or likewise in a case heard in the Tribunale di Milano where the amount of non-pecuniary damages suffered by relatives of a fatal car accident were at stake[10] and questioned on the grounds of different country of residence and culture.

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[7] The ECtHR has taken huge strides in its understanding of the ECHR's Art 14 anti-discrimination provisions in recent years so it now extends to the spheres of social security and arguably employment. This is despite the it often being derided and underestimated, see further R. O'CONNELL, *Cinderella Comes to the Ball: Article 14 and the Right to Non-Discrimination in the ECHR* Legal Studies, Vol. 29 No. 2, June 2009, pp. 211–229.

[8] See, for instance, G. Brüggemeier, A. Colombi Ciacchi, G. Comandé eds., *Fundamental Rights and Private Law in the European Union. Vol. I: A Comparative Overview and Fundamental Rights* and *Private Law in the European Union. Vol. II.: Comparative Analyses of Selected Case Patterns*, Cambridge University Press, 2010. See also Cherednychenko, O.O. (2010). *Fundamental Rights, Policy Issues and the Draft Common Frame of Reference for European Private Law*. European Review of Contract Law, 6(1), 39-45

[9] See Case C-164/07 *James Wood* as above in fn 8, at para. 16. The Court of Justice held that EC law precludes legislation of a member State which excludes nationals of other member States who live and work in its territory from the grant of compensation intended to make good losses resulting from offences against the person where the crime in question was not committed in the territory of that State, on the sole ground that they do not have the nationality of that State.

[10] See G. COMANDÉ, *La legge è uguale per tutti: il risarcimento tra "gabbie risarcitorie" e reciprocità*, in *Danno e Responsabilità*, 2009, 1135ff. Tribunale di Milano, Sent. n. 12099, 18 dicembre 2008, available at http://www.lider-lab.sssup.it/odp_pdf/immagine/milano_5-2008.pdf. The Tribunale recognised the principle of compensating aliens for damage to health resulting from an accident stranger, even apart from assessing the condition of reciprocity, for non-pecuniary damage, such as the loss resulting from killing of the spouse.

These phenomena are inevitably bound to increase both in number and complexity, thereby eventually affecting all areas of private law. Indeed, they seem to already be significantly infiltrating family law, contracts and the law of obligations in general specifically evoking so-called anti-discriminatory law.

Finally, when taken together the establishment of a European private law, of fundamental rights protection, of fundamental freedoms (of circulation) enforcement and the creation of an internal market by their very nature place distinct limits on the possibility of disparity of treatment[11].

Despite the fact that some EU Member States have long experience in receiving immigrants (e.g. UK, France, and the Netherlands) and in developing multicultural models[12], it is undeniable that contrasts of values and tensions among fundamental rights and freedoms are escalating[13]. For this reason a further analysis of the Canadian experience would provide a useful benchmark[14] and might provide inspiring solutions or, at least clear interpretative patterns for phenomena some European countries have not experienced before. After all Canada "openly promotes the values of diversity as a necessary, beneficial, and inescapable feature of Canadian society"[15].

Indeed, the choice of Canada to center the study has several justifications. Primarily, we should mention that Canada participates in the Council of Europe[16]. The Canadian multicultural tradition is by itself an analytical model for EU Member States. Moreover, the Canadian experience allows us to begin testing whether common and civil law systems use different approaches and techniques in private law when dealing with issues of migration and their interplay with private law[17]. Civil law and common law coexist in a unique constitutional setting in Canada and this experience can offer useful hints in the unifying "constitutional" framework of the Lisbon treaty.

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[11] See for instance and with referencerefrence to family the contributions in P. DE CESARI (edt.), *Persona famiglia*, *Trattato di diritto privato dell'Unione Europea*, Torino, Giappichelli Editore, 2008.

[12]See J. BERRYMAN, *Accommodating Ethnic and Cultural Factors in Damages for Personal Injury*, 40 U.B.C. Law rev., 2007, 1, at 24, affirming that "Multiculturalism is a value not a right".

[13] Fundamental rights and the protection of those rights should operate as an intersection and consolidation as a guarantee of harmonisation of the Community's social tissue and, on the other, as a guarantee for the different identities that exist therein. See further E. D'ORLANDO, *Fundamental Rights and New European Constitutionalism: an Italian Approach,* Transition Studies Review (2006) 13 (1): 201–209. In European integration law human rights are recognized as empowering citizens, as constitutionally limiting national regulatory powers, and as requiring governments to protect and promote human rights in all policy areas across national frontiers. See further E. PETERSMANN, *Time for a United Nations 'Global Compact' for Integrating Human Rights into the Law of Worldwide Organizations: Lessons from European Integration*, *European Journal of International Law* 2002 13(3):621-650.

[14] Canada has expressly devoted a law to the issue: Canadian Multiculturalism Act (1985, c. 24 (4th Supp.)). In general see the Canadian Charter of Rights and Freedoms 1982 to which we will refer later on in the text.

[15] S. V. WAYLAND, *Citizenship and Incorporation: How Nation-States Respond to the Challenges of Migration* (1996) 20-FALL Fletcher F. World Aff. 35 at 46.

[16] The Government of Canada started participating in CoE activities in the 1960s, but was not granted official observer status with the Committee of Ministers until 1996. In 1997, Canadian parliamentarians were granted official observer status with the Parliamentary Assembly of the CoE. Canada has helped develop and signed several Concil of Europe conventions, including the those on the Transfer of Sentenced Persons and on Cybercrime. See http://www.canadainternational.gc.ca

[17] Specific mention should be made to the Quebec's *Charte des droits et libertés de la personne*, L.R.Q., which expressly extends its reach to private law. See further, e.g. P.O. LAPORTE, *La Charte des Droits et Libertes de la Personne et son Application dans la Sphere Contractuelle*, 40 *R.J.T.* n.s. 287 (2006)

Also for this reason we will focus on the Canadian experience as such, but we will refer more in detail to the Québec and Ontario experience in order to contemplate both legal families. The specific policy in Québec, centered on the sharing of the French language and the respect of diversity, offers further insights[18]. In fact, countries where emigration traditionally occurred (such as Italy or Ireland) and which had a rather homogenous society (in relation to language and religion for instance) are amongst today's new-found 'immigration countries' adapting to migrants of diverse social, cultural, religious, and legal backgrounds (Asia, Latin America, Africa and Eastern Europe)[19] so the Canadian legal accommodation experience could prove useful at least to understand the issues we are facing. For these European countries, the way in which Canadian common/civil law has reacted in dealing with accommodating various cultures would offer a set of solutions tested in private law systems theoretically compatible with their own which could potentially be transplanted[20]. In addition, the way rather culturally uniform legal systems (as Québec) have faced the challenges of multiculturalism in the interplay with private relationships is a useful source of inspiration.

On the other hand, the traditional multicultural nature of Canadian society, by definition a country whose population was amassed through immigration and integration, and the coexistence of both civil and common law traditions in one institutional setting offers a potentially keys field-study both for EU Member States and the EU itself.

More precisely, in the growing common context of a "quasi" constitutional setting (for the EU treaties and the Lisbon treaty in particular), linked with an increasing interventionist European Court of Justice in defence of the fundamental rights protection of EU citizens[21] and of the ECtHR in the framework

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[18] BARREAU DU QUÉBEC, *Mémoire du Barreau du Québec présenté à la Commission de consultation sur les pratiques d'accommodement reliées aux différences culturelles « Les droits fondamentaux : Une protection pour toutes et tous »,* Décembre 2007, at 17: "Les droits de la personne représentent un ensemble cohérent, indivisible et universellement reconnu qui garantit le respect de la dignité humaine. Tous les droits de la personne ont donc une égale valeur en droit, bien que certains reçoivent une attention plus soutenue que d'autres dans le libellé des chartes nationales, et notamment dans celui de la *Charte canadienne des droits et libertés* et de la *Charte des droits et libertés de la personne* du Québec. L'énonciation variable des droits de la personne dans les documents constitutionnels ou quasi-constitutionnels nationaux n'altère toutefois pas le principe de leur indivisibilité et de leur interdépendance. Tous les droits ont la même valeur et la dignité de chacun dépend du respect de tous les droits de la personne."

[23]For OECD International Migration Statistics, see http://titania.sourceoecd.org/vl=20201853/cl=12/nw=1/rpsv/statistic/s12_about.htm?jnlissn=16081269.

[20] See A. WATSON, *Legal Transplants and Law Reform*, (1976) 92 *Law Quarterly Review,* p. 79: "…*whatever their historical origins may have been*, rules of private law can survive without any close connection to any particular people, any particular period of time or any particular place" (p. 81). But see K. ZWEIGERT and H KÖTZ, *Introduction to Comparative Law,* 3rd ed, Clarendon Press, Oxford, 1998, p. 17: "The reception of foreign legal institutions is not a matter of nationality, *but of usefulness and need*. No one bothers to fetch a thing from afar when he has one as good or better at home, but only a fool would refuse quinine just because it didn't grow in his back garden."

[21] Although reluctant to take on an overtly constitutional role, as seen recently in *Ayadi v. Council*, Case T-253/02 [2006] E.C.R. II-2139 and *Panayotova v. Minister voor Vreemdelingenzaken en Integratie*, Case C-327/02 [2004] E.C.R. I-11055, the ECJ has for some time referred to fundamental ights in dicta in *Stauder v. City of Ulm,* Case 29/69, [1969] E.C.R. 419, at 7, and *Internationale Handelsgesellschaft mbH v. Einfurh-und Voratsstellefur Getreide und Futtermittel,* Case 11/70, [1970] E.C.R. 1125, at 4 and in *Nold v. Commission* Case 4/73 [1974] E.C.R. 491 it confirmed that respect for fundamental rights forms an integral part of the general principles of Community law.

of the Council of Europe, the approaches developed in Canada could be a source of inspiration for policies aimed at balancing diverse legal frameworks, political agenda(s) and legal tools[22].

In addition, one of the main aims of the Canadian multiculturalism model is to reduce the pressure to assimilate by the majoritarian groups by way of recognizing «droits différenciés»[23]; it does not prevent integration but it redefines its conditions in a more equitable way. This does not contradict the fact that regular normativity adopts as its own the predominant groups' vision of the world (e.g. male, heterosexual, Christian, middle class, etc)[24]. On the contrary, the acknowledgment that the "predominant view" is already a partial one will help in the search for social justice and in reconciliation of the majority's view with the cultural models emerging from the immigrant and non-predominant groups.

Note also that this integration model does not lead to auto-determination in the sense of communities within State organizations[25] but offers a set of flexible tools to accomodate differences without, possibly, disrupting the social structure altogether[26]: a so called more "partaken citizenship".

The underlying idea is to empower the legal and regulatory framework of the majorities to accommodate social pluralism[27] (not necessarily only the ethno-religious one). Yet, as we shall see accommodation of group cultures should keep in mind the protection of vulnerable individuals[28] within the groups, either minority or majority ones. "This framework is thought to be a way in which minorities can retain cultural distinction without compromising their social equality"[29].

A specific reference might be necessary for the Quebec experience[30] which, it has been said, borrows both from the Anglo-Saxon multiculturalism and from the French republicanism in which plurality is

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22 See P. NOREAU, « *Le droit comme vecteur politique de la citoyenneté* , in. *Cadre d'analyse pour l'étude des rapports collectifs entre majorité et minorités* », in M. Coutu, P. Bosset, C. Gendreau et D. Villeneuve, « *Droits fondamentaux et citoyenneté. Une citoyenneté fragmentée, limitée, illusoire »*, Onati/Montréal, Thémis/Institut international de sociologie du droit, 2000. pp. 323-359.

23 W. KYMLICKA, *Multicultural Citizenship : A Liberal Theory of Minority Rights*, Oxford, Oxford University Press, 1995; W. KYMLICKA, *La voie canadienne. Repenser le multiculturalisme*, Montréal, Boréal, 2003, p. 95.

24 See I. M. YOUNG, *Polity and Group Difference : A Critique of the Ideal Universal Citizenship*, (1989) 99 *Ethics* 250-274. Of course this view does not buy agree with the normative neutrality argument as pretended defended by J. RAWLS, *A theory of justice*, Cambridge, Ma., 1971.

25 In the Canadian experience reference is often made to native americans people and Québec people. See among several, P. BOSSET and P. EID, *Droit et religion : de l'accommodement raisonnable à un dialogue internormatif,* Commission des droits de la personne et des droits de la jeunesse, Cat. 2.500.127, 2006, 9.

26 Indeed, the limits to the notion of duty to reasonable accomodation reflect this spirit.

27 See J. WOEHRLING, *L'obligation d'accommodement raisonnable et l'adaptation de la société à la diversité religieuse,* (1998), 43 *McGill L.J.* 325, at 398-401. With specific reference to religion see A. SARIS, *Les tribunaux religieux et le droit étatique*, Textes du Congrès 2005 du Barreau du Québec, 2005, p. 402-403.

28 See on the issue S. M. OKIN, *Is Multiculturalism Bad for Women, in J. COHEN, M. HOWARD et N. NUS SBAUM (edts.), Is Multiculturalism for Women? Susan Moller Okin with Respondents, Princeton, Princeton University Press, 1999, p. 1-24; N. BAKHT Arbitration, Religion and Family Law: Private Justice on the Backs of Women*, at http://www.nawl.ca/ns/en/documents/Pub_Report_ReligArb05_en.rtf.

29 N. BAKHT, *Arbitration, Religion and Family Law: Private Justice on the Backs of Women*, National Association of Women and the Law, 2005, at p.36.

30 See BARREAU DU QUÉBEC, *Mémoire du Barreau du Québec présenté à la Commission de consultation sur les pratiques d'accommodement reliées aux différences culturelles « Les droits fondamentaux : Une protection pour toutes et tous »,* Décembre 2007, at 33: "Le Québec de part son histoire est une terre d'immigration. On a qu'à se rappeler l'arrivée des premiers colons il y a 400 ans. Le respect de la diversité a toujours été essentiel pour maintenir une cohésion sociale. Considéré comme un facteur

not permitted as such[31]. The Québec resolutions talk in term of a "moral contract" between the Québec society and immigrants according to which French language is imposed but Québec acknowledges its pluralistic cultural identity and the heterogeneity of the Québec nation[32]. Nevertheless, the final outcome is not a sort of archipelago of groups in which a plurality of legal orders operates because the Québec charter defines the limits for the accommodation of groups in light of fundamental rights protection. Once again, the majoritarian and minoritarian views as well as individual rights are accommodated pragmatically in light of fundamental rights protection, equality and non discrimination. This continuously evolving equilibrium would, for instance, prevent any form of legal segregation which would ensue from the application of private (i.e. non State) family law regimes.
Having established a set of reasons for the work we can now turn to building up the analysis.

Background information: establishing what is problematic

Digging deeper in the matter of diversity and equal treatment the first issue that comes up is citizenship and different treatment of citizens versus non-citizens. Citizens are persons who have been recognized by a State as having an effective link therewith[33]. International law generally leaves the authority to each State to determine who qualifies as a citizen. Citizenship can ordinarily be acquired by being born in the country (known as *jus soli* or the law of the place), being born to a parent who is a citizen of the country (known as *jus sanguinis* or the law of blood), naturalization or a combination of these approaches.
According to international instruments, all persons should, by virtue of their essential humanity, enjoy all human rights. Exceptional distinctions, for example between citizens and non-citizens, can only be made if they serve a legitimate State objective and are proportional to the achievement of that objective or if they have been linked by the European Court of Justice (within the EU) to the protection of fundamental rights and their role in limiting fundamental freedoms[34]: the equality principle admits exceptions contrasting citizens and non-citizens but these exceptions are strictly scrutinized under fundamental rights protection. Indeed, all national constitutions drawn up after WWII limit the

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important pour le développement du Québec, l'immigration répond principalement et concrètement à des enjeux majeurs d'ordre démographique et économique."

[31] See in an historic perspective D. SCHNAPPER, *La citoyenneté : perspectives historiques et théoriques. La conception de nation, Citoyenneté et société, La documentation française, Les Cahiers Français, mai-juin 1997, no 281*. Sometimes the Québécois policy is termed "interculturalism".

[32] See literally DES COMMUNAUTÉS CULTURELLES ET DE L'IMMIGRATION (MCCI), *Au Québec pour bâtir* ensemble. *Énoncé de politique en matière d'intégration et d'intégration,* Gouvernement du Québec, 1990, p. 16-19: « À l'opposé de la société québécoise traditionnelle qui valorisait le partage d'un modèle culturel et idéologique uniforme par tous les Québécois, le Québec moderne s'est voulu, depuis plus de trente ans, résolument pluraliste […]. La possibilité de choisir librement leur style de vie, leurs opinions, leurs valeurs et leurs appartenances à des groupes d'intérêts particuliers, *à l'intérieur des limites définies par le cadre juridique*, constitue d'ailleurs un des acquis de la Révolution tranquille […]. La culture québécoise est ainsi une culture dynamique qui, tout en s'inscrivant dans le prolongement de l'héritage du Québec, se veut continuellement en mutation et ouverte aux différents apports. La Charte des droits affirme, de plus, « que les personnes ont le droit de maintenir et de faire progresser leur propre vie culturelle avec les autres membres de leur groupe.»..

[33] The Nottebohm Case (Liechtenstein v. Guatemala) International Court of Justice April 6, 1955, 1955 I.C.J. 4.

[34]See, Judgment of the Court (First Chamber) of 14 October 2004, *Omega Spielhallen- und Automatenaufstellungs-GmbH v Oberbürgermeisterin der Bundesstadt Bonn,* Case C-36/02 ECR 2004 p I-09609.

possible legitimate disparity of treatment between citizens and non-citizens. Moreover, in more expansive supranational communities (such as the EU) the possible different treatment of citizens of a different Member State is made increasingly problematic through the intervention of the courts[35].

Additionally, international courts (e.g. the ECHR, the ECJ) are increasingly ready to protect individuals' fundamental rights against illegitimate discrimination. Areas of judicial intervention can be easily found in labour law, family law and contract law, in which it is rather easy to find case law[36].

Judicial arguments often proceed along the lines of highlighting indirect impactson the fundamental rights protection of private relations, as embedded in either constitutions or binding international conventions. One alternative route expressly followed in some legal systems, such as the Canadian Provinces, includes looking to the equality principle as commanding a reasonable accommodation to avoid discrimination[37].

Against this legal background, social science literature[38] notices, on the one hand, a different attitude of migrants in modern globalized societies who enjoy access to enhanced long-distance communications and, on the other hand, a societal attitude more open to accommodating diversity, and managing it with social and legal tools (e.g. reasonable accommodation)[39].

Indeed, immigrants usually bring their traditions with them (e.g. cultural, legal, and religious). Furthermore, due to improved information and communication technology, modern immigrants are better able to maintain frequent contact with their original community and might be more reluctant to dismiss their practices and traditions for the sake of quicker and deeper integration into the host country. In short, in sub-local communities linked to their home country and through similar communities within the host country, they often replicate an insular society closely related to their original culture. This is also the case when dealing with matters governed by private law and this sort of insularity might enhance the tension between the respect of minority rights and cultures and fundamental rights protection within them.

It is rather intuitive that the maintenance of traditions and habits either unknown or at least "strange" to the local host community (e.g. Canada or Italy) might interfere with the actual enjoyment of rights

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[35] See for instance the contribution on citizenship from A. IANNIELLO SALICETI in P. De CESARI (a cura di), *Persona e famiglia*, quoted, *passim*. See J. L. MURRAY, *Fundamental Rights in the European Community Legal Order*, 32 *Fordham Int'l L.J.* 531 2008-2009, and J. H. WEILER, *Eurocracy and Distrust: Some Questions Concerning the role of the ECJ in the Protection of Fundamental Human Rights within the Legal Order of the European Communities* 61 Wash. L. Rev. 1103 1986.

[36]See, for instance, G. BRÜGGEMEIER, A. COLOMBI CIACCHI, G. COMANDÉ eds., *Fundamental Rights and Private Law in the European Union. Vol. I: A Comparative Overview and Fundamental Rights* and *Private Law in the European Union. Vol. II.: Comparative Analyses of Selected Case Patterns*, Cambridge University Press, 2010.

[37] *Ont. Human Rights Comm. v. Simpsons-Sears*, [1985] 2 S.C.R. 536, at para 22: "While no right can be regarded as absolute, a natural corollary to the recognition of a right [to equality] must be the social acceptance of a general duty to respect and to act within reason to protect it."554.

[38] Information Communication Technologies are used in both regular and irregular migration, in maintaining family relations, sustaining cultural identities, and supporting dependents from abroad so governments and civil society are seemingly working to increase access and use of ICTs. See, e.g. J.-Y. HAMEL, (2009): *Information and Communication Technologies and Migration.* Published in: Human Development Research Paper (HDRP) Series , Vol. 39, No. 2009.

[39] See *infra* in the text for the notion.

and interests within the private domain. In addition, the expansion of multicultural societies commands more respect for individual attitudes different from those which can be defined as mainstream or majority ones in any given country. This "novel" respect for diversity might in turn create tensions for the protection of individuals within the minority community. One clear example, often quoted in literature[40], is the protection of women in discrete communities which maintain their right to cultural,religious or legal diversity[41].

One could point, for example, to the recent debate in several western legal systems about establishing (or in some cases simply legally acknowledging the already operating) religious courts for family or contractual matters; or to the need to permit an *effet utile* of legal institutions generally prohibited in the host country (e.g. polygamy) in order to grant minimal protection to the weaker party in the relationship (e.g. the subsequent wife or the children technically born out of wedlock in the host country).

Consider also the "Kafalah" of Islamic legal tradition and its application in non-Islamic countries when deciding on the custody of children[42], or the use of rituals or the wearing of clothes contrary to public order or private agreements, or the closing/opening of shops, or the request of holydays contrary to work agreements in order to fulfil religious belief – the list is potentially endless.

All the above mentioned examples hinge upon the enjoyment of fundamental rights and liberties which have different legal and social relevance in any given legal system and require the adoption of a variety of balancing techniques when they conflict amongst themselves or indeed with the general legal framework (e.g. collective agreements, public offer settings, self-regulation, adhesion contracts…).

While all human beings are entitled to equality in dignity and rights, States may narrowly draw distinctions between citizens and non-citizens with respect to political rights explicitly guaranteed to citizens and their freedom of movement. Finally, we must contemplate, that in principle a non-national immigrating to any given country can acquire the local nationality. This is important to remember because, once citizens, their "different" treatment according to their legal, cultural or religious tradition

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[40] See, e.g. the debate in India: K. SANGARI, *Politics of Diversity: Religious Communities and Multiple Patriarchies* Economic and political weekly, Vol. 30, No. 51, December 23 1995. See generally, for instance, S. BENHABIB *The claims of culture: equality and diversity in the global era*, (2002) Princeton University Press.

[41]For instance, one reference could be to the permission of arbitration in family matters and the risk of undermining women rights in doing so. See as favourable to permitting religious arbitration the report to the Ontario General Attorney by M. BOYD, *Résolution des différends en droit de la famille : Pour protéger le choix, pour promouvoir l'inclusion*, 2004. The final outcome was rather different: see *Family Statute Law Amendment Act*, S.O. 2006, c. 1. In Québec in principle all private arbitration is forbidden « dans toute autre matière qui intéresse l'ordre public ». See *Code civil du Québec*, art. 2639.

One other example is the interplay between religious rules and privately agreed upon clauses in agreements related to family matters and divorce to the extent these are permitted in a given country. See *infra*.

[42] For an Italian example see, Corte di Cassazione, Sezione Prima Civile, Sentenza del 20 marzo 2008 n. 7472. Text available (in Italian) at http://www.programmaintegra.it/modules/dms/file_retrieve.php?function=view&obj_id=1868

raises a rather different set of issues in terms of equal treatment which can be permitted by constitutions for non-citizens but deemed illegal when citizens form part of the picture[43].

Furthermore, different groups of non-citizens can be identified, including permanent residents, migrants, refugees, asylum-seekers, victims of trafficking, foreign students, temporary visitors, other kinds of non-immigrants and stateless people. While each of these groups may have rights based on separate legal regimes, the problems faced by most, if not all, non-citizens are very similar when their choices effectively concerning daily life and ordinary activities are at stake[44].

In this study our main aim is to go in more depth into the impact that the circulation/migration of individuals is having on private law adjudication and through which techniques it occurs. To investigate the subject we will leave aside whether or not the individuals involved in a case are citizens or immigrants.

A sub-goal, capable of offering further policy guidelines, is the search for possible different techniques used by courts adjudicating in a common law or in a civil law legal system. It is for this reason that Canada is again a natural target of research. Indeed, once this initial research scope is ascertained it will be possible to investigate to what extent, how and to which level of impact the processes of circulation and migration have influenced and/or can influence the evolution of private law rules by posing new problems and issues, arising not only from economic asymmetries but also from social, education, cognitive, cultural, religious, linguistic asymmetries, to name but a sample. Indeed, this analytical process could well be of use in analyzing the anti-discrimination protections in national private laws.

Against this bedrock several problematic issues emerge as crucial in our societies and challenging for the legal systems that regulate them. In short, a map emerges when tackling:

1. the impact of the multiculturalism in some ways necessitated by the circulation of people[45] on private law rules and the potential tensions ensuing among liberties (e.g. freedom to dispose and contract);
2. the legal instruments used to foster integration in a given society without imposing full homologation (fundamental rights protection vs. reasonable accommodation according to the equality principle and non/discrimination)
3. the potential contrast between protection of minorities (as opposed to majorities) and the protection of individuals within the minorities;
4. the tensions, both new and old, in private law rules in light of the increase of intercultural changes (e.g. refusal to lease; ethnocultural arguments in litigation)[46].

[43]The investigation of the actual levels of different treatments between citizens and non-citizens in private law regulated relationships is not the aim of this article. Yet occasionally we will need to face this issue.

[44] These common concerns affect approximately 175 million individuals worldwide – or 3 percent of the world's population ("World demographic trends: report of the Secretary-General" (E/CN.9/2003/5, para. 53).

[45] A different pattern of this issue is due to the EU freedoms of circulation and will be dealt within a different article: G. COMANDÈ, *EU freedoms of circulation, multiculturalism and fundamental rights at the intersection of private law*, on file with author.

The four issues listed in the previous paragraph require further investigation and cannot be fully examined in their entirety in this contribution. Here we will confine ourselves to attempting to individuate the main problematic issues and to define a general overview of the avenues of solutions emerging by the analysis of some cases in the Canadian federal and provincial experiences. To do this we shall clarify some notions and the actual references to constitutional or quasi constitutional instruments.

Filling the notions: reasonable accommodation/accommodement raisonnable and its limits

As anticipated, a major technique used in Canada to deal with the problematic we have just outlined is the notion of *accommodement raisonnable* or reasonable accommodation for which in Canada a specific date can be found for its first clear acknowledgement[47]. Scholars[48] and courts refer to the so called *Simpsons-Sears*[49] case in which the judges found an instance of indirect discrimination[50] deriving from the right not to be discriminated against under the general duty to take reasonable steps to reach an agreement with the claimant, short of undue hardship in the regular course of the business[51].

In the words of the court: "The question [of the duty to accommodate] is not free from difficulty. No problem is found with the proposition that a person should be free to adopt any religion he or she may choose and to observe the tenets of that faith. This general concept of freedom of religion has been well-established in our society and was a recognized and protected right long before the human rights codes of recent appearance were enacted. Difficulty arises when the question is posed of how far the person in entitled to go in the exercise of his religious freedom. At what point in the profession of his faith and the observance of its rules does he go beyond the mere exercise of his rights and seek to enforce upon others conformance with his beliefs? To what extent, if any, in the exercise of his religion is a person entitled to impose a liability upon another to do some act or accept some obligation he

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[46]See art. 12 and 13 of Quebec Charter of Human Rights and freedoms, available at http://www.cdpdj.qc.ca/en/commun/docs/charter.pdf

[47] Similar notions can be found i Directive 78/200CE.

[48]See, for instance, S. BERNATCHEZ, « Les enjeux juridiques du débat québécois sur les accommodements raisonnables », (2007), 38 *R.D.U.S.* 233 – 286., 235.

[49] *Ont. Human Rights Comm. v. Simpsons-Sears*, [1985] 2 S.C.R. 536 (Appellant O'Malley alleged discrimination on the basis of creed against her employer, a retailer, because she was periodically required to work Friday evenings and Saturdays as a condition of her employment. Appellant's religion required strict observance of the Sabbath from sundown Friday to sundown Saturday. Given this conflict, appellant accepted part-time work because a full-time position not involving work on Saturday was not available to a person with her qualifications. Both the Divisional Court and the Court of Appeal upheld a Board of Inquiry's decision to dismiss the complaint. At issue was whether or not a work requirement imposed on all employees for business reasons discriminated against appellant because compliance required her to act contrary to her religious beliefs and did not so affect other members of the employed group.). See also, P. BOSSET, *Les fondements juridiques et l'évolution de l'obligation d'accommodement raisonnable*, Commission des droits de la personne et des droits de la jeunesse, Cat. 2.500.128, 1997, 20ff and ID., *Réflexion sur la portée et les limites de l'obligation d'accommodement raisonnable en matière religieuse*, Commission des droits de la personne et de la jeunesse , Cat. 2.120-4.20.1, 2005, 19.

[50] C. MASSE, *Le critère unifié de l'affaire Meiorin dans le contexte de la défense prévue à l'article 20 de la Charte québécoise*, dans *Les 25 ans de la Charte québécoise* (coll.), Barreau du Québec, Service de la formation permanente (no 142), Cowansville, Éditions Yvon Blais, 2000, p. 74.

[51]*Ont. Human Rights Comm. v. Simpsons-Sears*, [1985] 2 S.C.R. 536 *Ibid.* at 555.

would not otherwise have done or accepted? …To put the question in the individual context of this case: in the honest desire to exercise her religious practices, how far can an employee compel her employer in the conduct of its business to conform with, or to accommodate, such practices? How far, it may be asked, may the same requirement be made of fellow employees and, for that matter, of the general public?"[52].

In synthesis the court established that "Accepting the proposition that there is a duty to accommodate imposed on the employer, it becomes necessary to put some realistic limit upon it. The duty in a case of adverse effect discrimination on the basis of religion or creed is to take reasonable steps to accommodate the complainant, short of undue hardship: in other words, to take such steps as may be reasonable to accommodate without undue interference in the operation of the employer's business and without undue expense to the employer".[53]

Technically speaking, reasonable accommodation accords an individual remedy. Yet, the individual decision has a clear impact on others in similar situations regulating the entire subject.

It is worth noticing that the Canadian Supreme Court did not conceive the notion of reasonable accommodation from scratch. Indeed references are found in several American legislations before the 1980s[54] and several Canadian Provinces have integrated the notion in general or specific legislations against discrimination without adding very much to it. Among these, we could mention for their importance two statutes, *the Ontarian* Human Rights Code R.S.O. 1990[55], CHAPTER H.19 (art. 11), the Québec *Charte des droits et libertés de la personne (Charter of Human Rights and Freedoms)*,[56] one of which comes from a civil law system and the other from a common law environment, and to which we should add the federal *Loi canadienne sur les droits de la personne* (art. 15).

The duty of reasonable accommodation[57] has been qualified as "*obligation juridique*, applicable dans une situation de *discrimination*, et consistant à aménager une norme ou une pratique de portée universelle dans les limites du *raisonnable*, en accordant un traitement différentiel à une personne qui, autrement,

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[52] *Ibid.* at para 21.

[53] At para 23.

[54]There are precedents in US legislation. See also the amendaments to the 1972 *Civil Rights Act* (duty to accommodate religious practices), and the *Rehabilitation Act* of 1973 (handicap).

[55] See for the historical background of one of the oldest Canadian legislation on the issue I. A. HUNTER, *The Development of the Ontario Human Rights Code: A Decade in Retrospect*, (1972) 22 *Univ. T.L.J.* 237.

[56] Charte des droits et libertés de la personne, L.R.Q., c. C-12 (Québec). At federal level see Loi canadienne sur les droits de la personne, L.R.C. (1985).

[57] In Québec see the *Charte des droits et libertés de la personne*, L.R.Q., c. C-12, art. 10. for an application of the duty in relation to sex see *Colombie-Britannique (Public Service Employees Relations Commission)* c. *B.C.G.S.E.U.*, [1999] 3 R.C.S. 3; for pregnancy see *Commission des droits de la personne* c. *Lingerie Roxana*, [1995] R.J.Q.1289 (T.D.P.); for the ageing criteria see *Desroches* c. *Commission des droits de la personne du Québec*, [1997] R.J.Q. 1540 (C.A.); for handicap see *Colombie-Britannique (Superintendent of Motor Vehicles)* c. *Colombie-Britannique (Council of Human Rights)*, [1999] 3 R.C.S. 868; *Commission des droits de la personne du Québec* c. *Collège Notre-Dame du Sacré-Cœur*, [2002] R.J.Q. 5 (C.A.); *Centre de la communauté sourde du Montréal métropolitain* c. *Régie du logement*, [1996] R.J.Q. 1776 (T.D.P.); *Commission des droits de la personne du Québec* c. *Emballages Polystar*, (1997) 28 C.H.R.R. D/76 (T.D.P.); *CEGEP John-Abbott* c. *Blouin*, C.S. Montréal, n° 500-17-018750-045, 10 june 2004.

serait pénalisée par l'application d'une telle norme."[58]. Under its auspices we find an obligation "qu'on peut qualifier d'accessoires ou de procédurales, dont celle de faire des efforts « significatifs, sérieux et sincères » en vue de trouver un accommodement et celle, pour la partie qui réclame l'accommodement, de donner à l'autre partie le temps nécessaire pour ce faire"[59].

The notion is related to the principle of equality; a principle of equality which refuses equal treatment at all costs and fosters differential treatment for different situations to fulfil its goal[60]. To use a methaphor, the notion of reasonable accommodation is the offspring of both the notion of equality and the notion of discrimination[61]. It appeared on the Canadian legal scene during the 1980s within the discussion already raised by the enactment in the 1970s of the the *Loi canadienne sur les droits de la personne*, L.R.C. (1985) and of the Québec *Charte des droits et libertés de la personne*[62]. Yet these charters do not mention expressly the concept of reasonable accommodation.

Having thus been first established in the Canadian legal system in the 1980s, the duty of reasonable accommodation was then extended to all forms of prohibited, direct or indirect, discriminations the 1990s[63] consolidating a cultural tension which found its origins in the first antidiscrimination statutes during the course of the early sixties of last century.

According to the by now extended notion, the duty of reasonable accommodation works as a sort of objective element in finding a case of discrimination: discrimination can even be unintentional, what counts is the result of discriminatory exclusion[64]. In this sense it is a purely objective notion. Reasonable accommodation serves to take into account any previous disequilibria which possibly have been historically present among different groups of individuals and for which legal norms or socially acknowledged practices constitute a form of crystallization of a *status quo* which is only in appearance neutral[65]. Indeed, an apparently neutral rule can produce discriminatory effects on members of specific groups which have been the subject of historical or systematic biases: – a concept which has been clearly affirmed by the courts[66].

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58 P. BOSSET, *Les fondements juridiques et l'évolution de l'obligation d'accommodement raisonnable*, Commission des droits de la personne et des droits de la jeunesse, Cat. 2.500.128, 2007 p.4.

59P. BOSSET, *Les fondements juridiques et l'évolution de l'obligation d'accommodement raisonnable, Commission des droits de la personne et des droits de la jeunesse*, cit., at 4. recalling *Autobus Legault c. Commission des droits de la personne et des droits de la jeunesse, T.D.P. Abitibi* n° 615-53-000001-945, J.E. 94-1965 (T.D.P.), p. 26.

60 P. BOSSET, *Les fondements juridiques et l'évolution de l'obligation d'accommodement raisonnable*, *cit*., p.1 noticing that also for « l'accommodement raisonnable fait appel à l'esprit éthique: il suppose le respect d'autrui tel qu'il est, mais tient aussi compte d'un tissu social sans lequel il ne saurait exister de communauté humaine."

61 Ibid. at 4.

62 Charte des droits et libertés de la personne, L.R.Q., c. C-12 (Québec). At federal level see Loi canadienne sur les droits de la personne, L.R.C. (1985).

63 See *Colombie-Britannique (Public Service Employees Relations Commission)* c. *B.C.G.S.E.U.*, [1999] 3 S.C.R. 3.

64 On the issue see P. BOSSET, *Les fondements juridiques et l'évolution de l'obligation d'accommodement raisonnable, Commission des droits de la personne et des droits de la jeunesse*, *cit*., p. 3 and W. BLACK, *From Intent to Effect : New Standards in Human Rights*, (1980) 1 *C.H.R.R.* C/-C/6. Note, however, that under the Québec charter intention remains a condition for awarding punitive damages according to art. 49, al. 2. of the Charte.

65 See e.g. G. BALFOUR, *Falling Between the Cracks of Retributive and Restorative Justice: The Victimization and Punishment of Aboriginal Women,* Feminist Criminology, Vol. 3, No. 2, 101-120 (2008)

66 See *Commission des droits de la personne et des droits de la jeunesse c. Kayode*, 2007 QCTDP 25.

Such a notion results in the expansion of the reach of the equality principle so as to become larger and more profound than a simple reference to specific prejudices because it is able to embrace the entire institutional setting in which the unequal treatment takes place.

This duty and its realistic limits[67] are derived from the anti-discrimination charters[68].

Today's notion[69] of equality applies to any motive and to any individual. It covers gronds from disability[70] to religion, from sex discrimination[71] to pregnancy[72], from age[73] to national origin,[74] especially in work-related matters[75]. With reference to individuals, it applies to anyone and can impose, for example on hotels[76], restaurants[77] or bars, [78] a duty to provide for access for people in wheelchairs or with guide-dog.. The surrounding contexts may also be very different: covering public offices such as tribunals[79] and public school boards[80] or private institutions as schools[81].

(CanLII), *Colombie-Britannique (Public Service Employee Relations Commission) c. BCGSEU*, [1993] 3 R.C.S. 3. See in general BARREAU DU QUÉBEC, *Mémoire du Barreau du Québec présenté à la Commission de consultation sur les pratiques d'accommodement reliées aux différences culturelles « Les droits fondamentaux : Une protection pour toutes et tous », cit.*, at 18.

[67] *Ont. Human Rights Comm. v. Simpsons-Sears*, [1985] 2 S.C.R. 536: "Accepting the proposition that there is a duty to accommodate …, it becomes necessary to put some realistic limit upon it." at para 23.

[68]It is worth asking ourself if we can find similar principles at EU law arising from antidiscrimination directives and at. 13 of the treaty.

[69] See infra the discussion about the *get*.

[70]*Colombie-Britannique (Superintendent of Motor Vehicles)*c. *Colombie-Britannique (Council of Human Rights)*, [1999] 3 R.C.S. 868; *Commission des droits de la personne du Québec* c. *Collège Notre-Dame du Sacré-Cœur*, [2002] R.J.Q. 5 (C.A.); *Centre de la communauté sourde du Montréal métropolitain* c. *Régie du logement*, [1996] R.J.Q. 1776 (T.D.P.); *Syndicat des employés de techniques professionnelles et de bureau d'Hydro-Québec* c. *Hydro-Québec*, [2006] R.J.Q. 426 (C.A.), on appeal (C.S.C. no 31395); *Syndicat des infirmières du Nord-Est québécois* c. *Sylvestre*, [2003] R.J.Q. 1392 (C.A.); *Commission des droits de la personne du Québec* c. *Collège Notre-Dame du Sacré-Coeur*, [2002] R.J.Q. 5 (C.A.); *CEGEP John-Abbott* c. *Blouin*, C.S. Montréal, no 500-17-018750-045, 10 juin 2004; *Québec (Procureur général)* c. *Commission de la fonction publique*, J.E. 2003-259 (C.S.); *Association internationale des machinistes et des travailleurs de l'astronautique* c. *Hamelin*, [2002] R.J.Q. 168 (C.S.); *Commission des droits de la personne et des droits de la jeunesse* c. *Québec (Procureur général)*, J.E. 2005-780, [2005] R.J.D.T. 1110 (T.D.P.); *Commission des droits de la personne et desdroits de la jeunesse c. Centre hospitalier de l'Université de Montréal*, *Pavillon Notre-Dame*, J.E. 2000-1914 (T.D.P.); *Commission des droits de la personne du Québec c. Emballages Polystar*, (1997) 28 C.H.R.R. D/76 (T.D.P.); *Centre de la communauté sourde du Montréal métropolitain c. Régie du logement*, [1996] R.J.Q. 1776(T.D.P.). 28.

[71] *Colombie-Britannique (Public Service Employee Relations Commission) c. BCGSEU*, [1999] 3 R.C.S. 3; *Commission scolaire des Rives-du-Saguenay* c. *Rondeau*, J.E. 2002-2147, REJB 2002-35373 (C.S.). On the impact on handicapped individuals and women in Québec see M. GARON - P. BOSSET, *Le droit à l'égalité: des progrès remarquables, des inégalités persistantes*, in *Après 25 ans, la Charte québécoise des droits et libertés*, vol. 2 (*Études*), Commission des droits de la personne et des droits de la jeunesse, 2003, pp. 81-82 and 91-92.

[72]*Commission des droits de la personne c. Lingerie Roxana*, [1995] R.J.Q.1289 (T.D.P); *Commission des écoles catholiques de Québec c. Gobeil*, [1999] R.J.Q. 1883 (C.A.); *Commission des droits de la personne et des droits de la jeunesse c. Société de l'assurance automobile du Québec*, [2003] R.J.Q. 1737 (T.D.P.). See also M. DRAPEAU, *La discrimination fondée sur la grossesse mettant en cause la sécurité au travail : une solution s'impose, l'obligation d'accommodement* , (1997) 57 *R. du B.* 1047.

[73] *Commission droits de la personne du Québec* c. *Compagnie minière Québec-Cartier*, [1994] R.J.Q. 2729 (T.D.P.), appeal accorded on other reasons J.E. 99-211 (C.A.); *Desroches* c. *Commission des droits de la personne du Québec*, [1997] R.J.Q. 1540 (C.A.).

[74] *Commission des droits de la personne et des droits de la jeunesse c. Collège Montmorency*, J.E. 2004-966 (T.D.P.).

[75] C. BRUNELLE, *Discrimination et obligation d'accommodement raisonnable en milieu de travail syndiqué*, Éditions Yvon Blais, 2001.

[76] *Commission des droits de la personne et des droits de la jeunesse c. Hôtel Villa de France*, T.D.P. Montréal, 1998 IIJCan 43.

[77] *Commission des droits de la personne du Québec c. Restaurant Scampinata*, (1996) 23 C.H.R.R. D/392 (T.D.P.).

[78] *Commission des droits de la personne du Québec* c. *Bar La Divergence*, [1994] R.J.Q. 847 (T.D.P.).

[79] *Centre de la communauté sourde du Montréal métropolitain* c. *Régie du logement*, précitée. Imposing to offer an interpeter to deaf defeandants.

[80] See *Multani* c. *Commission scolaire Marguerite-Bourgeoys*, [2006] 1 R.C.S. 256 in which a kirpan was allowed into school as long as normal safety exigencies were respected (note that the decision was taken on freedom of religion grounds and reasonable accomodation was only quoted by analogy). See on the issue also: COMMISSION DES DROITS DE LA PERSONNE ET DES DROITS DE LA JEUNESSE, *Le port du foulard islamique dans les écoles publiques*, Montréal, La Commission, 1994; G.

The duty of reasonable accommodation encounters both internal and external limits. Regarding these latter ones we should mention the distinction between reasonable accommodation and the acknowledgement of other parallel legal orders of the State[82]. The duty of reasonable accommodation indicates the way in which to satisfy the legal rules or social/institutional practices in order remedy a discrimination which would otherwise ensue but without incorporating within State law, for instance, religious principles or ethnical practices.

Similarly, reasonable accommodation is not present any time there is a conflict of values (cultural or religious ones, for instance). In truth, it enters in the picture only when a discriminatory exclusion is present and this exclusion can be linked to one of the motives forbidden by specific legislation[83]: unless rights are affected there can be no reasonable accommodation issue[84].

Internal limits remain regarding the respect of the rights of others and, notably, on general welfare protections. These limits must be read as forbidding excessive restrictions (as expressed in *Simpson Sears*) to rights or general welfare[85].

The elements to be taken into consideration are many and varied. Broadly speaking they encompass amongst other things, the costs[86] and complications to the duty bearer.

OTIS – C. BRUNELLE, *La Charte des droits et libertés de la personne et la tenue vestimentaire à l'école publique : faut-il un accommodement sur mesure ?*, (1995) 36 *C. de D.* 599-643.

[81] *Commission des droits de la personne du Québec* c. *Collège Notre-Dame du Sacré-Coeur*, quoted obliging to grant admission to handicapped students able to follow the education programs established by the institution.

[82] See in Québec with reference to the duty to reasonable accommodate: P. BOSSET - P. EID, *Droit et religion : de l'accommodement raisonnable à un dialogue internormatif?*, dans *Actes de la XVIIe Conférence des juristes de l'État*, Cowansville, Éditions Yvon Blais, 2006, p. 63-95.

[83] E.g. the Québec charter.

[84] P.BOSSET, *Les fondements juridiques et l'évolution de l'obligation d'accommodement raisonnable,* in M. JÉZÉQUEL (edt.), *Les accommodements raisonnables : quoi, comment, jusqu'où?*, Cowansville, Yvon Blais, 2007, 3 at 20.

[85] See *Central Alberta Dairy Pool v. Alberta (Human Rights Commission)*, [1990] 2 S.C.R. 489, 520-521 for the majority: "I do not find it necessary to provide a comprehensive definition of what constitutes undue hardship but I believe it may be helpful to list some of the factors that may be relevant to such an appraisal. I begin by adopting those identified by the Board of Inquiry in the case at bar -- financial cost, disruption of a collective agreement, problems of morale of other employees, interchangeability of work force and facilities. The size of the employer's operation may influence the assessment of whether a given financial cost is undue or the ease with which the work force and facilities can be adapted to the circumstances. Where safety is at issue both the magnitude of the risk and the identity of those who bear it are relevant considerations. This list is not intended to be exhaustive and the results which will obtain from a balancing of these factors against the right of the employee to be free from discrimination will necessarily vary from case to case".

[86] The Commission des droits de la personne et des droits de la jeunesse (P. BOSSET – P. EID, *Droit et religion : de l'accommodement raisonnable à un dialogue internormatif*, Commission des droits de la personne et des droits de la jeunesse, Cat. 2.500.127, 2006, 6-7) summarizes as follows the elemnts to be taken into account:1) Les limites des ressources financières et matérielles : le coût réel de l'accommodement demandé; les sources extérieures de financement (prêts, subventions, crédits d'impôts et déductions fiscales, régime gouvernemental d'aide ou d'indemnisation, contribution personnelle de la victime de discrimination…);la nature de l'entreprise ou de l'institution (taille, composition de la main-d'œuvre, structure organisationnelle, structure de production, nature privée ou publique…); le budget d'opération total de l'entreprise (maison-mère et filiales réunies) ou de l'institution; la santé financière de l'entreprise ou de l'institution; la conjoncture économique. 2) L'atteinte aux droits: les risques pour la santé ou la sécurité du salarié, de ses collègues ou du public en général; la convention collective; l'effet préjudiciable de l'accommodement sur les autres employés; les conflits de droits. 3) Le bon fonctionnement de l'entreprise ou de l'institution: l'interchangeabilité relative des employés; l'adaptabilité des lieux, installations et équipements de travail; l'effet sur la productivité de l'entreprise; le nombre d'employés affectés par la mesure d'accommodement envisagée; l'effet bénéfique de l'accommodement sur les autres employés; la durée et l'étendue de l'accommodement".

In principle, potential limitations of the duty should be analyzed in the given social, economic and legal context. Therefore, the specific aims of a public institution shall be taken into account. For instance, in the *Multani* case[87] (where forbidding the wearing of a kirpan was found to be discriminatory and requiring reasonable accomodation) the court stressed several times the "unique environment" of school institutions, describing them as "living communities which, while subject to some controls, engage in the enterprise of education in which both teachers and students are partners"[88].

Similarly, according to an important Québécois statute (art. 2 *Loi sur les services de santé et les services sociaux*, L.R.Q., c. S-4.2)[89], the specificities of individual functional limitations and geographic, linguistic or ethno-cultural characteristics all have to be accounted for in organizing an health care institution providing service.

In addition, the status of the interacting individuals could be of importance – especially where goods and services are offered to the public and, for example, the discriminated persons are "captive" clients (such as in prisons) or incapable of searching for alternatives (e.g. the case of non authnonomus individual hosted at health care facilities).

Note that, while the reasonable accommodation duty arises from the reading of the equality principle as explained above, the definition of reasonableness in its application leaves room to take into account the social context in which the duty arises in order to avoid excessive modification in any given social environment and thereby helps in tackling the integration process. This is a key feature which finds its widest implications in the interplay with private law instruments enabling mechanisms for adapting the socio-legal context to the actual factual discrimination without disrupting the context as such, especially when discrimination is indirect or non voluntary.

The political choice to preserve the social structure is the inspiration of the principle[90] and this caracteristic avoid opening the door to every peculiarity or particularism[91] but continuously requires a balancing of general and special interests with the situation to be accommodated.

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[87] *Multani* c. *Commission scolaire Marguerite-Bourgeoys*, [2006] 1 R.C.S. 256.

[88] Ibid. at para 65.

[89]« [L]a présente loi établit un mode d'organisation des ressources humaines, matérielles et financières destiné à […] : 5° tenir compte des particularités géographiques, linguistiques, socio-culturelles, ethno-culturelles et socio-économiques des régions; 6° favoriser, compte tenu des ressources, l'accessibilité à des services de santé et à des services sociaux selon des modes de communication adaptés aux limitations fonctionnelles des personnes; 7° favoriser, compte tenu des ressources, l'accessibilité à des services de santé et des services sociaux, dans leur langue, pour les personnes des différentes communautés culturelles du Québec ».

[90]M. GARON - P. BOSSET, *Le droit à l'égalité : des progrès indéniables, des inégalités persistantes*, dans *La Charte québécoise des droits et libertés après 25 ans* (Vol. 2), Montréal, Commission des droits de la personne et des droits de la jeunesse, 2003, p. 64: " L'égalité n'est […] pas un simple objectif idéaliste, il s'agit bien au contraire d'un champ de lutte idéologique particulièrement féroce. L'égalité met en péril les avantages. Sous sa forme la plus radicale, elle déstabilise tout ce qui est familier, place chacun face aux risques personnels que les transformations requises lui feraient courir : son statut, ses pouvoirs, ses biens matériels, ses habitudes. Même sous ses formes plus réduites ou partielles, les arguments contre tel ou tel objectif d'égalité ne manquent pas : on invoque la liberté des choix, le poids à porter par des personnes qui ne sont pas responsables des inégalités observées, ou plus prosaïquement les coûts".

[91] See the COMMISSION DES DROITS DE LA PERSONNE ET DES DROITS DE LA JEUNESSE, *Le pluralisme religieux, un défi d'éthique sociale – Document soumis à la réflexion publique* (1995), at 14: "À cet égard, nous semble-t-il, aucune

As we have just seen, this continuous accommodation of the system evolves at the intersection of Charters' rights, specific pieces of legislation and judicial interventions[92]. While we deal with specific legislation in discussing our examples, it is important to give a brief overview of the charters we have been mentioning so far and their interplay.

Applicable charters and the particularity of the Québec Charter of human rights and freedoms

Before the main charters we have already mentioned were enacted, there were several legislative interventions, such as the 1960 Canadian Bill of Rights[93] which, in addition to the main protected rights also enumerates protections against some forms of discrimination. Nevertheless, this statute only applies to Canadian laws, tribunals and federal administrations and it has received a rather loose application from judges despite its quasi constitutional qualification[94].

At the federal level, for our purposes the most important sections of the *Canadian Charter of Rights and Freedoms* are sections:

- 1, 2, 15 (right to the equal protection and equal benefit of the law without discrimination and, in particular, free from discrimination based on race, national or ethnic origin, colour, religion, sex, age or mental or physical disability, without prejudice to any "law, program or activity that has as its object the amelioration of conditions of disadvantaged individuals or groups including those that are disadvantaged because of race, national or ethnic origin, colour, religion, sex, age or mental or physical disability."),
- 26 ("The guarantee in this Charter of certain rights and freedoms shall not be construed as denying the existence of any other rights or freedoms that exist in Canada.") and
- 27 ("This Charter shall be interpreted in a manner consistent with the preservation and enhancement of the multicultural heritage of Canadians.").

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solution valable, juste et réaliste à des conflits de droits ne saurait émerger de la tendance actuelle qui consiste à réclamer pour soi tous les droits et toutes les libertés, que l'on soit individu ou institution, sans se reconnaître aussi responsable d'aménager un espace commun, de renouer le lien social, afin d'en favoriser l'exercice pour tous. […] S'agissant de religion, les droits et libertés peuvent rapidement se retrouver érigés en absolus sacrés qui imposeraient des contraintes à l'ensemble de la société. Or, si les limites des choix privés et les exigences du lien social de réciprocité ne sont pas affirmées, pratiquées, gérées par des citoyens et des institutions capables de consentir à des aménagements du quotidien sans s'abîmer dans d'interminables procès, il y a fort à parier que nous y perdrons au change. C'est pourquoi nous croyons que le pluralisme religieux doit être traité comme toutes les autres formes de pluralisme et soumis aux limites fixées par les exigences de la vie en société". Similarly the Canadian Supreme Court in *Ont. Human Rights Comm. v. Simpsons-Sears*, [1985] 2 S.C.R. 536 at para 22: "In any society the rights of one will inevitably come into conflict with the rights of others. It is obvious then that all rights must be limited in the interest of preserving a social structure in which each right may receive protection without undue interference with others. This will be especially important where special relationships exist, in the case at bar the relationship of employer and employee. In this case, consistent with the provisions and intent of the *Ontario Human Rights Code*, the employee's right requires reasonable steps towards an accommodation by the employer".

92 Note that specific adjudicating institutions are created by statutes and charters to deal with discriminaton: See the Commission des droits de la personne et des droits de la jeunesse in Québec and the Ontario Human Rights Commission for instance.

93 L.R.C. (1985), App. III.

94 *Authorson c. Procureur général du Canada*,2003 CSC 39 (CanLII, [2003] 2 R.C.S. 40 (par. 31), REJB 2003-44762.

Also, we must keep in mind that this Charter does not apply to private law, at least, not directly. Nevertheless, it is of valuable interest to our work, since the Canadian Charter, as a part of the Constitution, is the "supreme law" of Canada. In other words, "human rights legislation must conform to constitutional norms, including those set out in the Canadian Charter". Thus, all specific Charters from the different Provinces must abide by its principles as they emerge from case law[95]. On this account it is worth noticing that Québec never agreed to the repatriation of the Constitution to which the Canadian Charter is included. Nevertheless, Québec citizens also enjoy the protection of the Canadian Charter[96] which is, in several directions, less extended than the one offered by the Québec Charter itself.

The Canadian Charter of 1982 was preceded by the Canadian Human Rights Act[97], which came into force in 1978 and outlaws discrimination in specific areas (employment and delivery of goods and services) with a list of grounds larger than the one contained in the Canadian Declaration: race, national or ethnic origin, colour, religion, age, sex, marital status, family status, pardoned conviction, disability, and sexual orientation. Similarly to the Québec Charter[98] the Canadian Human Rights Act established The Canadian Human Rights Commission (C.C.D.P.) and conferred upon it the role of hearing complaints of discrimination. It is worth noting also that the statute applies amongst private parties operating under federal law, and in this regard it enjoys a quasi-constitutional status[99].

Québec adopted its *Charte des droits et libertés de la personne* (*Charter of human rights and freedoms*)[100] in 1975 (it entered into force on June 28th 1976). The *Charte Quebecois* enumerates a large range of rights and

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by the Canadian Supreme Court).

[95] See, for instance with reference to the Québec charter Québec (Commission des droits de la personne et des droits de la jeunesse) c. Montréal (Ville); Québec (Commission des droits de la personne et des droits de la jeunesse) c. Boisbriand (Ville), [2000] 1 R.C.S. 665, par. 42: "...While there is no requirement that the provisions of the [Québec] Charter mirror those of the Canadian Charter, […] they must nevertheless be interpreted in light of the Canadian Charter. Thus, when a statutory provision is open to more than one interpretation, it must be interpreted in a manner consistent with the provisions of the Canadian Charter". See also: N. HOLMES, *Les lois sur les droits de la personne au Canada et la Charte : Guide comparatif*, Ottawa, Bibliothèque du Parlement, Service de recherche, 1992, c1997, at 7. More recently and for an overview see H. BRUN, *Chartes des droits de la personne*, 17e édition, Montréal, Wilson et Lafleur Ltée, 2004, p.839-855; C. BRUNELLE, Les droits et libertés fondamentaux , dans ÉCOLE DU BARREAU DU QUÉBEC, Volume 7 - *Droit public et administratif*, Cowansville, Éditions Yvon Blais, 2009, 125; Nancy HOLMES, *Human rights legislation and the Charter : A comparative Guide*, Ottawa, Parliament library, Law and Government Division, 1992, c1997, at 7, available at: http://dsp-psd.pwgsc.gc.ca/Collection-R/LoPBdP/MR/mr102-e.htm

[96] *Re : opposition à une résolution pour modifier la Constitution*, 1982 CanLII 219 (C.S.C.), [1982] 2 R.C.S. 793, 806; *Renvoi relatif à la sécession du Québec*, 1998 CanLII 793 (C.S.C.), [1998] 2 R.C.S. 217, REJB 1998-07695 (par. 47). For the interplay between the different legal instrments and their application in Québec see generally A.R. NADEAU, *La Chartedes droit et libertés de la personne: origins, enjeux et perspectives, in Revue du Barreau/ Numero thématique hirs série*, 2009, 1, 8ff and pertinent footnotes. Federal courts have ignored the Québec Charte for several years. See for the first application *Forget c. Québec*, [1988] 2 R.C.S. 90. See also N. HOLMES, *Les lois sur les droits de la personne au Canada et la Charte : Guide comparatif*, *cit*., 7.

[97] L.R.C. (1985), c. H-6.

[98] See *infra*.

[99] *Canada (Chambre des Communes) c. Vaid*, 2005 CSC 30 (CanLII) [2005] 1 R.C.S. 667, EYB 2005-90618 (par. 81).

[100] L.R.Q., c. C-12. It is worth noticing that the expression "droit de la personne" to refer to fundamental rights which raise from civil law finds its origins in the idea to proclaim in the civil code those fiundamental rights which havee a role in the interplay among private ijdividuals. See. P. MOREL, *La Charte québecoise: un document unique dans l'histoire légisdlative canadienne,* (1987) *R.J.T.*, 1 5-6. See generally A.R. NADEAU, *La Chartedes droit et libertés de la personne: origins, enjeux et perspectives, in Revue du Barreau/ Numero thématique hirs série*, 2009, 1, 7ff (critizing the reductionist approach to the Québec Charter.

liberties and institutes a *Commission des droits de la personne et des droits de la jeunesse* (C.D.P.D.J.) whose "jurisprudence" has been highly influential in the actual evolution of the protection offered by the equality principle. The goal of the Commission is mainly to promote the Québec *Charte* and to watch over the respect of the equality right. In 1982, the Charter experienced an enlargement of the list of discriminative motivations and the affirmation of its substantial preponderance on all laws of Québec[101]. The one just mentioned is a key reform which coincided with the entering into force of the *Canadian Charter of Rights and Freedoms* which is adopted as Part I of the *Constitution Act, 1982*, being Schedule B to the Canada Act 1982, ch. 11 (U.K.).

Note that Québec was among the last Provinces to adopt comprehensive antidiscrimination laws, while the first was certainly Ontario which adopted such a legislation in 1962 to protect people against discrimination in employment[102], accommodation[103], goods, services and facilities[104], and membership of vocational associations and trade unions[105]. The Ontario Human Rights Code today includes fifteen grounds of discrimination: race, ancestry, place of origin, colour, ethnic origin, citizenship, creed (religion), sex (including pregnancy), sexual orientation, disability, age (18 and over, 16 and over in occupancy of accommodation), marital status (including same sex partners), family status, receipt of public assistance (in accommodation only) and record of offences (in employment only).

The various instruments we have mentioned very often overlap in the protection they offer. Overall, a large array of discriminatory motivations are listed. In our further analysis we will refer mainly to the application of the Ontario and Québec antidiscrimination charters concentrating on the latter because of its special (and explicitated) relation with the Québec civil code.

The Québec Charter and its interplay with private law

The Québec *Charter of human rights and freedoms*, which applies in both private and public law contexts, was interpreted by the Canadian Supreme Court in a way which excluded the autonomous creation of a system of liability for its infringement[106]. Case law established that in order to receive compensation all the elements of liability required by the civil laws had to be shown (negligence, damages, causation).

[101] The Quebec *Charter* has a chapter of more than 20 articles devoted to «Droit à l'égalité dans la reconnaissance et l'exercice des droits et libertés».

[102] Including recruiting, application forms, interviews, office dress codes and shift schedule promotions.

[103] Including rental accommodation such as condominium apartments, college residences, hotel/motel facilities and housing.

[104] Schools, school boards, shops, restaurants ,ospitals, schools, correctional facilities and insurance services.

[105] See *Policy on creed and the accommodation of religious observances*, Ontario Human Rights Commission, ISBN – 0-7778-6518-1, 1996, 1.

[106] See *Béliveau St-Jacques c. Fédération des employées et employés de services publics Inc.*, (1996) 1 R.C.S. 345; *Curateur public c. Syndicat national des employés de l'Hôpital St-Ferdinand*, [1996] 3 R.C.S. 211.

Indeed, in the *Béliveau* case, the court interpreted art. 49 of the Charter (permitting compensatory and punitive damages) as excluding any autonomy for the rule[107].

In the *Curateur public c. Syndicat national des employés de l'Hôpital St-Ferdinand* the Canadian Supreme Court took the opportunity to specify the notions of integrity and dignity. Justice l'Heureux-Dubé specified that "The common meaning of the word "inviolability" suggests that the interference with that right must leave some marks, some sequelae which, while not necessarily physical or permanent, exceed a certain threshold. The interference must affect the victim's physical, psychological or emotional equilibrium in something more than a fleeting manner."[108]. Also, referring to dignity, the court clarified that "Having regard to the manner in which the concept of personal "dignity" has been defined, and to the principles of large and liberal construction that apply to legislation concerning human rights and freedoms, I believe that s. 4 of the *Charter* addresses interferences with the fundamental attributes of a human being which violate the respect to which every person is entitled simply because he or she is a human being and the respect that a person owes to himself or herself…. because of the underlying concept of respect, the right to personal dignity, unlike the concept of inviolability, does not require that there be permanent consequences in order for interference with that right to be found. Thus, even a temporary interference with a fundamental attribute of a human being would violate s. 4 of the *Charter*. This interpretation is also based on the nature of the other rights protected by s. 4 -- honour and reputation: *noscitur a sociis*. It is not necessarily a requirement, in order for there to be a violation of these guarantees, that there be permanent effects, although the effects may be permanent"[109]. Despite this broad definition, the court clarified that compensatory damages are linked to the presence of all elements of illegality according to *jus commune* while punitive damages under art. 49 are mainly related to the intentional character of the violation of the right. The language used is rather clear: "there will be unlawful and intentional interference within the meaning of the second paragraph of s. 49 of the *Charter* when the person who commits the unlawful interference has a state of mind that implies a desire or intent to cause the consequences of his or her wrongful conduct, or when that person acts with full knowledge of the immediate and natural or at least extremely probable consequences that his or her conduct will cause. This test is not as strict as specific intent, but it does

[107] Yet, there was a strong dissenting on the authonomy of punitive damages from the justices Heureux-Dubé and La Forest) according to which punitive damages compensation under art. 49 of the Charter presents an exception to *droit commun*. See *Béliveau St-Jacques c. Fédération des employées et employés de services publics Inc.*, cit., 411

[108] *Curateur public c. Syndicat national des employés de l'Hôpital St-Ferdinand*, [1996] 3 R.C.S. 211, 253. Similar arguments gahve been used in Italy to define the boundaries of compensable non-economic losses by the Supreme Court. See. For references A. D'Angelo, G. Comandé, D. Amram (edts), *La liquidazione del danno alla persona. Riflessioni e prospettive ad un anno dalle SS.UU. nn. 26972-26975 del 2008,* Milano, Il sole 24 ore, 2010.

[109] *Curateur public c. Syndicat national des employés de l'Hôpital St-Ferdinand*, cit., 211.

go beyond simple negligence. Thus, an individual's recklessness, however wild and foolhardy, as to the consequences of his or her wrongful acts will not in itself satisfy this test"[110].

Only two years later the court sustained that an infringement of the Charter is not sufficient to trigger compensation: "Where extrapatrimonial damages are concerned, we agree with Baudouin J.A. that the infringement of a right guaranteed by the *Québec Charter* is in itself insufficient to establish that damage has been sustained. Nor is an award of symbolic damages justified when the courts wish to punish the infringement of a right that will, in most cases, result in minimal injury. This would be contrary to the principles of civil responsibility. The damages must, therefore, be proven" [111]. Compensation (or more precisely non-economic damages) are not *in re ipsa*, *per se* in the violation of the Québec Charter. Damages must be proved and beyond a certain degree of tolerance otherwise the continuous threat of an action for damagers could have overreaching effects.

In dealing with discrimination based on disabilities the court stated in the *Boisbriand* case that "The objectives of the *Charter*, namely the right to equality and protection against discrimination, cannot be achieved unless we recognize that discriminatory acts may be based as much on perception and myths and stereotypes as on the existence of actual functional limitations. Since the very nature of discrimination is often subjective, assigning the burden of proving the objective existence of functional limitations to a victim of discrimination would be to give that person a virtually impossible task. Functional limitations often exist only in the mind of other people, in this case that of the employer"[112].

As we anticipated, the above examples and excerpts from several Canadian Supreme Court decisions show a clear trend from the Supreme Court to reduce the impact of the Québec Charter and to equate its notions to those included in the Canadian Bill of Rights and Charter and to conform the impact of damages compensation encompassed in the Québec Charter to the general rules provided for by the civil code.

Yet, the Québec Charter applies among private subjects and has a provision (art. 52) which proclaims for it a higher status than the civil code[113] and the *jus commune*: "No provision of any Act, even subsequent to the Charter, may derogate from sections 1 to 38, except so far as provided by those sections, unless such Act expressly states that it applies despite the Charter." This provision and the obsequy paid by Québec's courts casts the Quebec Charter at a sort of quasi constitutional status able to invalidate (better: to force a non discriminatory interpretation of the norm) any (even subsequent)

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110 *Curateur public c. Syndicat national des employés de l'Hôpital St-Ferdinand*, cit., 262, referring to *West Island Teachers' Association v. Nantel*, [1988] R.J.Q. 1569 (C.A.).

111 Contrary to several scholars' opinion (see, among several, L. PERRET, *De l'impact de la Charte des droits et libertés de la personne sur le droit civil des contrats et de la responsabilité au Québec*, 12 *Rev. Gen.* 122 1981). See *Aubry v. Éditions Vice-Versa*, [1998] 1 S.C.R. 591 at para 68-69.

112 *Quebec (Commission des droits de la personne et des droits de la jeunesse) v. Montréal (City)*; *Quebec (Commission des droits de la personne et des droits de la jeunesse) v. Boisbriand (City)*, 2000 SCC 27, [2000] 1 S.C.R. 665 at para 39.

113 In addition see the preamble to the Québec civil code quoted in the text.

Québec law in contrast with it. Of course, this state of the art might create tensions with the Canadian charter.

In addition, a special link with (and role for) the civil code is expressly acknowledged. The Preliminary Provision to the civil code provides that " The Civil Code of Québec, in harmony with the Charter of Human Rights and Freedoms and the general principles of law, governs persons, relations between persons, and property.

The Civil Code comprises a body of rules which, in all matters within the letter, spirit or object of its provisions, lays down the *jus commune*, expressly or by implication. In these matters, the Code is the foundation of all other laws, although other laws may complement the Code or make exceptions to it."

Because of this role, and recalling an old expression referred to in the French civil code[114], the Québec civil code has been referred to as the "civil constitution" (of Québec)[115]. Nevertheless, case law has not always been coherent with these premises[116].

The actual status of the interplay between the Québec Charter and the civil code as *jus commune* was clarified by the Court in the case *Quebec (Commission des droits de la personne et des droits de la jeunesse) v. Communauté urbaine de Montréal* [117]: "Despite occasional disagreements over the appropriate means of redress, the case law of this Court, although the law is undoubtedly still in its early stages of development in this area, stresses the need for flexibility and imagination in the crafting of remedies for infringements of fundamental human rights [..][118]. We should also not lose sight of the fact that enactments such as the *Quebec Charter* occasionally require interventions that are in no way related to the law of civil liability. It is sometimes necessary to put an end to actions or change practices or procedures that are incompatible with the *Quebec Charter* even where there is no fault within the meaning of the law of civil liability. The law of civil liberties may draw upon the law of civil liability where circumstances warrant. The law of delict does not set limits on the enforcement of the law of civil liberties. Thus, in the context of seeking appropriate recourse before an administrative body or a court of competent jurisdiction, the enforcement of this law can lead to the imposition of affirmative or negative obligations designed to correct or bring an end to situations that are incompatible with the *Quebec Charter*." In this way the Charter has an impact which goes beyond tort law and varies according

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114 J. CARBONNIER. *Le code civil,* in P. NORA (edt.), *Le lieux de la mémoire*, t. II, La Nation, 1986, Paris, Gallimard, 1986, 309.

115 See P.-A. CRÉPEAU, *La réforme du droit civil canadien. Une certaine conception de la recodification 1965-1977* in S. LORTIE, N. KASIRER, J.-G. BELLEY (dir.), *Du Code civil du Québec* (Montréal: Thémis, 2005), 23-25.

116 Please refer again to the cases quoted above. See generally for a synthesis F. ALLARD, *La Charte des droits et libertés de la personnee et le Code Civil du Québec : deux textes fondamentaux du droit civil québécois dans une relation d'«harmonie ambigüe », in Revue du Barreau/ Numero thématique hirs série*, 2009, 33, 66ff.

117 *Quebec (Commission des droits de la personne et des droits de la jeunesse) v. Communauté urbaine de Montréal*, 2004 SCC 30, [2004] 1 S.C.R. 789 at para 26.

118 Citation omitted in the text. See *Doucet-Boudreau v. Nova Scotia (Minister of Education)*, [2003] 3 S.C.R. 3, 2003 CSC 62, at paras. 24-25 and 94.

to the rights brought to the courts' attention[119]. Yet the potential availability of compensation remains one of the key enforcing instruments of the Charter[120].

Keeping this in mind we will further investigate case law (both in Québec and Ontario) without referring to the issues of tort compensation the Charter(s) since our restricted goal is now to ascertain some implications of the interplay between the Charters and private law at a larger scale.

Drawing from cases, designing from principles

A. The example of religious accommodation between secularization and multiculturalism in private law.

Section 3 of the Quebec *Charter*, which applies in both the private and public law context, states: "Every person is the possessor of the fundamental freedoms, including freedom of conscience, freedom of religion, freedom of opinion, freedom of expression, freedom of peaceful assembly and freedom of association."

The impact of the duty to reasonably accommodate when religious matters are involved is directly related to the notion of religion as adopted, and it is sometimes confused or mixed with the interplay with the freedom of religion[121].

The subjective definition[122] of creed built, for example, by the Ontario Human Rights Commission on previous decisions is a rather broad one. In practice it excludes the requirement of any offcial or institutional endorsement by a religious group or establishment:

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[119] See next paragraphs for examples and in general F. ALLARD, *La Charte des droits et libertés de la personnee et le Code Civil du Québec : deux textes fondamentaux du droit civil québécois dans une relation d'«harmonie ambigüe »*, *cit.,* 73ff. For the understanding that civil law is somehow subordinated to the charter see M. DRAPEAU, *La responsabilité* pour atteinte illicite aux droits *et libertés de la personne*, (1994), 28 *R.J.T.* 31.

[120] See L. LALONDE, *L'application de la Charte des droits et libertés de la personne dans le monde vécu, de la protection civiliste à la promotion des droits fondamentaux - Réflexion sur le rapport entre la Charte et le monde vécu in Revue du Barreau/ Numero thématique hors série*, 2009, 321ff. See also S. GAGNON, *Quelques observations critiques sur le droit à une reparation selon la Charte des droits et libertés de la Personne*, in TRIBUNAL DES DROITS DE LA PERSONNE ET LE BARREAU DU QUÉBEC, dir., *La Charte des drois et libertés de la personne : pour qui et jusqu'où?*, Cowansville, Cowansville, Yvon Blais, 2005, 269.

[121] See J. WOEHRLING, *L'obligation d'accommodement raisonnable et l'adaptation de la société à la diversité religieuse*, (1998) 43 *Revue de* droit *de McGill* 364.

[122] See *Syndicat Northcrest* c. *Amselem*, [2004] 2 R.C.S. 551. The court said literally: « only beliefs, convictions and practices rooted in religion, as opposed to those that are secular, socially based or conscientiously held, are protected by the guarantee of freedom of religion. Defined broadly, religion typically involves a particular and comprehensive system of faith and worship. Religion also tends to involve the belief in a divine, superhuman or controlling power. In essence, religion is about freely and deeply held personal convictions or beliefs connected to an individual's spiritual faith and integrally linked to one's self-definition and spiritual fulfilment, the practices of which allow individuals to foster a connection with the divine or with the subject or object of that spiritual faith. » (*Amselem*, par. 39). According to scholars virtually every judicial decision based on s. 2(*a*) of the *Canadian Charter* or s. 3 of the *Quebec Charter* concerns freedom of religion. However, it would appear that these decisions stress the subjective aspect of the believer's personal sincerity rather than the objective aspect of the conformity of the beliefs in question with established doctrine. See almost literally J. WOEHRLING, *L'obligation d'accommodement raisonnable et l'adaptation de la société à la diversité religieuse*, (1998), 43 *McGill L.J.* 325 at 385.

"Creed is interpreted to mean "religious creed" or "religion." It is defined as a professed system and confession of faith, including both beliefs and observances or worship. A belief in a God or gods, or a single supreme being or deity is not a requisite.

Religion is broadly accepted by the Commission to include, for example, non-deistic bodies of faith, such as the spiritual faiths/practices of aboriginal cultures, as well as bona fide newer religions (assessed on a case by case basis).

The existence of religious beliefs and practices are both necessary and sufficient to the meaning of creed, if the beliefs and practices are sincerely held and/or observed"[123].

Clearly enough, this notion reaches out for practices we would possibly classify as customs or cultural practices not related to religion and it does not take into account previous behaviours or practices of the claimant. Nevertheless, for the Canadian Supreme court "claimants seeking to invoke freedom of religion should not need to prove the objective validity of their beliefs in that their beliefs are objectively recognized as valid by other members of the same religion, nor is such an inquiry appropriate for courts to make…a person must show "[s]incerity of belief" and not that a particular belief is "valid""[124].

Put otherwise: "[The] Court's past decisions and the basic principles underlying freedom of religion support the view that freedom of religion consists of the freedom to undertake practices and harbour beliefs, having a nexus with religion, in which an individual demonstrates he or she sincerely believes or is sincerely undertaking in order to connect with the divine or as a function of his or her spiritual faith, irrespective of whether a particular practice or belief is required by official religious dogma or is in conformity with the position of religious officials"[125]. Consequently, "both obligatory as well as voluntary expressions of faith should be protected under the Quebec (and the Canadian) Charter. It is the religious or spiritual essence of an action, not any mandatory or perceived-as-mandatory nature of its observance, that attracts protection"[126].

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[123]See *Policy on creed and the accommodation of religious observances, Ontario Human Rights Commission*, ISBN – 0-7778-6518-1, 1996, 2. See also cases emphasizing the sincerity as an element important and sufficient to qualify something as a religious belief. See *R.* c. *Big M Drug Mart*, [1985] 1 R.C.S. 295; *R.* c. *Edwards Books and Arts*, [1986] 2 R.C.S. 713; *R.* c. *Jones*, [1986] 2 R.C.S. 284. Note that also in the US a subjective, personal and deferential definition of freedom of religion, centred upon sincerity of belief has been adopted in several cases. See, for instance, *Thomas v. Review Board of the Indiana Employment Security Division*, 450 U.S. 707 (1981), in which Justice Burger stated that ". the guarantee of free exercise is not limited to beliefs which are shared by all of the members of a religious sect. ... Courts are not arbiters of scriptural interpretation". see also *Frazee v. Illinois Department of Employment Security*, 489 U.S. 829 (1989), at p. 834 in which the court unanimously rejected "the notion that to claim the protection of the Free Exercise Clause, one must be responding to the commands of a particular religious organization"; it was satisfied that claimant'saction "was based on a sincerely held religious belief".

[124] *Syndicat Northcrest* c. *Amselem*, [2004] 2 R.C.S. 551at para 43 (quotations omitted).

[125] *Syndicat Northcrest* c. *Amselem*, *cit.*, at para 46.

[126] *Syndicat Northcrest* c. *Amselem*, *cit.*, at para 47.

In short it "protects personal religious beliefs, practices or observances, even if they are not essential elements of the creed"[127] but it "does *not* include secular, moral or ethical beliefs or political convictions"[128] and does not cover religions which incite to violence or odium. Conversely refusal to participate in religious practices or beliefs is protected[129]. This leads to an obligation to be tolerant towards different religious practices[130].

On these premises any behaviour or rule which denies equal treatment and does not pass any statutory justification test[131] amounts to discrimination[132] be it either direct or indirect.

Discrimination is direct, for example, in giving preference to a prayer over another in opening schools[133]. Discrimination is indirect, for example, in case of refusal to sublet because the landlord prefers to rent to people sharing her own religious beliefs[134]. Discrimination can also be constructive, if no justification for it applies, "*Where a requirement, qualification or factor exists that is not discrimination on a prohibited ground but that results in the exclusion, restriction or preference of a group of persons who are identified by a prohibited ground of discrimination and of whom the person is a member*"[135].

The Ontario *Human Rights Code* notion of duty to accomodate arises "when a person's religious beliefs conflict with a requirement, qualification or practice"[136].

In dealing with the need to accommodate religious belief it is noteworthy to discuss whether potential discriminatory factors which originally were born as clearly religiously oriented have now been secularized[137]. The issue has been posed clearly dealing with Good Friday as a now secularized

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127 See *Singh v. Workmen's Compensation Board Hospital & Rehabilitation Centre* (1981), 2 C.H.R.R. D/549 (Ontario Board of Inquiry); *Bhinder v. Canadian National Railway Co.* (1981), 2 C.H.R.R. D/546 (Cdn. Human Rights Tribunal), reversed [1983] 2 F.C. 531, affirmed [1985] 2 S.C.R. 561.

128 But see *Obdeyn v. Walbar Machine Products of Canada Ltd.* (1982), 3 C.H.R.R. D/712 (Ont. Bd. of Inquiry) at D/716 - D/717-. However it covers atheists and agnostics when the targeted individual does not share the same religious belief. It covers also authocton spirirtualistic beliefs. See P. BOSSET, *Réflexion sur la portée et les limites de l'obligation d'accommodement raisonnable en matière religieuse,* Commission des droits de la personne et de la jeunesse , Cat. 2.120-4.20.1, 2005, 8.

129 See in the Charter context *R. v. Big M Drug Mart Ltd.*, [1985] 1 S.C.R. 295 and *Ont. Human Rights Comm. v. Simpsons-Sears*, [1985] 2 S.C.R. 536.

130 See P. BOSSET - P. EID, *Droit et religion : de l'accommodement raisonnable à un dialogue internormatif*, Commission des droits de la personne et des droits de la jeunesse, Cat. 2.500.127, 2006, 5.

131 For instance, S. 24(1)(a) of the Ontario Human Rights Code permits to an institution primarily serving the interests of an identifiable religious group (so called special interest organizations) to prefer their members as job applicants.

132 See *Dufour v. J. Roger Deschamps Comptable Agréé* (1989), 10 C.H.R.R. D/6153 (Ont. Bd. of Inquiry) at 6170, establishing that "[h]arassment or discrimination against someone because of religion is a severe affront to that person's dignity, and a denial of the equal respect that is essential to a liberal democratic society".

133 See *Opening and Closing Exercises for Public Schools in Ontario* (Ministry of Education and Training, 1993). See also *Zylberberg v. Sudbury Board of Education (Director)* (1988), 65 O.R. (2d) 641 (Ont. C.A.).

134 S. 9 of the Ontario Human Rights Code.

135 Section 11(1) of the Ontario Human Rights Code.

136 It applies also in case of constructive discrimination. "Subsection 11(2) of the *Coe* imposes the duty to accommodate in cases of constructive discrimination: Subsection *11(2) OHRC. The Commission, the board of inquiry or a court shall not find that a requirement, qualification or factor is reasonable and bona fide in the circumstances unless it is satisfied that the needs of the group of which the person is a member cannot be accommodated without undue hardship on the person responsible for accommodating those needs, considering the cost, outside sources of funding, if any, and health and safety requirements, if any*".

137 For similar arguments used by a European court see the Dutch case *HR* 30 March 1984, *NJ* 1985, 350 (*Suikerfeest*), with a comment by ALKEMA. In general see C. MAK, *Fundamental Rights in European Contract Law. A Comparison of the Impact of Fundamental Rights on Contractual Relationships in Germany, the Netherlands, Italy and England*, Kluwer International, 2008.

holiday[138]. Yet, deciding the issue, the court went along in stating that "*Here the schedule of work is based upon the Catholic calendar of holidays. Nonetheless, I think the calendar should be taken to be secular in nature and thus neutral or non-discriminatory on its face. It will be remembered that the majority of the Court of Appeal determined that since the calendar did not have any religious aims, it was not discriminatory. With respect, I think this was an erroneous conclusion. It is true that this approach can properly serve to determine that there has been no direct discrimination. However, the analysis cannot stop there. Consideration must still be given to the effect of the calendar in order to determine if there is indirect or adverse effect discrimination*"[139].

The final outcome is that "secularization" of originally religious factors can impact on direct discrimination but it does not eliminate the threat of indirect discrimination[140]. Indeed, the notion of religion which is retained tries to take into account the changes in values experienced in modern western societies[141] and the fragmentations of religions[142] and more than secularity of the State we should talk about State neutrality[143].

The debate on reasonable accomodation relative to discrimination based on religious grounds (in the broad sense described) has a clear impact on private law matters. For instance, although the main grounds for the decision was freedom of religion, the judgment in the *Amselem* case remains a landmark

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138 *Commission scolaire régionale de Chambly v. Bergevin* (1994) 22 C.H.R.R. D/1 (S.C.C.) [three Jewish teachers employed by a Catholic school board were denied access to the special purpose paid-leave provisions in the collective agreement so that they could observe Yom Kippur, unless thay took a day off without pay]. As established per Mr. Justice Cory "... Christian holy days of Christmas and Good Friday are specifically provided for in the calendar. Yet, members of the Jewish religion must take a day off work in order to celebrate Yom Kippur. It thus inevitably follows that the effect of the calendar is different for Jewish teachers . . . [t[hey . . . must take a day off work while the majority of their colleagues have their religious holy days recognized as holidays from work. In the absence of some accommodation by their employer the Jewish teachers must lose a day's pay to observe their holy day. It follows that the effect of the calendar is to discriminate against members of an identifiable group because of their religious beliefs. The calendar or work schedule is thus discriminatory in its effect".

139 Emphasis in original.

140 The Ontario Human Rights commission derived from Chambly a set of principles useful to remember: "i) The employer has a duty to consider and grant requests for religious leave, including paid religious leave, unless to do so will cause undue hardship. ii) Equality of treatment requires at a minimum that employees receive paid religious days off, to the extent of the number of religious Christian days that are also statutory holidays, namely two days (Christmas and Good Friday). iii) The number of paid days may be three under some collective agreements which also make Easter Monday a holiday. iv) Beyond this point, *i.e.*, two or three days, individuals may still seek accommodation. For example, measures might include additional paid leave days such as floating days or compassionate leave days, if such exist under company policy or collective agreements, or through unpaid leave. v) The standard for *all* accommodation requests is undue hardship, which places a specific burden on the employer to produce evidence to the standard of undueness of the hardship and of its effect". See *Policy on creed and the accommodation of religious observances*, Ontario Human Rights Commission, ISBN – 0-7778-6518-1, 1996, 12.

141 See F. FOURNIER - M. COUTU, *Le Québec et le monde 1975-2000 : mutations et enjeux*, in *Après 25 ans, la Charte québécoise des droits et libertés de la personne*, (vol. 2), *2003*, at 7-10.

142 By the early 1990s Québec was already home to more than a thousand new religious or spiritual groups. See L. GAGNÉ, « Nouvel âge, nouvelles croyances », *Santé Société*, vol. 12 (1990), n° 4, p. 43. See also M. MILOT, *Laïcité dans le Nouveau Monde : le cas du Québec*, Éditions Brepols (Belgique), 2002, at 116.

143See J. WOEHRLING, *Neutralité de l'État et accommodements : convergence ou divergence?*, *Options politiques*, septembre 2007: "Il serait sans doute plus à propos de parler de la neutralité de l'État, comme principe voulant que «l'État se comporte de la même façon à l'égard de toutes les religions et qu'il n'en privilégie ou n'en défavorise aucune par rapport aux autres, de même qu'il ne privilégie ou ne défavorise pas les convictions religieuses par rapport aux autres attitudes à l'égard de la religion".

one and an important example of the ethnic-religious issues on private law. In *Amselem*[144] permission for the temporary building in his own balcony of a "succah" necessary for the purposes of fulfilling a biblically mandated obligation during the Jewish religious festival of "Succot"[145] was denied by the syndicate of co-owners in light of the declaration of co-ownership, which amongst other things forbade any alteration of the balcony itself since "a) On porches, an area at least as wide as is required under fire safety by-laws must be kept free of garden furniture and other accessories, as the porches serve as emergency exits. b) No owner may enclose or block off any balcony, porch or patio in any manner whatsoever or erect thereon constructions of any kind whatsoever." In addition "nothing other than usual outdoor furniture may be left or stored on a balcony or porch without first obtaining permission in writing from the Board of Directors. Under no circumstances may balconies or porches be used for drying laundry, towels, etc. No balcony or porch may be decorated, covered, enclosed or painted in any way whatsoever without the prior written permission of the co-owners or the Board of Directors, as the case may be."

Despite all these prohibitions, none of the co-owners, all Jewish observants, had read the declaration of co-ownership before purchase. The building administration proposed to accommodate the Succot requirements by permitting a common "succah" in the common area. One of the co-owners disagreed assuming this would not fulfil the biblical requirements. Hence, the issue of defining the relevant notion of "religious belief" showed its potential to become decisive.

In defining what is religion the court, per Iacobucci J., assumed the reasoning of Dickson J in *Big M Drug Mart Ltd.*[146] stating that a"… truly free society is one which can accommodate a wide variety of beliefs, diversity of tastes and pursuits, customs and codes of conduct. A free society is one which aims at equality with respect to the enjoyment of fundamental freedoms and I say this without any reliance upon s. 15 of the *Charter*. Freedom must surely be founded in respect for the inherent dignity and the inviolable rights of the human person. The essence of the concept of freedom of religion is the right to entertain such religious beliefs as a person chooses, the right to declare religious beliefs openly and without fear of hindrance or reprisal, and the right to manifest religious belief by worship and practice or by teaching and dissemination. But the concept means more than that. . . . Freedom means that . . . no one is to be forced to act in a way contrary to his beliefs or his conscience. . . With the *Charter*, it has become the right of every Canadian to work out for himself or herself what his or her religious obligations, if any, should be. .."[147].

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144 Relevant law for the case was 18 *Charter of Human Rights and Freedoms*, R.S.Q., c. C-12. Relevant provisions from the Civil Code of Québec were articles 1039, 1056, 1063.

145 According to *Syndicat Northcrest* c. *Amselem*, [2004] 2 R.C.S. 551at para 7: "Technically, a succah must minimally consist of a three-walled, open-roofed structure which must meet certain size specifications in order to fulfill the biblical commandment of dwelling in it properly according to the requirements of the Jewish faith. While a succah is usually festively decorated interiorly, there are no aesthetic requirements as to its exterior appearance."

146 *R. v. Big M Drug Mart Ltd.*, [1985] 1 S.C.R. 295 at para 40-41.

147 Emphasis added in J. Iacobucci quote.

According to Dickson J.[148]: "Viewed in this context, the purpose of freedom of conscience and religion becomes clear. The values that underlie our political and philosophic traditions demand that every individual be free to hold and to manifest whatever beliefs and opinions his or her conscience dictates, provided *inter alia* only that such manifestations do not injure his or her neighbours or their parallel rights to hold and manifest beliefs and opinions of their own."

In the *Anselem* case, despite the clear wording of the declaration of co-ownership the court maintained a judgement of discrimination on grounds of religion for not accommodating the need of a individual "succah". Again the main grounds of the decision remained the freedom of religion while the duty of reasonable accommodation was only recalled by analogy. Yet, a private agreement freely entered into by consentient adults did not resist the proof of accommodation.

It is therefore worth investigating further this example to gain more insights on the issue of the interplay between reasonable accommodation and private law[149].

B. The interplay between religious norms and State private law: some remarks and examples on marriage, divorce and damages.

Accommodating religious beliefs does not mean, in automatic terms, integrating religious norms into State law[150]. In reality, specific legislation exists which in various ways force us to take into account religious norms within the application of private law. Notably, in the domain of family law and divorce, the issue has been raised a number of times. According to some scholars[151] and some case law[152] there is not a complete ban, deriving from State religious neutrality, towards a normative pluralism in society[153] leading to the possibility of ascertaining on a case by case basis the compatibility with the State legal order of the ethical-normative content of norms deriving from moral or religious norms.

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148 In *R. v. Big M Drug Mart Ltd.*, [1985] 1 S.C.R. 295 at para 346.

149 On the interplay between civil rules and religious rules in the recent Canadian debate see R. LECKEY, *Profane Matrimony* , *Canadian Journal of Law and Society,* Vol. 21, No. 2, pp. 1-23, 2006.

150On the obligation of full religious neutrality for modern Canada and Quebec see José WOEHRLING, *L'obligation d'accommodement raisonnable et l'adaptation de la société à la diversité religieuse*, (1998) 43 *Revue de* droit *de McGill* 370-375.

151 B. BERGER, *The Limits of Belief : Freedom of Religion, Secularism, and the Liberal State*, (2002) (17)1 *Revue canadienne Droit et Société* 39-68.

152 *Contra* see *Levitts Kosher Foods Inc.* c. *Levin et al.* (1999) 175 D.L.R. (4th) (O.S.C.J.); *Kaddoura* c. *Hammoud*, (1999) 168 D.L.R. (4th) 503 (O.C.); *Marcovitz* c. *Brucker*, [2005] QCCA 835 (C.A.). But see *Chamberlain* c. *Surrey School District No. 36*, (2000) 191 D.L.R. (4th) 222 (B.C.C.A.), voided on: [2002] 4 R.C.S. 710.

153 "Freedom of religion is not absolute. It is only those manifestations of religious conscience that advance and protect human dignity, autonomy, and security – those manifestations of religious conscience that are resonant with civic values – that find protection under the Charter". See B. BERGER, *The Limits of Belief : Freedom of Religion, Secularism, and the Liberal State*, (2002) (17)1 *Revue canadienne Droit et Société* 67-68.

Is it possible to advance an inter-normative[154] dialogue between the State legal order and the set of norms emerging in religions without renouncing the supremacy of State law and the paramount protection of fundamental rights and liberties? In a sense the entire contractual law is already the production of private individuals, but this fact does not limit the unifying (and limiting) role of State law on it[155].

From the private law standpoint, acceptance of non-State norms (legal pluralism) is acceptable and workable as long as they can be "reduced" to the language of State law[156]. This can happen by way of open concepts (e.g. good faith, public order, moral customs, wrongfulness,…) and their use in the judicial process or the requalification of "external" norms in light of the constitutional (or Provincial Charters in the case of Canada) values.

In those contexts in which even the contract has an important relational component this process would require an even larger sensibility[157]. These inter-normative dialogues will often need to be expressly framed by the law.

A significant example is the Canadian legal provision to avoid blackmailing or abuses which can be found in contractual agreements, apparently neutral and fair, related to divorce by spouses who according to religious norms can maintain barriers to remarriage. In these instances Canadian law[158] permits the judge to "subject to any terms that the court considers appropriate, dismiss any application filed by that spouse under this Act, and strike out any other pleadings and affidavits filed by that spouse"[159].

The rule clearly applies in the example of the Jewish religious divorce. Under Jewish religious norms divorce is a mutual contract but to be valid the husband should formally (in front of a commission of three rabbis) convey to his wife the act of divorce (*Get*) and she should accept it for a valid divorce to

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154 M.M. KLEINHANS – R. MACDONALD, *What is a Critical Legal Pluralism*, (1997) 12(2) *Revue canadienne Droit et société* 39. For an early reflexion on the issue and reference to XX century legal theorists see J.G. BELLEY, *L'État et la régulation juridique des sociétés globales. Pour une problématique du pluralisme juridique*, (1986) 18(1) *Sociologie et sociétés* 11-33.

155 See in this directions M. COUTU, *Le pluralisme juridique chez Gunther Teubner : La nouvelle guerre des dieux?*, (1997) 12(2), *Revue Canadienne Droit et Société* 103-104.

156 M. COUTU, *Contrat et autoréférence en droit suivant Gunther Teubner : une "méprise constructive"* , (1998) 40 *Revue interdisciplinaire d'études juridiques*, 1-46: « *le système juridique connaît* […] *un conflit permanent entre le droit étatique et les ordres juridiques pluriels de la société* […]. *La conciliation des conflits de rationalité liés au déploiement du pluralisme juridique nécessite leur recomposition préalable en référence à la logique systémique spécifique* […] *à laquelle se rattachent les ordres juridiques autonomes* » (at 17).

157 A. ROY, *Le contrat en contexte d'intimité*, (2002) 47 *Revue de droit de McGill* 861, at 874: «sensible aux phénomènes d'internormativité, le professionnel du droit […] ne trouvera plus exclusivement les réponses aux problèmes qui lui sont soumis dans la loi et la doctrine officielle; il les repérera à travers le vécu des partenaires, leurs coutumes, leurs valeurs et leur environnement».

158 One example is the Canadian Divorce Act 1985 (art. 21.1) which enters indirectly on the religious divorces by establishing that (3) Where a spouse who has been served with an affidavit under subsection (2) does not (a) within fifteen days after that affidavit is filed with the court or within such longer period as the court allows, serve on the deponent and file with the court an affidavit indicating that all of the barriers referred to in paragraph (2)(e) have been removed, and (b) satisfy the court, in any additional manner that the court may require, that all of the barriers referred to in paragraph (2)(e) have been removed, the court may, subject to any terms that the court considers appropriate, (c) dismiss any application filed by that spouse under this Act, and (d) strike out any other pleadings and affidavits filed by that spouse under this Act".

159 See on the issue B. MOORE, *Le droit de la famille et les minorités*, (2003-4), *Revue de droit de l'Université de Sherbrooke* 238-239, and B. MOORE, *Contrat et religion - À la volonté de Dieu ou des contractants ?* Commentaire sur l'affaire *Marcovitz c. Bruker,* (2009) 43 *R.J.T.* 219 – 241.

materialize. Without this formality the woman remains married; she cannot remarry; she is *Agunah*; in case of cohabitation with another man she will be considered adulterous and their children and all their discendence will be considered *mamzerim* (bastards) and they will be able to marry religiously only with other *mamzerim*[160]. The husband does not suffer the same effects (e.g. his cohabitation will not, with exceptions, be considered adulterous). The Act permits, at the request of the spouse, the forced elimination of any religious remarriage impediments to avoid their "misuse" in forcing contractual terms (ostensibly freely accepted) upon the divorcing wife[161].

This interplay between State law and religious norms is even more evident under some State laws. Consider the Ontario Family Law Act[162] which authorizes the court to "set aside all or part of a separation agreement or settlement, if the court is satisfied that the removal by one spouse of barriers that would prevent the other spouse's remarriage within that spouse's faith was a consideration in the making of the agreement or settlement". The rule also allows "to consent orders, releases, notices of discontinuance and abandonment and other written or oral arrangements" and regardless of any contrary agreement (sub-section 7).

The rule is not a unique one. For instance, New York State law[163] goes even further. It allows the court to suspend divorce proceedings until any barrier to religious remarriage is removed and (since 1992)[164] permits an increase in the maintenance allowance payable by the spouse as a punishment for those who refuse to remove barriers to religious remarriage[165].

Yet these interplays remain problematic and open to questionable issues, especially in considering the jurisprudence which defend the freedom of religion. In an attempt to protect the freedom of religion of the husband the Québec Court of Appeal has refused compensatory damages to a wife for the fifteen-year-long refusal of her husband to fulfil the contractual obligation to convey the *Get*[166] on the basis of

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[160] For these informations see A. BARNETT, *Getting a "Get" – The Limits of Law's Authority? N. v. N. (Jurisdiction : Pre-Nuptial Agreement) [1999] 2 F.L.R. 745*, (2000) 8(2) *Feminist Legal Studies* 241-254. See also B. MOORE, *Contrat et religion - À la volonté de Dieu ou des contractants ? Commentaire sur l'affaire Marcovitz c. Bruker,* cit., 219– 241.

[161] As clearly stated by Judge Tannenbaum after rememberinng the religious rules in *Droit de la famille – 2296*, [1995] R.D.F. 728-731: "It is not too difficult to imagine that the above situation has, over the years, led to many instances where the treat [*sic*] of withholding consent has forced many women into accepting unfair agreements with respect to either custody, access, or financial arrangements in the civil divorce. With respect to people of the Jewish faith who are divorcing, section 21.1 of the Divorce Act is a way of levelling the playing field. The Jewish husband who threatens to withhold consent is subject to being denied the right to petition for corollary relief or even a civil divorce itself (p. 730-731)." The case has been followed by several decisions in the same line. See in *Québec H. (K.) c. S. (J.)*, REJB 2000-17013 (C.S.) and A.D. c. J.P., C.S. Montréal, n° 500-12-25913-017, 5 février 2004, j. Hurtubise, at : http://www.jugements.qc.ca/php/decision.php?liste=13806290&doc=57455A59561B0219.

[162] Ontario Family Law Act R.S.O. 1990, CHAPTER F.3 56(5) and subsequent.

[163] *N.Y. Dom. Rel. Law*, art. 236 B5 (5) (h) et 6 (d).

[164] *N.Y. Dom. Rel. Law*, art. 236 B5 (5) (h) et 6 (d).

[165] See in general M. GREENBERG-KOBRIN, *Civil Enforceability of Religious Prenuptial Agreements*, (1999) 32(4) *Columbia Journal of Law and Social Problems* 359-399.

[166] The case is *Marcovitz c. Bruker*, [2005] R.J.Q. 2482 (C.A.) revising *Marcovitz c. Bruker* [2003] R.J.Q. 1189 (C.S.) according to which "In Quebec, the object of a contract can be anything that is not contrary to public order (Article 1425 C.c.Q.). Since in this case there are no public order issues, the contract is valid. Simply put, a valid civil obligation with religious undertones was created. Since Defendant breached this obligation, Plaintiff is entitled to seek damages before a civil court." (par. 20, *Marcovitz c. Bruker* [2003] R.J.Q. 1189 (C.S.)). *Marcovitz c. Bruker*, [2007] 3 R.C.S. 607. See also See also B. MOORE,

the argument that "the substance of the . . . obligation is religious in nature, irrespective of the form in which the obligation is stated" and therefore it is a moral obligation not enforceable by a civil court[167].

The Canadian Supreme Court on appeal reversed the verdict[168]. Considering that "The judicial role in balancing and reconciling competing interests and values when freedom of religion is raised, is one that protects the tolerance Quebec endorsed in the *Québec Charter*. Section 9.1 states that in exercising their fundamental freedoms and rights — including freedom of religion — persons "shall maintain a proper regard for democratic values, public order and the general well-being of the citizens of Québec". This provision is a legislative direction that the courts are to protect the rights of Quebec's citizens in a way that is balanced and reconciled with other public values."[169].

In para 16 Justice Abella for the majority continues that "an agreement between spouses to take the necessary steps to permit each other to remarry in accordance with their own religions, constitutes a valid and binding contractual obligation under Quebec law" and applying the balancing mandated by s. 9.1 of the Quebec *Charter*, "any harm to the husband's religious freedom in requiring him to pay damages for unilaterally breaching his commitment, is significantly outweighed by the harm caused by his unilateral decision not to honour it"[170].

"Despite the moribund state of her marriage, Ms. Bruker remained, between the ages of 31 and 46, Mr. Marcovitz's wife under Jewish law, and dramatically restricted in the options available to her in her personal life. This represented an unjustified and severe impairment of her ability to live her life in accordance with this country's values and her Jewish beliefs. Any infringement of Mr. Marcovitz's freedom of religion is inconsequential compared to the disproportionate disadvantaging effect on Ms.

Contrat et religion - À la volonté de Dieu ou des contractants ? Commentaire sur l'affaire *Marcovitz c. Bruker,* cit., 219 – 241 and R. JUKIER – S. VAN PRAAGH, *Civil Law and Religion in the Supreme Court of Canada: What Should We Get Out of Bruker V. Marcovitz?*, *(2008) 43 S.C.L.R. (2d) 381*. Note that the French courts (e.g. Trib. civ. Seine, February 22, 1957, *Gaz. Pal.* 1957.1.246), the French Cour de Cassation (Civ. 2e, December 13, 1972, *D.* 1973.493 and Chambre civile 2, 15 juin 1988, no. 86-15476, Publié au Bulletin C34882), the European Commission of Human Rights (*D. v. France*, Application No. 10180/82, December 6, 1983, D.R. 35, p. 199) found in the refusal to convey the *Get* a delictual fault awarding damages. Similarly in *Brett v. Brett*, [1969] 1 All E.R. 1007, the English Court of Appeal ordered an additional lump sum spousal support payment by the husband if he refused to deliver a *get* by a certain date. Tthe Family Court of Australia awarded the wife a greater amount of spousal maintenance in order to "encourage" the husband to give her a religious divorce *in In the Marriage of Steinmetz* (1980), 6 F.L.R. 554. For American cases see *Waxstein v. Waxstein*, 395 N.Y.S.2d 877 (Sup. Ct. 1976) (aff'd 394 N.Y.S.2d 253 (App. Div. 1977)); *Rubin v. Rubin*, 348 N.Y.S.2d 61 (Fam. Ct. 1973); and *Minkin v. Minkin*, 434 A.2d 665 (N.J. Super. Ct. Ch. Div. 1981). Of course similar decisions emphasizing the risks of imbalances between the spouses are found under Israeli law and indeed in the landmark case of *Bavli v Bavli* (1992), where the Israeli High Court commanded the rabbinical court to reverse its decision and to divide property in accordance with principles of egalitarian community property rule the rabbinical courts simply refused. See further: Bogoch andHalperin-Kaddari, *Divorce Israeli Style: Professional Perceptions of Gender and Power in Mediated and Lawyer-Negotiated Divorces* Law & Policy, Vol. 28, No. 2, April 2006

[167] *Marcovitz c. Bruker*, [2005] R.J.Q. 2482 (C.A.) at par. 76. See to the contary Freedman C.J.M. dissenting in *Re Morris and Morris* (1973), 42 D.L.R. (3d) 550 (Man. C.A.) and quoted by the majority of the Supreme Court of Canada in *Marcovitz*: "That the [marriage] contract is deeply affected by religious considerations is not determinative of the issue. That is the beginning and not the end of the matter. Some contracts rooted in the religion of a particular faith may indeed be contrary to public policy. Others may not. Our task is to determine whether the rights and obligations flowing from the . . . contract — specifically, the husband's obligation to give and the wife's right to receive a *Get* — are contrary to public policy."

[168] *Marcovitz c. Bruker*, [2007] 3 R.C.S. 607.

[169] *Marcovitz c. Bruker*, cit., at para 15.

[170] *Marcovitz c. Bruker*, cit., at para 17.

Bruker's ability to live her life fully as a Jewish woman in Canada"[171]. Therefore the husband's refusal to provide a *Get* was not acceptable and thus recognized that the inability to remarry within one's religion represents a serious compensable injury[172]

In short, the lessons drawn from the case is that in ". …deciding cases involving freedom of religion, the courts cannot ignore religion. To determine whether a particular claim to freedom of religion is entitled to protection, a court must take into account the particular religion, the particular religious right, and the particular personal and public consequences, including the religious consequences, of enforcing that right." (para 18)[173].

Using other case law as a reference, courts are not asked to determine if a good Catholic should not work on Sundays[174] or if a good Sikh must wear the kirpan[175]; what they are asked to do is to ascertain in the eyes of the law if the violation of an obligation or a duty due to religious freedom is justifiable or not. It is not the business of the court to enter in religious interpretations or disputes.

C. Insights on discrimination, multi-culturalism and their interplay with contracts and property.

Canadian experiences in dealing with discrimination in contracts (especially tenancy contracts) is rather ample and linked to various situations. Reference should be made, for example, to the Ontario Human Rights Code whose application is mandated since 2003[176] in rental related cases when a cooperative arrangement is also involved[177].

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171 *Marcovitz c. Bruker*, cit., at para 96.

172 *Marcovitz c. Bruker*, cit., at para 20 : "The Court is not asked to endorse or apply a religious norm. It is asked to exercise its responsibility, conferred by the Quebec *Charter*, to determine whether the husband is entitled to succeed in his argument that requiring him to pay damages for the breach of a legally binding agreement violates his freedom of religion. No new principle emerges from the result in this case. Courts are routinely asked whether a contract is valid. And the inquiry under the Quebec *Charter* is the application of a classic and cautious balancing that courts are required to undertake in determining whether a particular claim to religious freedom is sustainable, one case at a time, attempting always to be respectful of the complexity, sensitivity, and individuality inherent in these issues."

173 *Marcovitz c. Bruker*, cit., at para 51: "…there is nothing in the *Civil Code* preventing someone from transforming his or her moral obligations into legally valid and binding ones. Giving money to charity, for example, could be characterized as a moral and, therefore, legally unenforceable obligation. But if an individual enters into a contract with a particular charity agreeing to make a donation, the obligation may well become a valid and binding one if it complies with the requirements of a contract under the C.C.Q. If it does, it is transformed from a moral obligation to a civil one enforceable by the courts". To the contrary per dissenting judge DESCHAMPS "Civil rights arise out of positive law, not religious law. If the violation of a religious undertaking corresponds to the violation of a civil obligation, the courts can play their civil role. But they must not be put in a situation in which they have to sanction the violation of religious rights. The courts may not use their secular power to penalize a refusal to consent to a *get*, failure to pay the Islamic *mahr*, refusal to raise children in a particular faith, refusal to wear the veil, failure to observe religious holidays, etc. Limiting the courts' role to applying civil rules is the clearest position and the one most consistent with the neutrality of the state in Canadian and Québec law." (*Marcovitz c. Bruker*, [2007] 3 R.C.S. 607 at para 184).

174 *Smart* c. *T. Eaton Ltée*, (1994) 19 C.H.R.R. D/446 (T.D.P.).

175 *Commission scolaire Marguerite-Bourgeoys* c. *Singh Multani*, [2004] R.J.Q. 824 (C.A.), requête pour permission de pourvoi à la Cour suprême du Canada. See also *Pandori* c. *Peel Board of Education*, (1990) 12 C.H.R.R. D/364 (Ont. Bd. Inq.).

176 *Walmer Developments* v. *Wolch* (2003), 67 O.R. (3d) 246 (Sup. Ct. (Div. Ct.)).

177 *Eagleson Co-Operative Homes, Inc.* v. *Théberge,* [2006] O.J. No. 4584 (Sup.Ct. (Div.Ct.)) in which a co-op sought to evict an occupant for failing to perform the two hours of volunteer work each month required by the co-op's by-law, despite the fact that she had provided a doctor's note that she was incapable of performing the volunteer work for medical reasons.

With reference to actual situations, they can arise from cultural practices of ethnically diverse tenants, for instance. In several jurisdictions cooking odours have been the subject of court decisions. In Ontario[178] a Tribunal found "that South Asian tenants were denied an apartment because of stereotypes regarding cooking odours"[179]. In a subsequent case[180] discrimination was found in the ordering ofa tenant to either cease producing odours by cooked foods in her home that were an expression of her ethnicity and ancestry or face being evicted[181].

From the above examples it is clear that discrimination can arise after a contract has been entered. A good illustration of this is the emotional and physical impact on a tenant resulting from racial slurs evidenced by tapes and testimonies which led to compensation[182].

Indirect discriminatory treatment can ensue as well. Consider the case of a tenant discriminated against for her association with a racialized person[183]. This was the case of *John* v. *Johnstone*[184] (eviction of a White woman, after she had a Black friend over for dinner) or of *Hill* v. *Misener* (No. 1)[185] in which condition of occupancy was the non-association of the tenant with "coloured" people and the complainant was a White woman with two bi-racial children. Note that she never rented the apartment because she was profoundly offended. Yet, the court still found actionable discrimination and awarded compensation.

Stereotypes can often form the basis of a discrimination, not least in the pursuit of housing accommodation. So it was in the case of the refusal to rent to a woman "in part because there was no man in her family to do the yard work"[186] .

In other types of contract the duty to accommodate arises routinely as well. Consider the employment contracts in which the school was required to accommodate the shift hours of a Seventh Day Adventist to accommodate participation in religious practices if this does not create undue hardships[187]. Note that the burden of proving undue hardship remains on the person required to accommodate[188] in order to ease protection against discrimination.

According to the court the co-op could have accommodated the claimant by assigning her tasks she could perform. In any event, the cost of accommodating with an exemption from the volunteer work requirement would have been unlikely to impose an undue hardship.

178 *Fancy* v. *J & M Apartments Ltd.* (1991), 14 C.H.R.R. D/389 (B.C.C.H.R.).

179 See *Human rights and rental housing in Ontario: Background paper*, Ontario human rights Commission, ISBN: 978-1-4249-4275-6, 2007, 26p.

180 *Chauhan* v. *Norkam Seniors Housing Cooperative Association* (2004), 51 C.H.R.R. D/126, 2004 BCHRT 262.

181 This was understood by the court as an attack to elements central to one's dignity.

182 See *King* v. *Bura* (2004), 50 C.H.R.R. D/213, 2004 HRTO 9.

183 Note that the Ontario human rights code offers specific protection: Art. 12: "Discrimination because of association A right under Part I is infringed where the discrimination is because of relationship, association or dealings with a person or persons identified by a prohibited ground of discrimination. R.S.O. 1990, c. H.19, s. 12."

184 *John* v. *Johnstone*, (September 16, 1977), No. 82, Eberts (Ont. Bd. Inq.).

185 *Hill* v. *Misener* (No. 1) (1997), 28 C.H.R.R. D/355 (N.S. Bd. Inq.).

186 *Conway* v. *Koslowski* (1993), 19 C.H.R.R. D/253 (Ont. Bd. of Inquiry).

187 See *Central Okanagan School District No. 23 v. Renaud* (1992), 16 C.H.R.R. D/425, Supreme Court of Canada. Note that this is a decision of the Supreme Court of Canada on a British Columbia case. It establish a general principle for all Provinces. In French the expression used is «contrainte excessive».

188 Contrast this with the EU directive and the Italian legislation quoted before in the text.

What is considered undue hardship has also been clarified. In establishing undue hardship, the costs and health and safety risks to the person requesting accommodation[189] and\or to the general public are taken into account with reference "to the size of the organization and its operations, the nature of its business, and its financial capabilities"[190]. The mentioned criteria render the notion od undue hardship relative and context-sensitive,[191] showing once again a tendency to define legal tools in a way working towards a balance of interests in discrimination cases which search for accommodation more than a zero-sum outcome

D. Ethnicity and the law: again contract, property and torts at issue but without adverse discrimination.

Discriminating criteria can have a positive role posing a different set of problematic issues.

For instance, ethnical reasons, not necessarily discriminatory ones, have proved to have a role also in property related cases. For instance, in *Urano v. Urano*[192] the court established a equal joint ownership among three Japanese brothers taking also into account that "the nature of the family and cultural relationship" would suggest property was held in trust for the three brothers and that "the family followed a traditional Japanese view and all would share in the bounty generated by the farming operation".

In *Soulos v. Korkontzilas*[193], the court held in trust the property disputed by the plaintiff and his broker, who broke his fiduciary duties towards his principal. The plaintiff wanted to buy a specific property because it was leased to his banker and to be the landlord of one's own banker would have brought him great prestige in the Greek cultural community. The court took into account this fact in deciding for the trust and selecting a property remedy instead of damages.

Also, differences in cultures can be reflected across the countries in a variety of criteria for assessing damages[194]. The increasing movement of people of different traditions and cultures paired with their maintenance of original traditions and customs may enhance the issues raised by the impact of these clear ethnical factors on purely private law issues. Specific physical injuries, for instance can be of higher social and cultural impact on some individuals than on others.

In a 1998 case of a 28-year-old Muslim woman, who was awarded damages after her obstetrician and gynaecologist negligently sterilized her without her consent, the court acknowledged on the doctor a

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189 This argument was not accepted in cases discussing the use of a kirpan at schools, for instance. See *Sehdev v. Bayview Glen Junior Schools Ltd.* (1988), 9 C.H.R.R. D/4881 (Ont. Bd. of Inquiry); *Pandori v. Peel Board of Education* (1990), 12 C.H.R.R. D/364, aff'd (1991), 14 C.H.R.R. D/403 (Ont. Div. Ct.), leave to Ont. C.A. refused.

190 See *Policy on creed and the accommodation of religious observances*, Ontario Human Rights Commission, ISBN – 0-7778-6518-1, 1996, 8ff.

192 *Urano v. Urano* 2005 ABQB 237, 15 E.T.R. (3d) 138, 138 A.C.W.S. (3d) 983.

193 *Soulos v. Korkontzilas*, [1997] 2 S.C.R. 217.

194 See H. Mc GREGOR, *Personal injury and death*, in *International Hencyclopedia of Comparative Law*, 1972, Parigi-New York - Tubinga, ch. 9, vol. XI.

duty to be 'sensitive to cultural issues'[195]. At time of the operation the woman did not speak, read, or write English. Her friend acted as an interpreter during the doctor's appointment after which the doctor performed a permanent sterilization procedure, which she thought was only a procedure to remedy her infection. The court, taking into account that "Ms'Adan's Somalian culture placed enormous significance on the ability to give birth which created an almost insurmountable barrier to prospect of remarriage"[196], warranted a substantial sum in compensation.

This example shows the existence and use of ethnical arguments to justify increases[197] in damages awards and points to the impact (a new duty on doctors, for instance) circulation of people and multiculturalism sustained by liberal theory have on various areas of private law even without touching the issue of discrimination or reasonable accommodation[198].

Investigating a little further on this issue, we find other cases already decided in court. For instance, the Chinese filial piety tradition (so called "Bau-Da") according to which the eldest son takes care of parents has been used to increase an amount for damages for the death of the son[199]. Similarly, the reduced prospects of remarriage for cultural reasons led to an increase in loss of dependency in *Buphal v. Connolly*[200], while the scare on a face of a young Korean boy was accepted, according to Korean cultural values, as a source of "shame and embarrassment to him and his family"[201].

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[195] *Adan v. Davis* (1998), 43 CCLT (2d) 262 (Ont. Gen. Div): "Ms Adan is a Muslim woman who had never used any form of birth control and whose reproductive capacity is fundamental to her status in society. Sterilization is not permitted under Islamic law. Although the observance of Islamic law can vary, I accept the plaintiff's evidence that, despite Islamic law, she was never prepared to be sterilized. Dr Hinnawi [expert witness], who trained as a physician in Jordan and who has a large practice of Muslim patients, testified that he had never known a Muslim woman to undergo a sterilization. I do not suggest that Dr Davis knew or ought to have known anything about Islamic law or about the plaintiff's particular religious practices. But, we live in a multicultural country where conformity to values and norms is variable and where careful inquiry must be made to ensure that our own values and norms are not inadvertently imposed on those who do not subscribe to them. It cannot be assumed that a 28 year-old woman with four children who are very close in age, and who has had a recent delivery by cesarean section, does not want any more babies. There was no careful inquiry here" (at p. 278).

[196] J. BERRYMAN, *Accommodating Ethnic and Cultural Factors in Damages for Personal Injury*, 40 U.B.C. Law rev., 2007, 1, at 2.

[197] What if arguments were used to lower compensation? Se for the analysis of such an attempt under Italian law G. COMANDÉ, *La legge è uguale per tutti: il risarcimento tra "gabbie risarcitorie" e reciprocità*, cit., *passim*.

[198] Note that somethimes the influence of these cultural-ethnical factor can appear as blind guessing, but this is not differnt from those guessings made by courts when awarding future losses of earnings or actualizing the amount of damages estimating future inflaation rate. See J. BERRYMAN, *Accommodating Ethnic and Cultural Factors in Damages for Personal Injury*, cit., at 4.

[199] See *Lai v. Gill*, (1978) 28 B.C.L.R. 21 (B.C.S.C.), rev'd (1978) 28 B.C.L.R. 17 (B.C.C.A.), rev'd [1980] 1 S.C.R. 431; *Fong Estate v. Gin Bros. Enterprises Ltd.*, [1990] W.D.F.L. 760, B.C.J. No. 1138 (S.C.); *Lian v. Money*, [1994] 8 W.W.R. 463, 93 B.C.L.R. (2d) 16, appeal allowed in part, [1996] 4 W.W.R. 263, 15 B.C.L.R. (3d) 1, 28 C.C.L.T. (2d) 301 (C.A.); and *Sum Estate v. Kan* (1995), 8 B.C.L.R. (3d) 91, appeal dismissed, (1997), 100 B.C.A.C. 17, 163 W.A.C. 17, 44 B.C.L.R. (3d) 250 (C.A.). One can argue wheter it would be the same if the argument is used, without claimand imput, by the defendant in order to reduce damages according to the very same custom. See arguing for the negative, J. BERRYMAN, *Accommodating Ethnic and Cultural Factors in Damages for Personal Injury*, cit., at 29-30. The author (at 31) mentions other cases in which the phylial piety argument was used: *Arruda v. Scarborough Hospital*, [2005] O.T.C. 639, 141 A.C.W.S. (3d) 134 (Ont. Sup. Ct.) (Portuguese parents); *Ayoub v. Dreer*, [2000] O.T.C. 538, 24 C.C.L.I. (3d) 96, 99 A.C.W.S. (3d) 360 (Ont. Sup. Ct.) (Palestinian parents).

[200] *Bhupal v. Connolly*, (1994) 49 A.C.W.S. (3d) 283 at para. 38. See also *Chui Estate v. Lang* [1993] O.J. No. 79 (Gen. Div.) (QL) in which an increase in compensation was argued on the basis of cultural isolation of a close-knit Chinese family living in a small town in Northern Ontario.

[201] *Lee v. BCSC* 2003, 1012 17 B.C.L.R. (4th) 80, at 17.

In using such "sterotypes" or cultural-ethnical arguments it is rather different if it is the plaintiffs who present evidence on why their own damages should be increased on ethnical-cultural grounds or if it is the defendant who autonomously uses them. In this latter case it might be said that the defendant is, somehow, imposing on the plaintiff the duty to abide by a practice or custom that is ethnically or culturally (or religiously) grounded[202]. Similarly, courts have refused to impose *prima facie* such a duty on a son[203]. Note the contradiction for the fact that other social-economic factors are permitted routinely in court: such as, for instance, criminal records and unstable family life or family life style and parental work status or the "vow of poverty"[204], to reduce future lost earning of a plaintiff while ethnical arguments are still disputed ones[205].

To the above considerations it can be added that, according to scholars and cases, the evidence requested of plaintiffs is rather "paltry"[206].

Concluding remarks

This rapid trip through the interplay among federal and provincial legal instruments of protection of fundamental rights and freedoms against discrimination has offered several useful insights to the European viewer of the cathedral. The notion of reasonable accommodation in Canadian case law would proof a useful benchmark for the implementation of Council Directive 2000/43/EC of 29 June 2000 implementing the principle of equal treatment between persons irrespective of racial or ethnic origin, and Council Directive 2000/78/EC of 27 November 2000 establishing a general framework for equal treatment in employment and occupation[207].

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202 Yet the instance of defendants raising the issue by themself is not unknown in the courtroom as Tribunale Milano and Venezia in Italy or in Canada show.

203 *Newson v Newson* 99 BCLR 2d 197 (1994, BCSC); 35 BCLR 3d 341 (1997, BCCA); 53 BCLR 3d 191 or 1998 BCJ. 751 (1998, BCSC); 39 RFL 4th 410 (1998, BCCA) and 65 BCLR 3d 22 (1998, BCCA).

204 *Turenne v. Chung*, (1962) 36 D.L.R. (2d) 197, 40 W.W.R. 508(Man. CA) but the court refused the argument.

205 See the argument of McKenzie J. talking about phylial piety in *Fong Estate v. Gin Bros. Enterprises Ltd.*, [1990] W.D.F.L. 760, B.C.J. No. 1138 (S.C.): "As the family members tell it this tradition prevails in Canada, whether the parents are rich or poor, as strongly as in Hong Kong. Need is not a governing consideration. To the contrary, there is evidence that the younger generations of oriental families have been influenced by North American standards and no longer adhere rigidly to the customary ways that prevail or prevailed in Hong Kong. This family moved to Canada in 1973 when the girl was a babe in arms".

206See See J. BERRYMAN, *Accommodating Ethnic and Cultural Factors in Damages for Personal Injury*, cit., 10-11, quoting *Osman v. Ontario Ltd.*, [2005] O.T.C. 555, 140 A.C.W.S. (3d) 291 (Ont. Sup. Ct.); *William v. Mould*, [1991] 3 C.N.L.R. 187, 29 A.C.W.S. (3d) 1165 (B.C.S.C.); *Chitale v. Sanford* (1980), 1 F.L.R.A.C. 614, 3 Fam. L. Rev. 147 (Ont. H.C.); *Sum Estate v. Kan* (1997), 100 B.C.A.C. 17, 44 B.C.L.R. (3d) 250.

207 These preliminary remarks on EU law and its impact in Italy should have already clarified that communitarian law is of paramount importance for our research (the devotion of the EU to non-discrimination is exemplified by art. 13 TUE, former art. 6A; art. 21, in part III of the Charter of Nice which, after the Lisbon Treaty entering into force, as gained a larger importance and in close connection with the decisions of the ECtHR which has been willing to accept that many situations fall within the 'ambit' of a right, thus allowing Art 14 ECHR's anti-discrimation clausse to bite even though the substantive Article may not have been violated, e.g. *Stec v United Kingdom* (2005) 41 EHRR SE18 at para 47–55).

The Canadian experience shows, overall, a tendency to integrate differences by way of policies in primary instruments, thereby leaving only an ancillary role to litigation. Nevertheless, as the interplay between freedom of religion and private law matters and the application of the examined antidiscrimination charters to ethnical or cultural biases show, the threat of litigation, especially when assisted by a sanctioning feature (whether or not punitive damages are available) has an important role to play and it would be important to foster research in this direction. In further comparative research it would be interesting to deepen the analysis and search for cases in European countries in which the content and value of compensatory damages has an actual role in terms of deterring discriminatory behaviours or at least sanctioning them with a sufficient incentive to sue.

In this view a significant role can be played by motives. Indeed, intention and *bona fide* have a significant role in driving findings of discrimination and\or violations of the duty to accommodate. In the occupational area, for instance, the Ontario Human Rights Commission has established clear principles for requirements, qualifications or factors that are neutral or non discriminatory on their face : "i) The requirement in question must be established in good faith with the intention of achieving its stated business objective, and not as a means to avoid the purpose of the Code; ii) The requirement must be objectively connected to its stated business purpose. iii) The requirement should be the least discriminatory alternative available, other things being equal"[208].

In Canada, both common law and civil law systems have faced in similar ways the interplay between protection of minority rights and the majority's view. This is already an interesting aspect for European Union countries where antidiscrimination framework has to be applied to Member States belonging to both legal families, as well as countries not necessarily sharing the same or even similar cultural settings. This first analysis of the Canadian experience shows similar patterns in both common and civil law systems. Yet, Canadian provinces share a common constitutional framework while the EU member states do not share such an uniform constitutional bedrock. With respect to this feature, an interesting pattern of research should be the potential impact of the Treaty of Lisbon in the interpretation of the non discrimination principle within the EU.

In our analysis, in both kinds of systems (common and civil law), the protection of fundamental rights and freedoms has played a crucial role and this is a confirmation that the patterns followed by Member States' courts and by the European Court of Justice are promising. Yet, all the investigated legal systems, regardless of whether they belong to common or civil law, have been struggling to create a balanced system in which there is not an automatic open doorway to individual or minority idiosyncracies nor a prevalence of one view over the others. Notwithstanding, tensions can remain between the individual protection of fundamental rights and freedoms, on the one hand, and the

[208] See *Policy on creed and the accommodation of religious observances*, Ontario Human Rights Commission, ISBN – 0-7778-6518-1, 1996, 16.

reduction of direct and indirect discrimination created by the apparent impermeability of State (private) law towards various religious creeds, for instance, as the Jewish divorce cases dealing with the interplay of private law and religious beliefs and freedom in Québec have shown.

In this case, as in others, a principle of tolerance and proportionality in the exercise of fundamental freedoms and rights was used by the Canadian Supreme Court in reversing the Québec Court of Appeal judgement, but its application is far from clear and easy, and thus requires further research and certainly more precise fine-tuning by the courts.

The special respect paid by the reasonable accommodation techniques to the preservation of the social environment is a key feature of the Canadian experience which should be taken into account in the European experience. It could be a flexible instrument which can be adopted in case law attempting to adapt different legal cultures to the general European (Union) framework and the persistence of different cultural preferences and perhaps of different reading of the same blurry notions of fundamental rights[209]. Yet, as mentioned in the previous paragraph this tecnnique might enter into tension with individual fundamental rights and freedoms (either within a minority or not) and this phenomenon would require further attention and sensibility by policy makers and courts. Indeed , after all, "…les chartes des droits de la personne sont des arbres vivants. Autrement dit, par leur interprétation judiciaire, les droits fondamentaux sont appelés à évoluer afin de tenir compte des changements sociaux." [210]

[209] BARREAU DU QUÉBEC, *Mémoire du Barreau du Québec présenté à la Commission de consultation sur les pratiques d'accommodement reliées aux différences culturelles « Les droits fondamentaux : Une protection pour toutes et tous »,* Décembre 2007. p 17-18 : "L'imprécision apparente de certains droits, tel le droit à l'égalité ou la liberté de religion et de croyance, est notamment contrebalancée par l'interprétation des tribunaux. Ils participent à l'élaboration d'une compréhension concrète des droits de la personne dans un contexte précis." . On the European situation see (G. Brüggemeier, A. Colombi Ciacchi, G. Comandé edts.) *Fundamental Rights and Private Law in the European Union. Vol. I: A Comparative Overview*, Cambridge University Press, 2010; ID, *Fundamental Rights and Private Law in the European Union. Vol. II.: Comparative Analyses of Selected Case Patterns*, Cambridge University Press, 2010 *passim*.

[210] BARREAU DU QUÉBEC, *Mémoire du Barreau du Québec présenté à la Commission de consultation sur les pratiques d'accommodement reliées aux différences culturelles « Les droits fondamentaux : Une protection pour toutes et tous »,* cit., at 18.

Paper n. 3

BIOETHICS AND EUROPEAN UNION: THE ADVANCED THERAPY MEDICINAL PRODUCTS' CASE

by

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BIOETHICS AND EUROPEAN UNION: THE ADVANCED THERAPY MEDICINAL PRODUCTS' CASE

by

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Abstract:

Advanced Therapy Medicinal Products (ATMP) are medicinal products which are based on human genes, cells and tissues. They are completely framed by European Union Law. They are covered by the European pharmaceutical general legislation and by a *lex specialis*: the regulation (EC) N°1394/2007 on ATMP. This legal framework has been accompanied with the adoption of many guidelines related to ATMP. Furthermore, ATMP raised important ethical questions which can not be ignored: human cloning, research on embryonic stem cells, chimeras … They principally come from the legal difference between the human body and its elements and the products derived from them or containing them.

However, EU law does not provide any treaty provisions conferring powers to the EU institutions to regulate ethical standards as such. EU principally has an economic purpose and ethics would be a Member States' prerogative. Hence, if the EU regulates ATMP and if ATMP and bioethics are undeniably linked, what about bioethics as regards the EU governance of ATMP?

This paper aims to demonstrate that even though the EU does not have a treaty conferred power to regulate ethics; it is active in this field through the regulation of ATMP. On the one hand, the most controversial ethical issues are excluded from the two main binding texts applying to ATMP (i.e. the directive on tissues and cells and the regulation on ATMP). On the other hand, and going beyond these two texts, many particular ethical considerations have been infiltrated within norms directly or indirectly related to ATMP.

Key words: Advanced Therapy Medicinal Products, European Union, Bioethics

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Advanced Therapy Medicinal Products (ATMP) are medicinal products which are based on human genes, cells and tissues. They raised important ethical questions which can not be ignored. The main reason for ethical concerns regarding ATMP comes from the legal difference between the human body and its elements and the products derived from them or containing them. The human body elements such as genes, cells and tissues are legally submitted to the regime of persons. As such, they are commonly protected by several human rights principles such as the respect of the human dignity, the respect of the integrity of the human body, the inalienable and inviolable characters, the non-commercialisation principle… However, when they are "transformed" into medicinal products, they are submitted to the market rules as goods or products, which are, by nature, subject to property rights. The distinction between persons and things, as an ancillary well known law rule, has been applied to the human body elements not without some difficulties. The latter are linked to the moral values attached to the human beings and their body. The use of human genes, cells and tissues raised mainly the problematic of human cloning, the level of respect to be given to the embryo and consequently the possible use of human embryonic stem cells. Nevertheless, ATMP lead to the development of new treatments either more efficient or nonexistent hitherto. As such, they would enhance the level of protection of human health. Thus, ATMP are closely linked to bioethics which could be defined as *"the determination, so far as that is possible, of what is right and wrong, good and bad, about the scientific developments and technological developments of biomedicine"*[1].

The European Union (EU) provides a legal framework for ATMP notably to guarantee a high level of health protection for European patients and to foster the competitiveness of European undertakings. Being medicinal products, they are covered by the general European pharmaceutical legislation which is principally constituted of directive 2001/83/EC on the Community code relating to medicinal products for human use[2]. Tissue-engineered products (TEP) lied outside any EU legislation although gene therapy and cell therapy have been regulated as medicinal products under the Community general legal framework. In order to bridge this regulatory gap, the EU institutions agreed on a new regulation addressing all advanced therapies, including TEP within a coherent and single framework.

On 13 November 2007, the European Parliament and the Council adopted the regulation (EC) N°1394/2007 on advanced therapy medicinal products and amending directive 2001/83/EC and regulation (EC) N°726/2004 (Here after "regulation on ATMP")[3]. It applied from 30 December

[1] D. Callahan, The social sciences and the task of bioethics, Daedalus, 1999, N° 128, p. 275-294

[2] Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use, OJ L311, 28.11.2001, p. 67. Directive as amended by Commission Directive 2003/63/EC, OJ L159, 27.06.2003, p 46, and Directive 2004/27/EC, OJ L136, 30/04/2004, p.34

[3] Regulation (EC) N°1394/2007 of the European Parliament and of the Council on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) N°726/2004 OJ L324, 10/12/2007, p.121

2008[4]. The regulation on ATMP is a *lex specialis* setting up a legal system stricter than the one enforceable to other medicinal products.

Human cells and tissues contained in ATMP are covered by directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells[5] (here after "directive on tissues and cells") for donation, procurement and testing while further aspects are covered by the regulation on ATMP[6]. The regulation on ATMP also referred to directive 2001/20/EC[7] on clinical trials[8] and to several guidelines for which the adoption is done or ongoing related to the specificities of ATMP regarding good clinical practices, good manufacturing practices, risk management…

Hence, if the EU regulates ATMP and if ATMP and bioethics are undeniably linked, what about bioethics as regards the EU governance of ATMP?

The adoption of the directive on tissues and cells and of the regulation on ATMP reflects the political conflict between the European Commission and the Council as well as the European Parliament regarding the EU competence to legislate on ethical matters. Although ATMP are completely framed at EU level, ethics is considered to be a prerogative of Member States. According to the principle of the conferred competences, "*the Union shall pursue its objective by appropriate means commensurate with the competences which are conferred upon it in the Treaties*"[9]. But there are no treaty provisions conferring powers to the EU institutions to regulate ethical standards as such. EU principally has an economic purpose (its vocation was originally purely economical) whereas ethical choices representing the fundamental values of the society come under national authorities and the direct expression of their political views[10]. Indeed, the European Commission supported by the Council considers that "*regulating on ethical matters is the competence of Member States*"[11]. In the same way *"the Commission also asserted that the principle of subsidiarity*

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[4] However, article 29 of the regulation on ATMP provides a transitional period. Advanced therapy medicinal products "which were legally on the Community market in accordance with national or Community legislation on 30 December 2008", shall comply with this regulation no later than 30 December 2012 for tissue engineered products and no later than 30 December 2011 for the others. This period is important because it implies no treatment interruption. However, the expression "legally on the market" is raising problems. Indeed, there are differences of what is "legally on the market" or not according to the Member States.

[5] Directive 2004/23/EC of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, OJ L102, 07/04/2004, p. 48

[6] Article 3 and Recital (14) of the regulation on ATMP, cf. note 3

[7] Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, OJ L121, 01/05/2001, p. 34

[8] Article 4 and Recital (16) of the regulation on ATMP, cf. note 3

[9] Article 3§6 of the consolidated version of the Treaty on European Union, OJ C83, 30/03/2010, p. 13 (ex-article 5§1 of the European Community Treaty). However, the doctrine of implied powers and ex-article 308 of the EC Treaty (new article 352 of the Treaty on the functioning of the European Union, OJ C83, 30/03/2010, p. 47-199) undermine this principle. See notably, S. Douglas-Scott, Constitutional Law on the European Union, 21 June 2002, Longman, p. 160; J.H. Weiler, The transformation of Europe, Yale Law Journal, 1991, V. 100, p. 2403.

[10] M. Tallacchini, Governing by values. EU Ethics: Soft Tool, Hard Effects, Minerva, 2009, N° 47, p. 281-306

[11] Commission report on embryonic stem cell research provides basis for discussion on ethics, Brussels, 7 April 2003, IP/03/506.

demands that the Commission leave the "prerogatives to legislate on matters of ethics to the Member States themselves" and consequently the Commission is unable to *"impose any constraints on the freedom of states to lay down the conditions under which they wish to regulate research"*[12].

Nevertheless, the adoption of texts (binding or not) applying to ATMP is part of the EU initiative to enlarge its intervention on economics to include health and to become a wider political Union. The legal basis of the Treaties at issue are article 168§4a [ex-article 152§4 of the European Community Treaty (Here after "EC Treaty")] on the protection of human health and article 114 (ex-article 95 of the EC Treaty) on the approximation of laws regarding the establishment and the functioning of the internal market. The directive on tissues and cells is based on ex-article 152§4 of the EC Treaty whereas the regulation on ATMP is based on ex-article 95 of the EC Treaty. It is notably through the adoption's processes of these two binding texts that the European Parliament hardly defended the integration of ethical aspects within the EU legislation. But the European Parliament also sustains ethical positions through non binding law such as its numerous resolutions against human cloning[13]. The European Commission also got interested in ethics – historically, she was the first one with the Biotechnology Initiative in 1980's[14]- and emphasized the need for ethical discussions on the development of biotechnology[15]. In 1991, the establishment of the Group of Advisers on the Ethical Implications of Biotechnology (which became the European Group on Ethics in Science and New Technologies (EGE) when its areas of applications were extended[16]) implied that ethics will always be, at least, "considered" within the EU in these areas. Its opinions even non binding have a strong weight and have been very often mentioned during the adoption of binding texts related to biotechnology, such as those related to ATMP. Even if the EU does not have a conferred competence in ethics, it is however active in this field through questions of ATMP which are closely linked.

Focusing on the principal texts related to ATMP, i.e. the directive on tissues and cells and the regulation on ATMP, it appears that the most ethical controversies related to human cloning, chimera and hybrid and embryonic cells were widely discussed at the European Parliament. Even though the latter pressed on the Council and the Commission, most of its amendments were defeated. This paper will highlight the way of exclusion of the most sensitive ethical controversies during the adoption of the

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[12] In response to European Parliament Question P-2852/00, cited in T. K. Hervey and H. Black, The European Union and the Governance of stem cell research, Maastricht Journal of European and Comparative Law, 2005, 12 (3), p. 11- 48

[13] Resolutions of the European Parliament on the ethical and legal problems of genetic engineering and "in vivo" and "in vitro" artificial insemination of 16 March 1989; on the cloning of human embryos of 28 October 1993; on cloning of 20 September 1996 and 12 March 1997; on human cloning of 15 January 1998, 30 March 2000 and 7 September 2000.

[14] COM (1983) 672; see S. Hennette-Vauchez, L'émergence d'un droit communautaire de la biomédecine, RTD eur. 45 (1), Janv.-mars 2009

[15] Commission's Communication to the European Parliament and Council 'Promoting the competitive environment for industrial activities based on biotechnology within the Community', 1991, (SEC (91) 629 final). According to M. Tallacchini, "after the first European ethics body was created, the language of the Commission suddenly changed radically, shifting from the need for market normalization and legitimation to an ad hoc narrative about ethics as a way to "represent" citizens' values, to bring society closer to European institutions and to establish the European identity", cf. note 10

[16] Commission Decision on the renewal of the mandate of the European Group on Ethics in Science and New Technologies, 11 May 2005, 2005/383/EC

directive on tissues and cells and of the regulation on ATMP (I). Then, through a wider approach going beyond the two texts studied in the first part, it will be shown that some specific ethical aspects are nevertheless part of the EU governance of ATMP. Even if the EU uses a flexible approach, several ethical principles or considerations within texts related to ATMP can be identified (II).

I. The exclusion of the most controversial ethical issues

Focusing on the directive on tissues and cells and on the regulation on ATMP, it will be shown up what are the main so-called "ethical amendments" of the European Parliament regarding particular "ethically sensitive" tissues and cells and products derived from them which were not retained in the final text of regulation on ATMP and/or of directive on tissues and cells. However, this part is not exhaustive regarding all of the controversies raised by ATMP.

A. European Parliament's arguments regarding ethical controversies raised by ATMP

The European Parliament which represents the European citizens became the most protective EU institution regarding ethical values. An analysis of its proposed amendments during the adoption of the directive on tissues and cells and the regulation on ATMP confirms this reality. The main so called 'ethical amendments' of the European Parliament are related to human cloning, human-animal hybrids or chimeras and to the modification of the germ line (1) as well as particular tissues and cells, especially human embryonic cells and products derived from them (2).

1. Human cloning, hybrids or chimeras and modification of the germ line

Regarding the directive on tissues and cells, the main "ethical amendments" of the European Parliament aims principally to prohibit human cloning.

Firstly, the European Parliament provided that Member States must explicitly ban the use of tissues and cells from cloned human embryos and of hybrids derived from germ cells or totipotent cells of human origin[17]. This mandatory ban was based on ethical reasons, on reasons connected with "*the*

[17] Amendment 8, Recital (7) of the European Parliament in 1st reading, Report on the proposal for a European Parliament and Council directive on setting standards of quality and safety for the donation, procurement, testing, processing, storage, and distribution of human tissues and cells (COM(2002) 319 – C5-0302/2002 – 2002/0128(COD)), 25 March 2003, A5-0103/2003

extremely high medical risk involved" and on the repeatedly oppositions of the European Parliament[18] and the Council of Europe[19] on any form of human cloning.

Secondly, Member States shall at least prohibit research on human cloning for reproductive purposes and research designed to create human embryos solely for research purposes or to supply stem cells, including by means of the somatic cell nuclear transfer. Inversely to the associated justification, these activities undermine respect for life and human dignity and involve the use of human beings including the embryo as a material[20]. As a consequence, the European Parliament tried to make binding the prohibition of any form of human cloning which it repeatedly claimed.

Regarding the regulation on ATMP, three Committees of the European Parliament were in charge of the European Commission proposal on ATMP: the Committee on the Environment, Public Health and Food Safety (ENVI), the Committee on Industry, Research and Energy (ITRE) and the Committee on Legal Affairs (JURI). Their amendments notably aim to prohibit products which modify the human germ line and/or which are derived from human-animal hybrids or chimeras.

On the one hand, these three Committees uphold the integration of a ban on products modifying the human germ line: *"No authorisation shall be granted to products modifying the germ line genetic identity of human beings"*[21]. It was justified by reference to the Oviedo Convention which makes clear that human dignity is compromised when the inheritance of genetic identity is altered. Moreover, products which modify the human germ line are excluded from clinical trials by directive 2001/20/EC[22] and they are not legally patentable under directive 98/44/EC[23]. Thus, to be harmonised with the existing EU legislation, they should not be eligible for authorisation under the regulation on ATMP.

On the other hand, ENVI, JURI and ITRE also wished to integrate a ban on products derived from human-animal hybrids or chimeras or containing tissues or cells originating or derived from human animal hybrids or chimeras. However, the transplantation of somatic animal cells or tissues to

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[18] Reference is made to several resolutions of the European Parliament (cf. note 13) and to the European Parliament and Council Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions, OJ L 213, 30.7.1998, p. 13–21.

[19] Reference is made to the Convention for the protection of human rights and the dignity of the human person with regard to the application of biology and medicine (4 April 1997) and the annexed protocol prohibiting the cloning of human beings (12 January 1998); and Recommendation 1046 of the Council of Europe Parliamentary Assembly on the use of human embryos and foetuses in scientific research (24 September 1986).

[20] "The European Union like the Member States should regulate and focus research efforts on techniques that do not undermine respect for life and human dignity and should prohibit any technique involving the use of human beings as a material, even at the embryo stage", Justification Amendment 30, article 4§2b (new) of the European Parliament in 1st reading, cf. note 17

[21] Amendment 14 of ITRE, Opinion, 20/06/2006, Amendment 19 of JURI, Opinion, 17/07/2006, and Amendment 21 of ENVI, Draft Report on the proposal for a regulation of the European Parliament and of the Council on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD)), 30/05/2006, provisional 2005/0227 (COD).

[22] "No gene therapy trials may be carried out which result in modifications to the subject's germ line genetic identity", Article 9§6 of Directive 2001/20/EC

[23] Article 6§2 (b) of Directive 98/44/EC, cf. note 18

the human body for therapeutics purposes or xenotransplantation would be allowed *"as far as it does not interfere with the germ line*"[24]. These Committees justified this ban recalling that the physical and mental integrity of the person and human dignity must be respected as it is underlined in articles 1 and 3 of the Charter of Fundamental Rights of the EU (here after "the EU Charter")[25]. They consider that *"the creation of human-animal hybrids or chimeras is a threat to the right to integrity of a person and a violation of human dignity*"[26]. ENVI and JURI also provided definitions[27] for "chimera"[28] and "hybrid"[29]. ENVI's Committee also added that *"the Directive 98/44/EC on the legal protection of biotechnological inventions stresses that the production of chimeras from germ cells is excluded from patentability. Therefore, no authorisation under this regulation should be granted to products containing or derived from such tissues and cells"*[30].

2. Embryonic stem cells and products derived from them

The adoption of a directive on tissues and cells gave rise to numerous tensions around the regulation of specific cells and tissues especially embryonic stem cells. Once again, the European Parliament introduced several "ethical amendments". The main ones will be considered.

Firstly, it tried to introduce a right of Member States to prohibit the use of particular cells, which should be especially germ cells, foetal and embryonic cells: Member States have a **right** to ban donation, experimentation, processing, storage, distribution and use of any other kind of particular cells or human tissues or of cells of a particular origin and of products originating from particular tissues or cells, or particular tissues or cells having a particular origin.[31]

Secondly, the European Parliament encouraged the use of "insensitive" or at least the less sensitive cells and tissues by specific positive **actions**: the promotion at EU and Member States levels

[24] See notably: Amendments 22 of the Draft Report on the proposal for a regulation of the European Parliament and of the Council on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD)), 30/05/2006, provisional 2005/0227 (COD); Amendments 20 of the JURI's Opinion

[25] OJ C 364, 18/12/2000, p. 1-22

[26] See notably: Amendments 6and 22 of the Draft Report on the proposal for a regulation of the European Parliament and of the Council on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (COM(2005)0567 – C6-0401/2005 – 2005/0227(COD)), 30/05/2006, provisional 2005/0227 (COD); Amendments 3 of the ITRE's Opinion; Amendments 5 and 20 of the JURI's Opinion

[27] These definitions are based on the Canadian assisted human reproduction Act of 2004.

[28] "Chimera means: an embryo into which a cell of any non-human life form has been introduced; or an embryo of any non-human life form into which a human cell has been introduced; or an embryo that consists of cells of more than one embryo, foetus or human being", Amendment 15 of JURI's Opinion and Amendment 18 of ENVI, Draft Report. The second possibility of meaning for "chimera" comes from the JURI'S Opinion.

[29] "Hybrid means: a human ovum that has been fertilised by a sperm of a non-human life form; an ovum of a non-human life form that has been fertilised by a human sperm; a human ovum into which the nucleus of a cell of a non-human life form has been introduced; an ovum of a non-human life form into which the nucleus of a human cell has been introduced; or a human ovum or an ovum of a nonhuman life form that otherwise contains haploid sets of chromosomes from both a human being and a non-human life form", Amendment 16 of JURI's Opinion and Amendment 19 of ENVI, Draft Report.

[30] Amendment 20 of the JURI's Opinion

[31] The ban may also be extended to the importation of such tissues or cells or products. Amendment 8 of the European Parliament in 1st reading, recital (7), cf. note 17

and obstacles'removal. It underlines *"there is no consensus within the European Union as to whether, and in what circumstances, embryonic stem cells may be processed. The processing of stem cells, and in particular the creation of stem cells in cases in which the embryos from which they originate has to be destroyed, is scientifically and ethically controversial and illegal in many Member States"*[32]. On the contrary, the processing of adult stem cells and of stem cells from the umbilical cord seems to be not (or rather less) scientifically and ethically controversial within EU Member States. That is why, such non controversial alternative solutions should be specifically promoted by the EU and the Member States and obstacles must be removed.

Thirdly, the European Parliament considered that if Member States authorise the use of particular tissues and cells, they should respect the minimum quality and safety standards laid down by the directive as every tissues and cells shall be covered. Hence, it proposed a new paragraph 1a for article 2 providing that *"this Directive shall also apply to: a) haematopoietic peripheral blood, placenta and bone marrow stem cells; b) reproductive cells (eggs, sperm); c) feotal tissues and cells, adult and embryonic stem cells"*[33]. The logic of the European Parliament could be the following: If it is legally unfeasible and/or politically unacceptable to make compulsory for Member States to ban the use of ethically sensitive tissues and cells, at least their uses should be controlled by the respects of minimum standards. But minimum standards should be extended to specific standards for sensitive tissues and cells: Additional tests should also be required for embryonic stem cells, and cells and tissues derived from them given rise to their *"well-established inherent ability to form tumours […] and their potential to form cancer through many different routes"*[34].

In the same way, the European Parliament considered that if Member States do not prohibit the use of germ cells and embryonic and foetal stem cells (which shall respect the directive's standards), they shall specifically regulate the use of cells of an ethically 'sensitive' origin *"by means of appropriate legislation"*[35].

Therefore, the European Parliament did not try to integrate direct mandatory ban on the use of particular tissues and cells such as germ cells and foetal and embryonic stem cells. However, it used strong disincentives: a right to ban for Member States, the promotion of non controversial alternative solutions, and control by the insertion within the scope of the directive and by specific appropriate national legislation.

Regarding the regulation on ATMP, the European Commission tried to avoid the sensitive debate on the use of human embryonic stem cells (hESC), which already took place during the

[32] Amendment 9, recital 7a (new) of the European Parliament in 1st reading, cf. note 17
[33] Amendment 20, article 2§1a (new) of the European Parliament in 1st reading, cf. note 17
[34] Amendment 73, annex V section 2a (new) of the European Parliament in 1st reading, cf. note 17
[35] Amendment 31, article 4§4a (new) of the European Parliament in 1st reading, cf. note 17

adoption of the directive on tissues and cells[36]: *"The issue of embryonic stem cells was extensively debated during the adoption of the Directive on the quality and safety of human tissues and cells (Directive 2004/23/EC). In this context, the legislators have recognised that there is, to date, no consensus among Member States upon which harmonised decisions at EU level could be taken on the use or prohibition of embryonic stem cells"*. Therefore, the European Commission suggested to follow the same logic than the one followed for the directive on tissues and cells: a Member State can authorise or forbid the use of a specific kind of human cells, such as hESC, as *"the regulation of advanced therapy medicinal products at Community level should not interfere with such decisions"*[37]. Consequently, article 28 of the proposal modifies the directive 2001/83/EC as following: "*This Directive and all Regulations referred to therein shall not affect the application of national legislation prohibiting or restricting the use of any specific type of human or animal cells, or the sale, supply or use of medicinal products containing, consisting of or derived from these cells. The Member States shall communicate the national legislation concerned to the Commission"*[38].

However, the JURI's Committee tried to exclude explicitly ethical controversies related to hESC from the proposal. It principally proposed to exclude ATMP that *"contain or are derived from human embryonic and foetal cells, primordial germ cells and cells derived from those cells*"[39]. The justification of such amendment has to be found under recital (6): this regulation is based on ex-article 95 of the EC Treaty which is a single market harmonisation measure: *"It is not designed to cover situations in which significant national legislative differences are intended to remain (c.f. ECJ Case C-376/98[40]). It is therefore necessary to exclude from the scope of this regulation products using materials which are controversial and for which differing Member States legislative provisions are intended to remain. In any case, products using these materials are unlikely to be ready to be placed on the market in the foreseeable future*"[41].

Thus, according to the JURI's Committee, as products based on embryonic and foetal cells are sensitive from an ethical point of view, they could not be covered by a harmonisation measure (a regulation based on ex-article 95 of the EC Treaty), otherwise Member States would enforce different legal rules. Moreover, the JURI's Committee provides that Member states have the right to refer to article 30 of

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[36] See M. Blanquet et N. De Grove-Valdeyron, « Les enjeux et les apports du règlement communautaire concernant les médicaments de thérapie innovante », RAE 2006/4, p. 687 and M. Favale and A. Plomer, « Fundamental disjunctions in the EU legal order on human tissue, cells & adavanced regenerative therapies », Maastricht Journal of European and Comparative Law, 2009, 16 (1), p. 89-111.

[37] "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, or animal 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", recital (6) of the European Commission proposal for a Regulation of the European Parliament and of the Council on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 {SEC(2005) 1444}, COM/2005/0567 final - COD 2005/0227

[38] New article 4§5 of directive 2001/83/EC created by article 28 of the European Commission proposal, cf. note 37.

[39] Amendment 12 of the JURI's Opinion

[40] According to this case-law : regarding public health, "the Treaty excludes any harmonisation of laws and regulations of the Member States designed to protect and improve human health […] Other articles of the Treaty may not, however, be used as a legal basis in order to circumvent the express exclusion of harmonisation".

[41] Amendment 2 of the JURI's Opinion

the EC Treaty when they want to prohibit or restrict the access of certain medicinal products (such as those based on hESC) to their market as this regulation is a partial harmonisation measure[42].

Most of the above-mentioned ethical amendments of the European Parliament were rejected. They were related to the most controversial aspects related to ATMP on which Member States' approaches are very diverse. Far away to do a choice at the European level even through a flexible manner on the most sensitive questions, they are relied on Member States which benefit from a wide action margin within the final version of the directive on tissues and cells and the regulation on ATMP

B. The final versions of the directive on tissues and cells and the regulation on ATMP

Concerning the directive on tissues and cells, most of the so-called "ethical" amendments of the European Parliament have been defeated and especially those related to the prohibition of research on human cloning, the use of tissues and cells from cloned human embryos and of hybrids derived from germ cells or totipotent cells of human origin. The legal basis for the directive on tissues and cells was ex-article 152§4 of the EC Treaty (new article 168§4a) on the protection of human health. According to the European Commission and the Council[43], ethical provisions proposed by the European Parliament cannot be accepted as *"they fall outside the scope of Article 152 that provides for public health protection and not the implementation of ethical objectives as such"*[44]. The European Parliament had argued that this justification given by the Commission and the Council was *"formal"* and *"by no means valid"* as "*all the 'ethical issues' addressed are also linked to protecting the health of donors and recipients"*[45]. This argument has been taken into account regarding the ethical principles of donation[46] but not regarding the use of particular cells and tissues.

However, the European Parliament obtained the extension of the scope of directive on tissues and cells even though it is a recital which is not legally binding contrary to the articles of the directive. It provides: *"This Directive should apply to tissues and cells including haematopoietic peripheral blood, umbilical-cord*

[42] Amendment 43 of the JURI's Opinion

[43] "In particular, the Council shares the Commission's argument that amendments of an ethical nature are not acceptable, since they fall outside the scope of Article 152 of the Treaty", Common Position adopted by the Council Council with a view to the adoption of a Directive of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, storage and distribution of human tissues and cells, 9 July 2003, 10133/03

[44] See Amended Proposal for a Directive of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, storage, and distribution of human tissues and cells (presented by the Commission pursuant to Article 250 (2) of the EC Treaty), COM/2003/0340 final - COD 2002/0128

[45] Explanatory Statement, European Parliament, Recommendation for second reading on the Council common position adopting a European Parliament and Council directive on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (10133/3/2003 – C5-0416/2003 – 2002/0128(COD)), 12 November 2003, A5-0387/2003

[46] See part II. Of this article

(blood) and bone-marrow stem cells, reproductive cells (eggs, sperm), foetal tissues and cells and adult and embryonic stem cells"[47].

Furthermore, the final text of the directive does not provide a right for Member States to ban the use of particular tissues and cells it only provides the directive *"**should not interfere with**"*[48] and *"**does not affect**"*[49] the decisions of the Member States prohibiting the donation, procurement, testing, processing, preservation, storage, distribution or use of any specific type of human tissues or cells or cells from any specified source, including germ cells and embryonic stem cells.

Even though most of the amendments were not retained regarding the most sensitive issues on particular cells and tissues, the European Parliament obtained to protect them by their insertion within the scope of the directive. Consequently, the minimum quality and safety standards are the same in all of the EU member States even regarding specific type of human tissues or cells or cells from any specified source, including germ cells and embryonic stem cells. Member States are free to authorise or prohibit their uses but if they are authorised, they should respect the provisions of the directive on tissues and cells.

Concerning the regulation on ATMP, the amendments of the European Parliament which provided a ban for products which modify the human germ line and/or which are derived from human-animal hybrids or chimeras were defeated. The Council also rejected the exclusion of ATMP that contain or are derived from human embryonic and foetal cells, primordial germ cells and cells derived from those cells. It is interesting to notice that the exclusion of such products from the scope of the regulation on ATMP would have deprived them of the benefit of the numerous incentives and notably the economical ones provided by this regulation. It would thus have been more economically interesting to develop "insensitive" or "more ethical" ATMP[50]. Paradoxically, it would also have impeded any control on them whereas the requirements of the regulation on ATMP are quite "heavy" notably regarding traceability and stricter than those provided for "classical" medicinal products. The approach of the European Parliament which wished to exclude sensitive ATMP from the scope of the regulation on ATMP is contrary to the one it had regarding the integration of sensitive tissues and cells within the scope of the directive on tissues and cells.

Furthermore, similarly to the directive on tissues and cells, the regulation on ATMP *"**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, or animal cells"*[51]. And according to article 28§3 which amends directive

[47] Recital (7) of Directive 2004/23/EC, cf. note 5
[48] Recital (12) of Directive 2004/23/EC, cf. note 5
[49] Article 4§3 of Directive 2004/23/EC, cf. note 5
[50] Cf. note 36
[51] Recital (7) of Regulation (EC) N°1394/2007, cf. note 3

2001/83/EC by adding the following article 4§5: "*This Directive and all Regulations referred to therein* ***shall not affect*** *the application of national legislation prohibiting or restricting the use of any specific type of human or animal cells, or the sale, supply or use of medicinal products containing, consisting of or derived from these cells, on grounds not dealt with in the aforementioned Community legislation. The Member States shall communicate the national legislation concerned to the Commission. The Commission shall make this information publicly available in a register"*. It could be noticed that the text of article 28 of the regulation on ATMP is more cautious than article 4§3 of the directive on tissues and cells as the terms *"**shall not affect**"* are used instead of *"**does not affect**"*.

Finally, the regulation on ATMP avoids any position regarding the controversies on which Member States are divided such as the use of human embryonic cells. It just follows the approach of the directive on tissues and cells.

It is therefore interesting to highlight that the uses of the most "ethically sensitive" tissues and cells- such as human embryonic stem cells- and products which are derived from them, are respectively covered by the directive on tissues and cells and by regulation on ATMP if they are authorised according to the concerned national legislation. Member States are left free to prohibit the donation, procurement, testing, processing, preservation, storage, distribution or use of any specific type of human tissues or cells. They are also free to adopt restrictive rules reflecting national cultures on the use of any specific type of human or animal cells, or the sale, supply or use of medicinal products containing, consisting of or derived from these cells. In both texts, the action margin of Member States is very wide. It relies on the subsidiarity principle and on the partial harmonisation. On the one hand, the subsidiarity principle requires, in areas which do not fall under the exclusive competence of the Community, that the Union should only act when the proposed objectives cannot be sufficiently achieved by the Member States and can be better achieved by the Community[52]. On the other hand, Article 28 of the regulation on ATMP permits Member States to apply national legislations prohibiting or restricting the use of any specific type of human or animal cells, *"on grounds not dealt with the aforementioned Community legislation"*. Even though the explicit reference to ex-article 30 of the EC Treaty[53] was defeated, ATMP could benefit from its limitations given rise to the partial harmonisation of the regulation on ATMP and to the principle of free movement of goods enforceable to ATMP. The public morality would probably be the most relevant limitations which could be invoked by Member States to restrict or prohibit the use of "specific type" of medicinal products. However, they have to

[52] Article 5 of the EC Treaty
[53] Article 36 of the Treaty on the functioning of the European Union, OJ C83, 30/03/2010, p. 47-199

respect the proportionality principle[54]. Also, Member States measures shall not constitute *"a means of arbitrary discrimination or a disguised restriction on trade between Member States"*[55].

Even if the EU considers that regulating ethics is a Member States' prerogative, ethical aspects can be found within the EU legislation and within non binding law. In spite of the defeat of the most controversial amendments, especially regarding human embryonic cells, several ethical aspects have been infiltrated within the EU texts applying to ATMP. Beyond the directive on tissues and cells and the regulation on ATMP, ethical considerations are present at almost all stages of ATMP development.

II. The infiltration of particular ethical considerations

Ethics and ethical principles have been taken into account and recognised during all stages of development of ATMP from research until commercialisation going beyond the directive on tissues and cells and the regulation on ATMP. Considering binding norms as well as non binding norms, the manner to integrate ethics always reflects flexibility. This part aims to identify the ethical principles and considerations within the norms related to ATMP and demonstrate the EU flexibility approach in this context. The studied norms are either directly (1) or indirectly (2) related to ATMP.

A. Norms directly related to ATMP

The norms which are directly related to ATMP and which include ethical principles are the directive on tissues and cells, the directive on clinical trials and the regulation on ATMP. These norms as EU secondary law are binding. Moreover, there are also many guidelines (non binding) which are related to ATMP. They have been adopted by the European Medicines Agency with the involvement of the Committee for Advanced Therapy (CAT) and/or the Committee for Medicinal Product for Human Use (CHMP)[56], and/or by the European Commission. Most of the time, these guidelines do not contain ethical aspects as they are very technical, but they always refer to above-mentioned relevant secondary law. However, we will pay attention to one guideline adopted by the European Commission and related to clinical trials which contains ethical considerations.

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[54] "restrictions may be justified only if they are suitable for securing the attainment of the objective pursued and do not go beyond what is necessary in order to attain it": see Case C-36/02 *Omega* [2004] ECR I-9609, paragraph 36, and Case C-438/05 *International Transport Workers' Federation and Finnish Seamen's Union* [2007] ECR I-0000, paragraph 75

[55] See note 53

[56] Guideline on Safety and Efficacy Follow-up – Risk Management of Advanced Therapy Medicinal Products, 20 November 2008, EMEA/149995/2005; Procedural Advice on the certification of quality and non-clinical data for small and medium-sized enterprises developing Advanced Therapy Medicinal Products, 17 April 2009, EMEA/CAT/418458/2008 (corr. 1 (23/09/09),…

It should preliminary be noticed that a kind of sliding occurred as ethical aspects are sometimes considered either on the ground of fundamental rights or on the ground of safety and public health objectives[57].

On the one hand, regarding fundamental rights, the directive on clinical trials provides that *"the accepted basis for the conduct of clinical trials in humans is founded in the protection of human rights and the dignity of the human being with regard to the application of biology and medicine, as for instance reflected in the 1996 version of the Helsinki Declaration"*[58]. Moreover, both the directive on tissues and cells and the regulation on ATMP respect the fundamental rights and observe the principles reflected in the EU Charter and take into account as appropriate the Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine[59]. The EU Charter recognizes the human dignity and accordingly the right to the integrity of the person especially in the fields of biology and medicine with the free and informed consent, the prohibition of eugenic practices, the prohibition on making the human body and its parts as such a source of financial gain, the prohibition of the reproductive cloning of human beings[60]. Although, the European Parliament tried to encompass the respect of the fundamental rights, the EU Charter and the Oviedo Convention within the directive's body, these amendments were never retained. With the Lisbon Treaty[61], which entered into force on 1st December 2009, the EU Charter obtained the same legal value as the Treaties[62] and the European Union *"shall accede to the European Convention for the Protection of Human Rights and Fundamental Freedoms"*[63]. But the formulation used regarding these principles within the EU Charter and the Oviedo Convention let a wide margin of discretion to Member States. It permits to maintain an acceptable co-existence of the Member States specific rules which express their moral and legal national political choices.

On the other hand, regarding safety and public health objectives, both the directive on tissues and cells and the regulation on ATMP notably provides that *"Voluntary and unpaid tissue and cell donations are a factor which may contribute to high safety standards for tissues and cells and therefore to the protection of human health"*[64]. Recital (2) of the regulation on ATMP also provides that *"the essential aim of any rules governing their [ATMP] production, distribution and use must be to safeguard public health"*. Similarly, Recital (2) of the directive on tissues and cells provides *" […]In order to safeguard public health and to prevent the transmission of*

[57] See M. Blanquet et N. De Grove-Valdeyron, « Les enjeux et les apports du règlement communautaire concernant les médicaments de thérapie innovante », RAE 2006/4, p. 687.
[58] Recital (2) of the directive 2001/20/EC, cf. note 7
[59] Recital (22) of Directive 2004/23/EC, cf. note 5 and recital (8) of Regulation (EC) N° 1394/2007, cf. note 3
[60] Article 3§2 of the EU Charter, cf. note 25
[61] Treaty of Lisbon amending the Treaty on the European Union and the Treaty establishing the European Community, signed at Lisbon, 13 December 2007, OJ C 306, 17/12/2007, p. 1.
[62] Article 6§1 of the consolidated version of the Treaty on European Union, OJ C 83 of 30/03/2010, p. 13
[63] Article 6§2 of the consolidated version of the Treaty on European Union, OJ C 83 of 30/03/2010, p. 13
[64] Recital (19) of directive 2004/23/EC, cf. note 5 and Recital (15) of Regulation (EC) N° 1394/2007, cf. note 3

infectious diseases by these tissues and cells, all safety measures need to be taken during their donation, procurement, testing, processing, preservation, storage, distribution and use".

In this presented context of respect of human rights and protection of safety and public health, more specific ethical issues are taken into account.

Firstly, the directive on tissues and cells applies to ATMP which contains human tissues and cells for the donation, procurement and testing of those cells or tissues[65]. This directive on tissues and cells includes ethical principles which obtained a legal value given rise to their integration within the directive. Indeed, these principles are provided by the "recitals" but also by the article of the directive. However, according to S. Hennette-Vauchez, ethical principles originally only appeared within the recitals of the directives[66]. In 1993, the EGE provided: *"Yet, it is wondering whether the amendments [regarding ethical considerations] are to be considered as part of the directive's body. The appropriate place to address and resolve some of those considerations seems to be the recitals of the directive"*[67]. But, in the most recent texts, such as the directive on tissues and cells and regulation on ATMP, ethical considerations are placed in the recitals as well as in the directive's or regulation's body within the articles.

The main ethical and legal principles which can be identified within the directive on tissues and cells are: voluntary and unpaid donations, consent, non profit basis of procurement of tissues and cells, data protection and confidentiality.

Regarding the principle of voluntary and unpaid donations, article 12§1 of directive on tissues and cells provides *"Member States shall endeavour to ensure voluntary and unpaid donations"*. However, a limitation to this principle has been adopted as *"donor may receive a compensation, which is strictly limited to making good the expenses and inconveniences related to the donation"* following the amendments of the European Parliament. Recital (15) of regulation on ATMP also provides *"as a matter of principle, human cells or tissues contained in advanced therapy medicinal products should be procured from voluntary and unpaid donation"*. In that case, Member States define the conditions under which compensation may be granted.

Regarding the principle of procurement on non profit basis, *"Member States shall endeavour to ensure that the procurement of tissues and cells as such is carried out on a non profit basis"*[68]. This is also recalled within the regulation on ATMP: *"Member States should be urged to take all necessary steps to encourage a strong public and non-profit sector involvement in the procurement of human cells and tissues"*[69].

Regarding the principle of consent, according to article 13§1 of the directive on tissues and cells, *"The procurement of human tissues or cells shall be authorised only after all mandatory consent or authorisation*

[65] Article 3 of the regulation (EC) N° 1394/2007, cf. note 3
[66] Cf. note 14
[67] EGE, Opinion N°3 on ethical questions arising from the Commission proposal for a Council directive on legal protection for biotechnological inventions, 30/09/1993
[68] Article 12§2 alinea 2 of Directive 2004/23/EC, cf. note 5
[69] Recital (15) of Regulation (EC) n° 1394/2007, cf. note 3

requirements in force in the Member State concerned have been met". The Commission directive 2006/17/EC[70], which supplements the directive on tissues and cells, sets out technical requirements for the donation, procurement and testing of human tissues and cells[71]. It provides that the consent has to be obtained in accordance with article 13 of the directive on tissues and cells before the procurement of tissues and cells as well as several requirements regarding living and deceased donors.

Finally, according to 14§3 of the directive on tissues and cells: *"Member States shall take all necessary measures to ensure that the identity of the recipient(s) is not disclosed to the donor or his family and vice versa, without prejudice to legislation in force in Member States on the conditions for disclosure, notably in the case of gametes donation"*.

It should be noticed that the vocabulary used for ethical aspects seems quite weak as it only implies recommendations although it is binding when it is integrated in the directive's body. The expression used are: "*Member States shall endeavour*", *"Member States shall, in keeping with their national legislation, take all necessary measures"*, *"shall be made"*,… However, according to S. Hennette-Vauchez, recommendations can be transformed into imperative specific criteria. She qualifies this process as a "solidification process"[72].

Secondly regarding clinical trials, recital (16) of the regulation on ATMP appears quite wide as it provides: *"Clinical trials on advanced therapy medicinal products should be conducted in accordance with the overarching principles and the ethical requirements laid down in Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulation and administrative provisions of the Member State relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use"*. More specifically, article 4 of regulation on ATMP only referred to articles 6 (7) and article 9 (4) and (6) of the directive 2001/20/EC on clinical trials which set up specific conditions for national ethics committees to act with gene and somatic cell therapy medicinal products. As a consequence, these conditions also apply to tissue engineered products as well as to combined ATMP. Furthermore, the European Commission adopted guidelines in accordance with the regulation on ATMP. The "detailed guidelines on good clinical practice specific to advanced therapy medicinal products"[73] contains some ethical considerations regarding the role of the Ethics Committee for clinical trials

[70] Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells, OJ L 38, 09/02/2006, p. 40

[71] Annex IV 1. 1. 1. a of the Commission directive 2006/17/EC, cf. note 70

[72] She gives the following example: For instance, the directive on tissues and cells provides: *"Member States shall endeavour to ensure voluntary and unpaid donations of tissues and cells"*. From this recommendation, the EGE deduced that *"no financial incentives have been offered to donate embryos for research at any stage, in line with Art. 12 of Directive 2004/23"* (Opinion N° 22 « Recommendations on the ethical review of hESC FP7 research projects"), Cf. note 14

[73] 3 December 2009, ENTR/F/2/SF/dn D(2009) 35810 : "The final adoption of this guideline by the College of Commissioners is foreseen once more practical experiences have been gained with the specificities of clinical trials involving advanced therapy medicinal products. Pending the final adoption of this guideline, it is recommended to apply the rules and principles set out in this text".

involving an advanced therapy investigational medicinal product (ATIMP). It should in particular check the arrangements *"for traceability as regards provisions for subject data protection and confidentiality*[74]*, for follow up before and after the end of the trial […]*[75]*, when follow up needs to include close contact and offspring of the recipients*[76]*, the written informed consent as regards ethical concerns of particular relevance for ATIMPs*[77]*, the circumstances where a representative of the sponsor experienced in the administration of the ATIMP needs to be present during the application of the ATIMP to the subject"*[78]. This guideline also provides what should be taken into account by the Ethics Committees when assessing the ethics of a clinical trial involving an ATIMP: *"the irreversible nature of certain ATIMP applications, and the information provided to subjects in that context; the peculiarities of situations where the donor is a relative of the subject to be included in the trial, in particular the protection from "sibling/parent" pressure"*[79]. It is already unexpected to observe that the European Commission gives recommendations to the Ethics Committees for the ethical assessment of a clinical trial involving an ATIMP. But it is even more surprising that recommendations of the European Commission given to the Ethics Committees are more verbose than those given to the national competent authorities.

Thirdly, regarding the ethical aspects of the regulation on ATMP, it does not only refer to the directive on tissues and cells, to the directive on clinical trials and to further guidelines. It also sets up a centralised and unique marketing authorisation at the EU level. A sixth Committee is created within the European Medicine Agency, the Committee for Advanced Therapy (CAT) which plays a major role for the assessment of ATMP. It is interesting to notice its members shall be chosen for their scientific qualification or experience in scientific areas relevant to ATMP, including notably ethics[80]. Thus, it could be expected that the assessment of ATMP by the CAT will also be made from an ethical's point of view.

As it has been shown several ethical issues have been taken into account within norms directly related ATMP through a flexible approach coming from the wording used and/or from the character non binding of the ethical provisions. However, the complete EU framework regarding ATMP being recent, it is interesting to observe that ethical issues are also present within norms either less specific

74 Point 47(a) of the guideline, cf. note 73
75 « including after subjects withdrawn from the study and including the information (alert card) to be provided to each subject for use in the event of problems arising after the end of the trial », Point 47 (b) of the guideline, cf. note 73
76 Point 4 (c) of the guideline, cf. note 73
77 Point 47(d) of the guideline, cf. note 73
78 Point 47(e) of the guideline, cf. note 73
79 Point 48 of the guideline, cf. note 73
80 "…the final composition of the Committee for Advanced Therapy provides appropriate and balanced coverage of the scientific areas relevant to advanced therapies, including medical devices, tissue engineering, gene therapy, cell therapy, biotechnology, surgery, pharmacovigilance, risk management and ethics", Article 21§2 of Regulation (EC) N°1394/2007, cf. note 3

regarding biotechnology in general and/or human rights or pointed out specific ethical issues which indirectly apply to ATMP.

B. Norms indirectly related to ATMP

The main norms which are indirectly related to ATMP and which contains ethical considerations are the decisions for the adoption of framework programmes for scientific and technological objectives, the directive on the legal protection of biotechnological inventions[81], and soft law such as the resolutions of the European Parliament and the Opinions of the EGE.

At the research stage, the EU provides an ethical assessment of the research projects it funds. Indeed, the EU financing of research projects is notably conditioned by the respect of fundamental ethical principles recognised in Member States' national laws, EU law and international law. This is assessed by an experts' panel. The manner to take into account ethics at the research stage within the EU has evolved through the adoption of successive Framework Programs for research and technological development (FP). Although several references to ethics have occurred though the first three FP, it is the 4th FP (1994-1998) which stated for the first time the existence of binding ethical rules. From the 4th FP, questions regarding biomedical research and notably embryonic stem cells research became very important. The 4th FP explicitly forbade the modification of the genetic constitution of human beings and cloning[82]. This interdiction has also been integrated within the 5th FP (1998-2002)[83] after the opinion of the European Group on Ethics[84] required by the European Commission. It became more problematic for the 6th FP (2002-2006)[85] as two kinds of cloning were distinguished (the so called "reproductive" and "therapeutic cloning"). The general ban was not considered appropriated and tensions occurred around this 6th FP. Finally, it was adopted without any dispositions regarding the former interdiction. A moratorium on the financing of such research was adopted and applicable until 31 December 2003 but the problem of its lack of legal value was raised.

[81] Directive 98/44/EC, cf. note 18

[82] "No research modifying, or seeking to modify, the genetic constitution of human beings by alteration of germ cells or of any stage of embryo development which may make these alterations hereditary, nor research seeking to replace a nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo or subsequent development of an embryo, known as cloning, will be carried out under this framework programme", Decision N°1110/94/EC of the European Parliament and of the Council of 26 April 1994 concerning the fourth framework programme of the European Community activities in the field of research and technological development and demonstration, OJ L 126, 18/05/1994, pp. 1-33.

[83] Decision N°182/1999/EC of the European Parliament and of the Council of 22 December 1998 concerning the fifth framework programme of the European Community for research, technological development and demonstration activities (1998 to 2002), OJ L 26, 1.2.1999, p. 1–33

[84] European Group on Ethics, Opinion n°10, Ethical aspects of the 5th Research Framework Programme, 11/12/1997

[85] Decision N°1513/2002/EC of the European Parliament and of the Council of 27 June 2002 concerning the sixth framework programme of the European Community for research, technological development and demonstration activities, contributing to the creation of the European Research Area and to innovation (2002 to 2006), OJ L 232, 29.8.2002, p. 1–33.

Consequently, the Council adopted a decision[86] which authorised research on embryonic stem cells under conditions such as systematic ethical review and submission of the research project to a regulatory Committee. However, research activities aiming at human cloning for reproductive purposes, intended to modify the genetic heritage of human beings which could make such changes heritable, or intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer, shall not be financed under the 6th FP. At the end of 2004, several calls for research projects regarding stem cells were published within the 6th FP. The same problems were raised for the adoption of the 7th FP (2007-2012)[87] as the European Parliament wished and obtained to introduce again a general ban concerning reproductive cloning as well as therapeutic cloning. However, *"research on human stem cells, both adult and embryonic, may be financed, depending both on the contents of the scientific proposal and the legal framework of the Member State(s) involved"* in accordance with the "subsidiarity" principle. Moreover, the EU does not finance research activities which destroy human embryos, including for the procurement of stem cells. However, this does not prevent the EU to fund subsequent steps involving human embryonic stem cells (hESC): only research activities involving hESC in culture can receive European funds[88]. The EU financed neither the creation of embryos for research purposes- however; it financed researches using supernumerary embryos - nor the research on embryos and embryonic cells in a State which forbids it.

Thus, an ethical assessment is provided for all research projects concerning ATMP to be funded by the EU with a specific and limitative frame regarding ATMP based on embryonic cells. This way of governance has been called 'governance by dominium' as it would avoid the problems of legislative process by using financial incentives to attain public policy objectives[89].

Moreover, regarding the directive on the legal protection of biotechnological inventions, ATMP should be patentable if the three characters of the patentability are fulfilled: they must be new, they must involve an inventive step and they must be susceptible of industrial application[90]. However, they shall be considered as non patentable where their commercial exploitation would be contrary to 'public

[86]Council Decision N°2002/834/EC of 30 September 2002 adopting a specific programme for research, technological development and demonstration: "Integrating and strengthening the European Research Area" (2002-2006), OJ L 294, 29.10.2002, p. 1-43.

[87] Decision N°1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013), OJ L 412, 30.12.2006, p. 1–43

[88] Declarations of the Commission of 24 July 2006, OJ L 412, 30. 12. 2006, p. 42, and Rules for submission of proposals, and the related evaluation, selection and award procedures, version 3, 21 August 2008, COM (2008) 4617.

[89] See T. Daintith, "The techniques of Governement" in J. Jowell and D. Oliver (eds.), The changing Constitution, OUP, 1994, p. 209-236 and T. K. Hervey and H. Black, The European Union and the Governance of stem cell research, Maastricht Journal of European and Comparative Law, 2005 12 (3), p. 11- 48

[90] Article 3 of Directive 98/44/EC, cf. note 18

order' or "morality"[91]. A non exhaustive list of non patentable inventions is provided: *"(a) processes for cloning human beings; (b) processes for modifying the germ line genetic identity of human beings; (c) uses of human embryos for industrial or commercial purposes; (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes"*[92]. Given rise to these limitations it seems that ATMP can be covered by products patents. However, the patentability of processes appeared more controversial and the coverage could be discussed[93]. The patentability of ATMP which involves elements of the human body is controversial as other biotechnological inventions because it is principally in conflict with the principle of the non-commercialisation of the human body. However, according to this directive, ATMP could be patentable if the above-mentioned conditions are respected. Here again, the patentability of ATMP is conditioned by ethical principles which became legal principles by their insertion within this directive[94].

Finally, ethical aspects related to ATMP appeared in many 'soft law" rules. The aim is not to provide an exhaustive list of all these 'soft law' measures, but to understand the role they can play to integrate ethics within the EU governance of ATMP. According to T. K. Hervey and J.V. McHale, measures of 'soft law' may be significant forces in the EU integration process. First, *"they may provide an interpretative reference point for measures of 'hard law"*[95]. For instance, the EU Charter, as a soft law measure before obtaining the value of primary law with the Lisbon Treaty, was often used to interpret hard law provisions[96]. Moreover, disincentives might come from soft law measures which indicate that a specific activity is considered illegal and/or non patentable as contrary to ethics such as the repeated opposition to human cloning provided by the EGE opinions[97] and the resolutions of the European Parliament[98]. Second, *"They may promote convergence through articulation of agreed statements of good practice and recommendations, against which national policies are measured, eventually prompting voluntary changes to bring national systems in line with an agreed 'European norm' "*. In this context, the opinions of the EGE are very important. They are taken into account within minimum harmonisation measures such as the directive on tissues and cells at EU level. They could also operate at national level as a reference for the national legislators and for national ethics committees. Third, *"they may carve out areas of 'Community concern', where formal legal competence is lacking, thus paving the way for future developments in action taken by EU institutions, sometimes ultimately leading to the enactment of binding and directly effective EU-level legal provisions"*. Here again, the EU Charter can be cited,

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[91] "However, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation", Article 6§1 of Directive 98/44/EC, cf. note 18

[92] Article 6 §2 of Directive 98/44/EC, cf. note 18

[93] Regarding the patentability of stem cells, see T. K. Hervey and H. Black, The European Union and the Governance of stem cell research, Maastricht Journal of European and Comparative Law, 2005 12 (3), p. 11- 48

[94] Cf. note 93

[95] T. K. Hervey and J.V. McHale , Health Law and the European Union (2004), Cambridge University Press

[96] See for instance C-377/98, Pays-Bas v Parliament and Council, 09/10/2001

[97] See for instance EGE Opinions N°9 of 28 May 1997on "Ethical aspects of cloning techniques" and N°15 of 14 November 2000 on "Ethical aspects of human stem cell research and use"

[98] Cf. note 13

as the vocation of the EU was originally economical. With the development of a more political Union, the EU Charter, initially non binding, became binding.

Conclusion

Even though the EU regularly recalled that regulating ethics is a Member States' prerogative, several ethical issues are integrated within the EU norms related to ATMP due to the inseparable link between the governance of ATMP and the ethical questions it raised. The European Parliament has been playing a major role for the protection of bioethics values notably through its numerous amendments. The analysis of bioethics through the ATMP governance shows up the limits of the EU categorisation regarding the sharing of competences between the EU and its Member States and the market, public health and fundamental rights grounds.

The most controversial issues regarding human cloning, uses of embryonic and germ cells, creation of hybrids and chimeras have been excluded from the EU binding secondary law as it has been shown through the study of the EU directive on tissues and cells and the regulation on ATMP. These questions are dealt with at the national level as the margin of discretion of Member States is very wide given rise to the principle of subsidiarity, and the minimum and partial harmonisation.

However, several ethical aspects have infiltrated the EU governance of ATMP with the strong influences of the European Parliament and the EGE. But it seems that the EU tried to present ethical principles either as fundamental rights or as objectives of safety and public health. It also always uses a flexible approach. Regarding the general principles of bioethics such as the respect of the human dignity and the reference to the fundamental rights, when they are considered, it is either within the recital of binding secondary law or within soft law. Therefore, it constitutes only a recommendation although this would probably change with the new primary law value of the EU Charter through the adoption of the Lisbon Treaty. It could be envisaged that the EU Court of Justice would strengthen the competencies of the EU, principally on the basis of the EU Charter and of public health. However, by all appearances, the EU Court of Justice will not do it for Poland and for the United Kingdom on the basis of the EU Charter. Indeed, article 1 of Protocol N°30 on the application of the Charter of fundamental rights of the European Union to Poland and to the United Kingdom provides: *"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"*[99]. Furthermore, *"To the extent that a provision of the Charter refers to national laws and practices, it shall only apply to Poland or the United Kingdom to the extent that the rights or principles that it contains are recognised in the law or*

[99] Article 1 of Protocol N°30 on the application of the Charter of fundamental rights of the European Union to Poland and to the United Kingdom, OJ C83 of 30/03/2010, pp. 313-314

practices of Poland or of the United Kingdom"[100]. Thus, this protocol can have two consequences. On the one hand, the protocol directly impedes the EU Court of Justice to extend the EU competencies on the basis of the EU Charter where it is in contradiction with Polish and English laws. But as it has already been done, the EU Court of Justice could subtly use other legal basis such as EU secondary law at the risk of political incident. On the other hand, as this protocol refers only to Poland and to the United Kingdom and does not concern any other member State, would it indirectly mean that the EU Court of Justice could extend the EU competencies on the basis of the Charter for other EU member States?

Furthermore, more specific ethical principles such as "voluntary and unpaid donation" and "consent" are integrated within the binding part of secondary law but in flexible formulation referring to the national legislation. They can be more detailed within soft law such as guidelines. Here again, Member States are quite free. Nevertheless, the effect of the infiltration of such ethical principles even through a very flexible manner should not be underestimated[101]. Indeed it could have a strong impact on Member States and for instance on entities which want to be funded by the EU for their researches.

But if bioethics within EU law could be considered as an unacceptable secrete objective to completely and relevantly frame ATMP in the context of the European integration[102], it should also be considered as a tool, notably because as 'subsidiarised' it strengthens national sovereignties legitimizing State-based ethics[103].

[100] Article 2 of Protocol N°30 on the application of the Charter of fundamental rights of the European Union to Poland and to the United Kingdom, cf. note 99

[101] V. Tournay, De la bioéthique à l'action publique en matière de biotechnologies : la production des thérapies cellulaires, cahiers internationaux de sociologie, N°53, Vol. CXXI (Juillet-Décembre 2006)

[102] From a general point of view, see: S. Saurugger, Théories et concepts de l'intégration européenne, Presses de Science-Po, 2010.

[103] For the all of characteristics of EU ethics as a tool, see M. Tallacchini, Governing by values. EU Ethics: Soft Tool, Hard Effects, cf. note 10

Paper n. 4

COMPETITION IN PUBLIC BIDDING EXERCISES FOR PHARMACEUTICAL PRODUCTS

by

Chiara Sammarco

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COMPETITION IN PUBLIC BIDDING EXERCISES FOR PHARMACEUTICAL PRODUCTS

by

Chiara Sammarco♦

Abstract:

The present paper stems from the need, shared by several European states, to identify compatible and adequate tools capable of containing the cost of medicines, fostering research and development (R&D) of new pharmaceuticals and allowing all patients access to appropriate drugs. Certain Member States have achieved significant savings to the benefit of consumers when health insurers carried out tenders or similar processes for some products. This contribution intends to evaluate both whether the purchase of medicines through a tendering system can bring efficiencies into the pharmaceutical market and also how this can be achieved. Particularly the following analysis has focused on the comparative study of the features of the tendering system and of the peculiarities of the pharmaceutical market in order to identify 1) the general mechanisms of the tender that are compatible with the features of pharmaceuticals and 2) the specific needs of the drugs that require further adaptations of the tendering procedures. According to my conclusions, the purchase of medicines through tendering enhances efficiencies in the pharmaceutical sector provided that public procurement rules are adapted to suit the particular features of the pharmaceutical products and market. This study will therefore focus on three main areas analysing: I) the diffusion of tendering of drugs in European countries, II) the competition potentials of tenders in general and the application of the same to the Italian system, III) the principles which should be enforced to ensure that tenders for the purchase of drugs are an efficient tool, in terms of cost savings and incentive to encourage R&D. Although the analysis is limited to the Italian market where public tenders of pharmaceuticals take place mainly in the hospital sector, the conclusions drawn can well be applied, *mutatis mutandis,* to other experiences.

Key words: Pharmaceutical tenders; Italian tendering system; generic drugs; monopsony; co-marketing.

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1 – Development of the tendering system in European countries

In order to find solutions to the most common problems in the public health field, in 2005 the European Commission established a Pharmaceutical Forum in which a "High Level Group On Innovation and Provision of Medicines" identified a number of mutual issues around which it invited international stakeholders to debate. Three groups were created with different purposes i.e.: I) working group on information to patients, II) working group on pricing and reimbursement, III) working group on relative effectiveness. In October 2008 the Forum produced its report[1] containing partial conclusions emerging from the debate. However the primary role of the Forum was to give strategic direction and a political push for further initiatives. Consequently following the impulse given by the European debate, several international organizations became interested in scrutinizing problems connected to pricing and reimbursement policies and protection of intellectual property rights. For example the recent competition inquiry of the European Commission[2] into the pharmaceutical sector dealt with evaluating why generic medicines entered the European Market late. According to the European inquiry *"Member States that want to fully benefit from the potential budget savings brought about by generic products also need to reflect about policies that facilitate speedy generic uptake in volume terms and effective price competition among generic producers"* [3]. In this light, the Commission invited Member States to consider the use of tenders as a tool that can help ensure that price reductions offered by generic companies do not stay in the distribution system, but are passed on to consumers and reduce costs for public health budgets[4]. Besides, also according to the opinion of the OECD[5], tendering procedures can be used to achieve significant savings in the pharmaceutical market, particularly in cases where purchasing power is high and there are multiples potential sources for the product. A comparative study was conducted by Austrian institute of research ÖBIG-FP[6]. It investigated the issue of the functioning of public procurement of pharmaceuticals in European states (within European Union and European Economic Area) in order to verify whether such a procedure could be a general bargaining tool capable of ensuring greater savings for public funds, while increasing healthcare. The final ÖBIG-FP's Report stressed that tendering is an important tool in the purchase of pharmaceuticals. Indeed, it is used in a significant number of EU and EEA Member States. In particular, while some circumscribe the use of tendering for pharmaceuticals to the hospital setting, others expand their application to other public uses, involving

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[1] High Level Pharmaceutical Forum 2005-2008, *Final Conclusions and Recommendations of the High Level Pharmaceutical Forum*, October 2008, available at http://ec.europa.eu/pharmaforum.

[2] European Commission, *Pharmaceutical Sector Inquiry. Final Report,* 8 July 2009, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html.

[3] European Commission, *Pharmaceutical Sector Inquiry. Final Report,* 8 July 2009, supra note 2, § 13.

[4] European Commission, *Pharmaceutical Sector Inquiry. Final Report* , 8 July 2009, supra note 2, § 1605.

[5] See OECD Health Policy Studies, *Pharmaceutical Pricing in a Global Market*, September 2008, p. 150.

[6] Cf. ÖBIG-FP, *Tendering of pharmaceuticals in Europe and EAA countries*, June 2008, available at http://ppri.oebig.at/Downloads/Publications/Final_Report_Tendering_June_08.pdf. This study was conducted by the Austrian institute of research ÖBIG-FP (ÖBIG Forschungs- und Planungsgesellschaft mbH) and it was commissioned by ESIP (European Social Insurance Platform) which was a member of the working group on pricing and reimbursement created by the European Commission in 2005. Please note that the study results are based on questionnaires filled out by Countries such as Iceland, Ireland, UK, France, Belgium, Germany, Switzerland, Denmark, Norway, Sweden, Finland, Czech Republic, Austria, Slovenia, Hungary, Romania, Lithuania, Estonia, Malta, Cyprus.

specific product groups (such as pharmaceuticals involved in pandemic plans) or defined patient groups (e.g. military). Only a few countries apply tendering for pharmaceuticals in ambulatory care distributed through retail pharmacies[7].

Surprisingly ÖBIG-FP's Report mentioned but did not describe in depth the German trading system and nor did it deal with the Dutch system, which nonetheless deserves a brief mention here. This note is of added value considering the position occupied by these states in the pharmaceutical market. In fact the German trading system is capable of influencing the process of price bargaining in other nations and this is the case because this country is a role model regarding the price of medicines. Besides in Germany the public price of drugs is fixed by the companies and, as in the case of the Netherlands, a reference pricing system applies at molecular level, which has also been extended to molecules that are considered to be therapeutically equivalent (known as "jumbo reference groups"). As regards the German tendering system, it is one of the few examples in Europe of tendering in the ambulatory care setting. According to national regulations, there are several *Krankenkassen* (German public health insurance companies), which cover the health and pharmaceutical expenses of citizens: each one is responsible for a part of the territory. In order to obtain the maximum discount, the *Krankenkassen* negotiate the price of drugs with manufacturers through the so-called rebate or discount agreements which might somehow evoke tendering procedures, although they are partially different[8]. In fact the procedures for procuring the rebate contracts vary from contracts negotiated directly with specific manufacturers to competitive procedures that allow manufacturers to compete with each other[9]. Discount agreements work as follows: firstly, sickness benefit funds define a number of drugs considered equivalent. Secondly, they enter into discount agreements with every single company and negotiate the price at which each company intends to sell its drug, in the retail market. Only the company which offers the lowest price and a full range of that product's portfolio (i.e. the number of product presentations based on dosage) will be awarded the framework contract and obtain the reimbursement for the sale of that drug in the territory where *Krankenkasse* works. The duration of the contracts vary in time but normally they have been for one to two years: this means that medicines which do not obtain the contracts are effectively excluded from the reimbursement in that particular

[7] For a specific reference to countries affected by the results and for an in-depth view of the individual national system see ÖBIG, *Tendering of pharmaceuticals in Europe and EAA countries*, supra note 6, p. 5 et seq.

[8] For further discussion about the adjustment of the drug purchase in Germany see P. Kanavos, L. Seeley and S. Vandoros LSE Health London School of Economics, *Tender systems for outpatient pharmaceuticals in the European Union: Evidence from the Netherlands, Germany and Belgium*, October 2009, available at http://ec.europa.eu/enterprise/sectors/pharmaceuticals/files/docs/study_pricing_2007/tendering_systems_en.pdf.

[9] P. Kanavos, L. Seeley and S. Vandoros LSE Health London School of Economics, *Tender systems for outpatient pharmaceuticals in the European Union: Evidence from the Netherlands, Germany and Belgium*, October 2009, supra note 8, p. 23 et seq.

area. As a consequence, manufacturers lose a share of the market and their product has to be purchased by patients exclusively out-of-pocket[10].

On the other hand the peculiarity of the Dutch tendering system is that it is mainly performed for specific group of pharmaceuticals bound to be supplied in the retail market. Particularly in the Netherlands in order to achieve lower prices of medicines, health insurers have implemented a new purchase method called "Preference Policy"[11]. Under this scheme, national drug procurement is tendered for off-patent (branded or unbranded) medicines containing the same active ingredient, that are eligible for reimbursement. Only manufacturers proposing the lowest price, or prices within 5% of the lowest price can be designated as the preferred suppliers. Products outside that range are not eligible for reimbursement. Consequently, except in the case of medical need, insured patients have to pay for non-preferred products out-of-pocket. Moreover the status of preferred product remains valid for a period of six months, after which procurement begins again in order to stimulate competition between companies and give other manufacturers the chance to supply the market.

Putting aside the specific legislations described and returning to the EU's perspective, it can be concluded from the comparison of the experiences in European states that the purchasing of pharmaceuticals by tendering enhances efficiency within the healthcare system. In fact, the ÖBIG-FP's Report shows that an effective tendering process ensures the availability of the required drugs, in appropriate quantities, at reasonable prices and of an acceptable standard of quality. Besides according to this survey an added value may be obtained in terms of transparency when using public funds to purchase pharmaceuticals through tendering[12]. However, the conclusions of the Report also point out that in order for the tendering procedures to have a competitive impact in the pharmaceutical sector, "*it is essential that these activities [be] performed in a pre-defined and structured framework, meaning that there should be an underlying legal basis specifying e.g. award criteria, the frequency of tenders and the obligation of publishing the outcomes*"[13]. Therefore, establishing the specific conditions under which tenders should develop is what this paper is trying to address.

2 – Tendering procedures as a guarantee of competition, Italian experience

[10] For further information on the German system of drug price bargaining see ECJ of 16 March 2004, in Case C-264/01 – AOK-Bundesverband e.a., GU C 94, 17.04.2004, p. 2; cf. ECJ of 11 June 2009, in Case C-330/07 – Hans & Christophorus Oymanns, GU C 19 dal 24.01.2009, p. 6; see M. Bedau and B. Tugendreich, *Are German health insurers obliged to purchase drugs by public tender?,* August 2007, available at http://www.pharmacist.or.kr/webapps/attach/data/pds03/Aug07_Euralex_MBedau_BTugendreich.pdf.

[11] See P. Kanavos, L. Seeley and S. Vandoros LSE Health London School of Economics, *Tender systems for outpatient pharmaceuticals in the European Union: Evidence from the Netherlands, Germany and Belgium*, October 2009, supra note 8, p. 7 et seq.

[12] On this matter see C. Dawson (European Social Insurance Platform member), *Cost Containment in the pharmaceutical sector,* July 2008, available at http://www.peer-review-social-inclusion.eu/peer-reviews/2008/cost-containment-in-the-pharmaceutical-sector-innovative-approaches-to-contracting-while-ensuring-fair-access-to-drugs/stakeholder-esip/download.

[13] Cf. ÖBIG, *Tendering of pharmaceuticals in Europe and EAA countries*, supra note 6, p. 20

Tendering procedure is widely used in any purchase made by the public administration. Through public tenders, procurement entities can choose the best bid and, at the same time, guarantee both the transparency in the management of public funds as well as the incentive of the competition among the participating companies[14].

In Italy, unlike other European countries, public procurement is employed for the purchase of reimbursable medicines and not for fixing the price of the reimbursable products; in fact, this price is decided in a previous phase. More specifically, the price of in-patent drugs is established through negotiation between AIFA (Italian Drug Agency) and pharmaceutical companies, while the reimbursable pricing of off-patented medicines is decided with the system of "reference pricing". According to "reference pricing", several clusters of equivalent off-patented (branded and un-branded) drugs are identified and the National Health Service (NHS) then identifies within each cluster which drug has the lowest price: this will be the reimbursed price. In actual fact, the Italian government has recently tried to introduce a selection procedure – which in some respects looks like Dutch "preference policy" – to limit the entry of drugs into those reference clusters. In fact, Article 9, paragraph 9 of the draft conversion law of emergency decree n. 78 of 2010 proposed that the reference price for reimbursable medicine should be decided on the basis of a cluster constituted by not more than four drugs. It also suggested that the medicines with lower prices which were eligible to compose clusters should be selected through a tendering procedure organized by AIFA. Furthermore, according to this law, two kinds of pharmaceuticals should be excluded from participating in tendering procedures: the pharmaceuticals that are losing their patent (branded off-patent drugs) and those that benefited from such a patent before it was lost (branded off-patent drugs produced in co-marketing regime)[15]. The suggested amendment was never passed, and consequently the application of the tender system continues to be important only in the distribution phase. In particular, currently in Italy pharmaceuticals are purchased through public tender in order to achieve two aims: firstly to meet the needs of hospitals and, secondly to deliver the drugs direct to the patients in home care or discharged from hospital[16]. In both cases, the purpose of the rules governing purchases is to ensure the maximum

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[14] Cf. G. Fidone, S. Gambuto, G. Mele, *Meccanismi elusivi e limitazione della concorrenza nella prassi amministrativa degli appalti pubblici.* Biennal reports of the CSC, Centro Studi Confindustria, edited by I. Cipolletta, S. Micossi, G. Nardozzi, S. Trento, March 17 of 2006 Biennal Conference, Rome. Document available at http://www.confindustria.it/AreeAtt/DocUfPub.nsf/3087977852662c0ac1256f65003aa57c/5bf88442620420eac1257132005edcc1/$FILE/PAPER_7d.pdf.

[15] For a comment on Article 9, paragraph 9 of the draft conversion law of the emergency decree No 78 of 2010 see Polo M., *Un ministro comprensivo,* 25.06.2010, WWW.LAVOCE.INFO Sanità/ Concorrenza e Mercati, available at http://www.lavoce.info/binary/la_voce/articoli/cache_pdf/UN-MINISTRO-COMPRENSIVO-1001799.pdf. Pammolli F., Salerno N. C., *Il prezzo di riferimento e le gare sui farmaci off-patent : quanta confusione anche tra esperti,* CERM, SHORT NOTE N. 2/2010.

[16] With regard to the first function, Article 9 of Law No. 386 of 1979 requires pharmaceutical companies to grant Primary Care Trusts a discount of at least 50% on the retail price of pharmaceuticals. An exception to this rule is the case in which drugs are approved by mutual recognition or by centralized procedures (the reference is to those medicines which represent a truly therapeutic or scientific innovation) for which, according to the CIPE's deliberation of 1 February 2001, the

availability of pharmaceuticals at the lowest price, to correlate protection and cost savings for public funds.

According to some authors[17], if tendering procedures were applied to a market such as that of health care – characterized by high specialization, contracts and detailed but necessarily incomplete specifications and few potential competitors – they could be considered inefficient tools because in this way the dialogue between procurement officials and contractors might be eliminated. However another scholar, Mario Libertini[18], defines public tenders in general as a tool that does not always ensure the efficient functioning of the markets but is certainly an acceptable compromise to avoid any irregularities by public administration. This is by virtue of its weakness, in that it represents both individual and collective interest, or conversely as a result of its power, due to the monopsony position that it enjoys in the bargaining process, which could produce distortion of competition in the relevant markets. Furthermore, as noted by the same scholar[19], tendering develops in a monopsony regime in which only one body represents demand while some competitors meet, repeatedly but intermittently, to decide who is to be the supplier for that demand[20]. In such a market, the protection of competition should not be understood only in the static sense as a guarantee of legislative measures aimed at restoring the balance, but also in the dynamic sense as an introduction of mechanisms that are intended to create conditions for the free development of competition[21]. Therefore, starting from Libertini's point of view, the author of the present article will analyze the specific use of public procurement in the pharmaceutical market and attempt to demonstrate that purchasing drugs through tendering procurement can help to achieve significant savings to the benefit of consumers.

3 – Criteria to incentivize fair competition in public procurement

In order to achieve an efficient result, it is necessary to pay attention to how the procurement entities behave in the application of both general criteria enforceable on all tenders and also those criteria

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bargaining price (ex-factory price i.e. the retail price without VAT and distribution margins) may be subjected only to the discounts arising from tendering procedures and not also that of 50%.

Instead with regard to the second function, in accordance with Article 8 subsection a) of L. No. 405 of 2001, the Region can enter into agreement with the trade union association of the pharmacies operating within the National Health Service, that can be public or private, to allow patients to be provided with medicines where they require frequent control.

[17] Cf. G. Fidone, S. Gambuto, G. Mele*, Meccanismi elusivi e limitazione della concorrenza nella prassi amministrativa degli appalti pubblici,* supra note 14.

[18] Cf. M. Libertini, *La tutela della concorrenza e i giudici amministrativi nella recente giurisprudenza*, in Giornale di Diritto Amministrativo No. 6/2007 pp. 632-642.

[19] Cf. M. Libertini, *La tutela della concorrenza e i giudici amministrativi nella recente giurisprudenza*, supra note 18.

[20] With this statement the author intends to embrace the opinion that for the tendering procedures the relevant market could be limited to the market in which tendering develops. *Ex plurimis* cf. State Council, sent. No. 1796, sect. VI, March 25 0f 2009; cf. State Council, sent. No. 548, sect. VI, February 10 of 2006; cf. State Council, sent. No. 926, sect. VI, March 2 of 2004.

[21] Cf. Constitutional Court, sent. No. 14 of January 2004, in Giur. It, 2004, p. 853. In this decision, the judges of the Supreme Court assert the importance of safeguarding competition that must be understood in a dynamic sense. The sentence was passed on state aid but it represents a leading case which has inspired subsequent judgements also in the tendering area. For further details on this matter cf. C. Lacava, *I contratti pubblici tra Stato e Regioni e la tutela della concorrenza*, in Giorn. di Dir. Amm. No. 6/2008, pp. 624-632.

particularly influenced by the features of the pharmaceuticals. With regard to the general criteria, importance is attached to the application of i) the transparency in the tender process and i) the guarantee of maximum participation. On the other hand, analysis of the criteria that are strictly related to the features of the pharmaceuticals is aimed at: i) the defining of the composition of the tender lots and ii) the choosing the award of contract.

3.1 – First general criterion, the difficult balance on the choice of degree of transparency

Transparency is a peculiar feature that must be respected in the development of all tendering procedures. In fact since tenders are a tool for collaboration between public authorities and private operators[22], the rules governing public procurement are structured according to the principles of transparency and the publicity of the relationships. However a high degree of transparency legitimates the award of the tender but can make communication among competitors easier, encouraging collusion between the parties. It is no coincidence that there are a lot of judgements passed by European and Italian authorities[23] aimed at punishing agreement of regulated prices and planned division of contracts between competitors in the same tender. In fact the higher the level of market transparency, the greater the risk of collusion. It is *"the combination of both the pre-existing level of transparency and how the information exchange changes this level that will determine how likely it is that the information will have appreciable negative effects"*[24]. Particularly, according to the European Commission opinion[25], an increase in transparency might facilitate collusion when the available information can be used by companies to determine the actions of their competitors. Indeed, rules on public procurement call for the standardization and harmonization of the economic conditions presented by each independent subject, promoting contacts between participants. Consequently the disclosure of information such as the identity of bidders and the terms and conditions of the bid, would allow competitors to come to agreement, identify deviations from possible previous collusive agreements, punish companies and coordinate future bids more

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[22] Cf. G. della Cananea, *Dalla concorrenza per il mercato alla concorrenza nel mercato: gli appalti pubblici nei servizi di comunicazioni elettroniche*, 2005, available at www.iisa.it/documenti/atti%2028.01.05/Della%Cananea_PPPiisa_BUP.pdf, p. 136; Cf. R. Caponigro, *La motivazione della scelta del contraente negli appalti aggiudicati con il criterio dell'offerta economicamente più vantaggiosa*, Report on IGI conference on corrective 3 to the public contracts code, held in Rome in October 14 of 2008, available at http://www.giustizia-amministrativa.it/documentazione/Caponigro_Motivazione.htm; Cf. M. D'Alberti, *Interesse pubblico e concorrenza nel codice dei contratti pubblici*, in Dir. Amm. No. 2/2008, pp. 297-311.

[23] Cf. European Commission, Jdgmt - *European Sugar Industry*, in G.U.C.E of 26/5/1973, L140/17; Cf. European Commission Jdgmt – *Building and Constructing Industry in the Netherlands* – in G.U.C.E. del 7/4/1992, L92/1; Cf. European Commission, Jdgmt – *Pre-Insuleted Pipes*, in G.U.C.E of 21/10/1998, IV/35.691/E-4, L24/1; Cf. CFI of 20 March 2002, in Case T-9/99 - *HFB et al. Vs. Commissione,* GU C 156, 29.06.2002, p. 13; cfr. ECJ of 3 March 2005, in Case C-21/03 - *Fabricom SA vs. Etat belge,* GU C 106, 30.04.2005, p. 5; Cf. AGCM of 13 June 2002, dec. No 10831 (I463) - *Pellegrini/Consip*, in Boll. No. 24/2002; Cf. State Council, sect. VI, No. 926 of 2004.

[24] European Commission, *COMMUNICATION FROM THE COMMISSION, Guidelines on the applicability of Article 101of the Treaty on the Functioning of the European Union to horizontal co-operation agreement*, May 2010, available at http://ec.europa.eu/competition/consultations/2010_horizontals/index.html, § 74.

[25] European Commission, *COMMUNICATION FROM THE COMMISSION, Guidelines on the applicability of Article 101of the Treaty on the Functioning of the European Union to horizontal co-operation agreement*, supra note 24, § 74 e seq.

effectively[26]. According to some authors[27], the flow of information exchanged between candidates and public purchasers in order to find a common solution – as is the case in particularly complicated tendering procedures – would prepare the ground for the spreading of significant distortions in technical planning and signalling of price. The setting of a "reserve price", in the sense of identifying a maximum price that the station contractor is willing to pay for given goods or services, is also debatable. According to some[28], setting a "reserve price" would limit the opportunity for participants to collude because they cannot negotiate a higher price than the one stated. In the opinion of another scholar[29], the "reserve price" could be an incentive for creating a syndicate which would have as a reference point the maintenance of the price stated in head office. The same author[30] also affirms that, when a central price is not indicated, collusion might be possible between the parties if they inquire about the prices that are paid by public purchasers in the previous tenders.

Therefore in the arrangement of the call for bids there exists a trade-off between: i) the guarantee of non-discriminatory procedures which is controlled by applying a transparent process and ii) the need to exclude collusion by the interested parties where the conditions offered by them are clear and known.

One of the aims achieved by the public procurement Directive 2004/18/EC, which is enforced also in pharmaceutical tendering, is to avoid restrictions on competition related to the exchange of information between candidates and the public purchaser. However, the limit of the law is that cooperation is a natural feature of the tender process and consequently it is impossible to prevent collusive effects by imposing a rule[31]. According to a study conducted by the OECD[32], the risk of collusion between competitors exists both in the "ordinary" market and also in public tenders: however, unlike the private purchaser, the public buyer does not possess the flexibility to choose its purchasing strategy and this is due to limitations imposed by legislation and detailed administrative regulations and procedures on procurements. From this observation it is possible to make a series of comments about how procurement entities could behave in order to bring greater flexibility to the purchase procedure. First of all the auction design should not be "one size fits all" but should be adapted to suit the specific market where it intends to proceed. Consequently i) in the procurement market where there are enough firms to sustain reasonable competition, efficient procurement outcomes can usually be achieved

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[26] Cf. OECD, *Public Procurement: The Role Of Competition Authorities In Promoting Competition*, 2007, available at http://www.oecd.org/dataoecd/25/48/39891049.pdf.

[27] Cf. A. Sánchez Graells, *Distortions of Competition Generated by the Public (Power) Buyer: A Perceived Gap in EC Competition Law and Proposals to Bridge It*, August 2009, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1458949.

[28] Cf. AGCM, AS333, *Previsioni sul modello di gara da adottare per l'evoluzione della rete unitaria per la pubblica amministrazione (rupa) nell'ambito del sistema pubblico di connettività*, in bulletin No. 8/2006; Cf. L. Fiorentino, Lo stato compratore. L'acquisto dei beni e dei servizi nella pubblica amministrazione, Series I, Quaderni di Astrid, Il Mulino publisher, Bologna 2007, Chapter IV.

[29] Cf. A. Sánchez Graells, *Distortions of Competition Generated by the Public (Power) Buyer: A Perceived Gap in EC Competition Law and Proposals to Bridge It*, supra note 27.

[30] Cf. A. Sánchez Graells, *Distortions of Competition Generated by the Public (Power) Buyer: A Perceived Gap in EC Competition Law and Proposals to Bridge It*, supra note 27.

[31] Cf. A. Sánchez Graells, *Distortions of Competition Generated by the Public (Power) Buyer: A Perceived Gap in EC Competition Law and Proposals to Bridge It*, supra note 27.

[32] Cf. OECD, *Public Procurement: The Role Of Competition Authorities In Promoting Competition*, supra note 26.

through a simple auction or tender process; ii) where there are not enough firms to sustain competition, more sophisticated arrangements may be necessary to achieve an efficient outcome. The choice of the most suitable bidding model, given the circumstances of the procurement, is therefore the starting point of any attempt to prevent collusion in public procurement[33]. Moreover in order to decrease the possibility of collusion, the study suggests reducing the frequency of procurement to minimize the opportunities for the parties to meet. Nevertheless the present advice also glosses over the existence of a trade-off between the need to limit the possibility of colluding and to avoid a market foreclosure in the medium to long term. In fact the European Commission warns against the risks arising from over-long award periods[34]. This is the case because in order to safeguard free competition, the state and other public authorities should not give individual operators the advantage of acting outside of competitive pressure[35]. Besides, the duration of supply is particularly important in the pharmaceutical sector because the longer the award period, the more likely it is that patented products will lose their sole selling right[36]. Finally, the last consideration discussed in the OECD's Report is the possibility of training public agencies to recognize potential collusive behaviours among competitors. This idea was inspired by countries such as Canada, Switzerland and the United States where proper check-lists have been developed to help procurement entities to stop instances of possible collusion. A similar investment could be expensive in terms of resources and time, but could produce significant benefits in the long term. The advice given by the OECD's Report does not represent guidelines that must be applied by procurement entities. Nevertheless it shows that it is not enough for public procurement rules, such as transparency and publicity principles, to be correctly enforced but they must also be balanced and adapted to suit the conditions required by each actual case.

3.2 – Second general criterion, the selection of companies and the increase of participation in tenders through a temporary consortium of contractors.

Actual and potential entry of new competitors in a market is probably the most important force that at the same time limits collusion and spurs a greater competition. According to Sánchez Graells[37], the public procurement procedure would introduce an unjustified restriction on the "free market" because

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[33] Cf. OECD, *Public Procurement: The Role Of Competition Authorities In Promoting Competition*, supra note 26, p. 8

[34] European Commission, *Pharmaceutical Sector Inquiry. Final Report,* 8 July 2009, supra note 2, § 1605.

[35] Cf. G. della Cananea, *Dalla concorrenza per il mercato alla concorrenza nel mercato: gli appalti pubblici nei servizi di comunicazioni elettroniche*, 2005, supra note 22, p. 139.

[36] Serafino S., *Problematiche antitrust nel settore farmaceutico: le gare come strumento per incentivare la concorrenza,* September 2008, available at http://www.assogenerici.org/articolihome/II_Congresso_Nazionale/Presentazione_Stefania_Di_Serafino.pdf. This author states that in Italy tenders include revision clauses (the so-called renegotiation procedures) of the contracted prices, according to which pharmaceutical prices can be renegotiated if their patent expires during the award period. However in the author's opinion, the same possibility of renewing the contract or of awarding a particularly long contract, could constitute an obstacle to entry of generic drugs and an advantage for the original manufacturers.

[37] Cf. A. Sánchez Graells, *Distortions of Competition Generated by the Public (Power) Buyer: A Perceived Gap in EC Competition Law and Proposals to Bridge It*, supra note 27.

it is based on rules that restrict the ability of potential suppliers to take part in a tender: this statement is basically true but needs to be mitigated. In fact, it is indisputable that tendering procedures, as designed, allow access only to those companies possessing certain qualifications in terms of economic, financial or technical capability. Nevertheless, in the auction the lack of selection criteria could lead to privileging businesses that do not have the skill, but are ready to present bids that are only apparently more advantageous[38]. Consequently, it is essential for tender auctions to specify the qualities that the firms should have in order to compete. However the guarantee of a broad participation of qualified firms is of primary importance in the pharmaceutical field because it ensures that doctors have a wide selection of pharmaceuticals from which they can choose the drugs they consider appropriate for the diseases under treatment. Considering this, on some occasions the Italian Competition Authority (the so-called AGCM) has intervened with advice aimed to steer selection procedures towards what is reasonable and impartial. In general, the Authority has explained that in order for public tenders to become a useful tool to promote competition and prevent anticompetitive behaviour, it is essential that the principles of equal treatment and proportionality should be respected and also that procurement officials must refrain from providing further qualifications other than those fixed by the law[39]. Another way to encourage greater participation of companies in tendering, suggested by AGCM, is to allow firms to join a temporary consortium of contractors (the so-called ATI). However, in AGCM's opinion[40], the temporary consortium of contractors should not be permitted if 1) each firm has the economic, financial and technical capabilities to supply on its own the procured products and/or 2) the firms produce the same goods or services. In order to protect competition, the AGCM hopes that the use of ATI would be limited to really indispensable events, in order to increase, and not to reduce, the number of the participants in a tender[41]. In fact the temporary consortium of contractors is admissible only when the pooling of the resources and the sharing of the business risk produces efficiencies in the

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[38] Cf. M. Libertini, *La tutela della concorrenza ed i giudici amministrativi nella recente giurisprudenza*, note 18.

[39] In particular after a careful observation of some selection criteria included in the auctions of ASL (Local Health Agencies) and hospitals, the AGCM has outlined a set of parameters that should be followed in preparing the notification of auctions. In order to ensure the broadest participation of the stakeholders in the selection process it is necessary that:
1 – Decisions on the admission of the firms to the tender are taken not only in relation to their turnover. The Authority condemns all those clauses which require either a minimum sales ceiling disproportionate to the extent of the tender or a turnover calculated on the specific geographic market in which the tender takes place. In fact these forecasts tend to exclude smaller firms from the tender and those capable of performing the requested service on the basis of the experience gained in different geographic markets. Indeed in the pharmaceutical sector the companies' suitability for supplying pharmaceuticals is certified by a complex system of marketing authorizations, consequently the level of turnover cannot be a binding criterion for participation and award of a tender.
2 –The fact that the firms have previously supplied other public bodies should not be taken into account. In fact the only effect of this forecast is to favour those firms that have already worked for the public administration and to unjustifiably exclude both the remaining categories of companies and potential competitors who want to enter the market.. (Cf. AGCM, advice AS097, *Gare pubbliche per le forniture di prodotti sanitari*, in bulletin No. 29/1997; Cf. AGCM advice AS187, *Bandi di gara in materia di appalti pubblici*, in bulletin No. 48/1999; Cf. AGCM advice AS251, *Bandi predisposti dalla concessionaria servizi informatici pubblici – CONSIP S.P.A*, in bulletin No. 5/2003).

[40] Cf, AGCM advice AS187, supra note 39; Cf. AGCM advice AS251, supra note 39.

[41] Cf. AGCM advice AS187, supra note 39.

market, otherwise the same consortium could be considered a cartel[42]. The AGCM's concerns are very important in the hospital setting, in fact in this field there are many examples of agreement during tenders with the purpose of sharing the market between the firms[43]. Nevertheless it is interesting to note that doctrine[44] and jurisprudence[45] have recently taken a more indulgent position than that expressed by AGCM on ATI[46]. In particular, the supporters of the recent position suggest abandoning general and *a-priori* rules which consider ATI an anticompetitive agreement and state the need to evaluate the possible distortion created by the ATI case by case[47]. Finally it is important to repeat that the observations made so far are general; they summarize the concerns of the AGCM which often originate from pharmaceutical auctions but they are enforceable in all tenders. The following will highlight the peculiar features of pharmaceutical products that should influence the choices of the procurement officials in composing pharmaceutical lots and on selecting award criteria more appropriate to the object of the tender.

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[42] Cf. M. Libertini, *La tutela della concorrenza e i giudici amministrativi nella recente giurisprudenza*, supra note 18.

[43] Cf. AGCM of 17 October 2002, in Case 11305 – *Test diagnostici per il diabete*, available at bulletin No. 42/2002; Cf. AGCM of 26 April 2006, in Case 15393 – *Prodotti disinfettanti*, available at bulletin No. 17/2006; Cf. AGCM of 03 March of 2007, in Case 17135 – *Gare per la fornitura di dispositivi per stomia*, available at bulletin No. 30/2007.

[44] Cf. P. Piselli, *I raggruppamenti temporanei fra le esigenze di tutela della concorrenza nelle pubbliche gare e salvaguardia della libertà di iniziativa economica*, in Riv. Trim. degli Appalti, 2006, pp. 133-151; Cf. T. Fiorella, *ATI e disciplina antitrust*, in Urbanistica e appalti No. 7/2009 pp. 829-835

[45] Cf. ECJ of 19 May 2009, in Case C-538/07 – *Assitur,* GU C 153 04.07.2009 p.9; Cf. State Council, sect. IV, sent. of 25 March 2009, No. 1796; Cf. State Council, sect. VI, sent. of 25 January 2010, No. 247.

[46] In particular, the advice No. AS251 (supra note 39) of the AGCM provides two restrictive statements. According to the first statement, only in exceptional cases properly justified in the auction, can the temporary consortium of contractors be permitted even if the participant firms produce the same goods or services. According to the second statement, firms that have monitoring or connection relations (as stated by Article 2359, paragraphs I, II and III of the Italian Civil Code) cannot compete in the same tender, either as individual firms or as participants in the temporary consortium of contractors.

[47] With regard to the prohibition of association for companies that produce the same goods or services, according to some authors (i.e. P. Piselli, *I raggruppamenti temporanei fra le esigenze di tutela della concorrenza nelle pubbliche gare e salvaguardia della libertà di iniziativa economica*, supra note 44; T. Fiorella, *ATI e disciplina antitrust*, in Urbanistica e *appalti*, supra note 44), the imposed restriction would limit the freedom of economic initiative which is guaranteed by Article 41 of the Italian Constitution. In fact the concept of ATI allows participant companies not only to achieve the requirements stated by the auction, but also to introduce a higher efficiency in the organization of its activities. For example, the temporary consortium of contractors allows both the business risk on the individual contract to be reduced and the business resources to be split over a greater number of orders.

Whereas with regard to prohibition imposed on firms with monitoring or connection relations from competing in the same tender, some scholars (Cf. M. Libertini, *La tutela della concorrenza e i giudici amministrativi nella recente giurisprudenza*, supra note 18; Cf. L. Fiorentino, *Lo Stato compratore. L'acquisto dei beni e dei servizi nella pubblica amministrazione*, supra note 28) welcome the restriction imposed by the Authority because they think that the existence of a control relationship between firms is a-priori capable of favouring, in competition terms, the participant firms which are referable to a single centre of interests. However according to a recent jurisprudential direction (Cf. ECJ of 19 May 2009, in Case C-538/07 – *Assitur*, GU C 153 04.07.2009 p. 9: on this judgement is modelled the sentence of Council of State, sect. VI, of 25 January 2010 No. 247) "*Community law precludes a national provision which, while pursuing legitimate objectives of equality of treatment of tenders and transparency in procedures for the award of public contracts, lays down an absolute prohibition on simultaneous and competing participation in the same tendering procedure by undertakings linked by a relationship of control or affiliated to one another, without allowing them an opportunity to demonstrate that that relationship did not influence their conduct in the course of that tendering procedure… Such legislation, which is based on an irrebuttable presumption that tenders submitted for the same contract by affiliated undertakings will necessarily have been influenced by one another, breaches the principle of proportionality in that it does not allow those undertakings an opportunity to demonstrate that, in their case, there is no real risk of occurrence of practices capable of jeopardising transparency and distorting competition between tenders* (See paras 23, 28-30 and operative part of the ECJ decision of 19 May 2009, in Case C-538/07).

3.3 – First specific criterion, the composition of the tender lots

The composition of the tender lots represents the heart of the problem in the public procurement of pharmaceuticals, in this regard the competition Authority has also provided guidelines. Advice notes AS187 and AS251[48] say that in order to allow the competitive development of the tender, the object of the same cannot be artificially expanded or restricted. In fact the AGCM clarify that if the lot was expanded too much, those firms that can furnish only a single supply would be excluded; on the other hand, if the tender object was subdivided this could allow procurement entities to evade the application of EC regulations and consequently to exclude the participation of foreign firms. Finally the Authority advises careful definition of the tender object which must be highly qualified in technical and economic terms, but at the same time must not bear identifying marks or references to a specific brand or patent. However if these indications are sufficient to guide the activities of the procurement officials in most of the market, they are not sufficiently adapted to suit the drug supply setting where it is necessary to consider various other constraints that come into play. In general it can be argued that in the pharmaceutical sector the need to ensure the selection of a large number of products guarantees doctors a greater choice in selecting the most suitable drug for each disease. Furthermore, the difficulty of a drug in being successful in hospital tenders has repercussions on the diffusion of the same also in the retail market, given the existing continuity between hospital and home therapy[49]. Therefore to provide hospitals with a product is particularly important for pharmaceutical companies because it is also a form of marketing that will be useful for the success of the same drugs in the retail market[50]. However, what criteria should be enforced to establish a balance between cost containment and the availability of appropriate, effective and innovative treatment is under discussion.

With regard to the composition of pharmaceutical lots, in Italy rules that can direct the activities of procurement officials in the pharmaceutical sector do not exist, so sentence number 549 of 2003 of Emilia Romagna TAR (Regional Administrative Court) can be considered the only guidelines. According to the administrative court, it is hoped that a single tender lot includes medicines composed of different active substances but belonging to the same therapeutic class ATC3[51]. This stance is

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[48] AGCM, advice AS187, *Bandi di gara in materia di appalti pubblici*, supra note 39; AGCM, advice AS251, *Bandi predisposti dalla concessionaria servizi informatici pubblici – CONSIP S.P.A,* supra note 39.

[49] Cf. AGCM, Advice AS440, *Procedure di acquisto di farmaci tramite gare a pacchetto*, in bulletin No. 48/2007.

[50] The existence of a relationship between hospital market and retail market is recognized by doctrine and jurisprudence. In this matter, see the decision of the director general of fair trading No. CA98/2/2001 of 30 March 2001, *NAPP pharmaceutical holdings and subsidiaries (NAPP)*, available at: http://www.oft.gov.uk/shared_oft/ca98_public_register/decisions/napp.pdf. In this decision fines were imposed on a pharmaceutical company by the UK competition authority for selling its products to hospitals at very low prices, whilst selling the same products via pharmacies at very high prices to patients, a strategy that could be sustained as doctors were found to be strongly influenced by the brands used in hospitals.

[51] According to the Anatomical Therapeutic Classification (the so-called ATC: the classification system adopted by the Nordic Council on Medicines of Uppsala), pharmaceuticals with the same therapeutic properties are included in the same ATC third level: they are considered as substitutes for the treatment of the same disease.

justified by the fact that the above-mentioned criterion of homogeneous therapeutic categories[52] - stated by Article 8, paragraph 10/13 of the Act of 1993 No 537 - is used to define the list of medicines reimbursable by the NHS and consequently it could be considered an effective criterion also to settle on a single award lot. In reality the criteria adopted to establish a list of reimbursable medicines are very different from those criteria required to define a group of drugs which will come into direct competition. In fact, building a homogeneous category of medicines, considered deserving of being reimbursed for the same price, means that all products in this category will be reimbursed under the same conditions. Instead, if drugs belonging to the same category are in competition with each other, only the selected product will be purchased and consequently will have access to the market[53]. Indeed, in the pharmaceutical field the identification of mutually replaceable products represents the result of a very complex operation. As regards to that, the Italian competition Authority has established[54] that the ATC3 therapeutic class is the most used to define the "market of product". This means that, in general, the drugs belonging to the ATC3 class can be considered substitute products. Nevertheless, the Authority has also specified that this rule does not always work, since the ATC3 class medicines sometimes have important different features. For example, the problem of precisely assembling a group of interchangeable drugs in order to limit the "market of the product" is particularly significant within parallel imports of pharmaceuticals[55]. On this matter, there are many decisions which define the relevant market in very different way; in particular, in order to detect the existence of a dominant position, some Courts qualify the relevant market as that one constituted by medicines belonging to the same ATC3 class[56]. Nevertheless, in other decisions, the relevant market coincide sometimes with the ATC4 class[57], sometimes with the individual branded pharmaceutical[58], or with the single drug prescribed by the physician[59]. Certainly, the *ratio* governing the two branches of the law is very different. In fact, in the regulation of parallel imports the definition of the relevant market is a preliminary step to

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[52] In particular, the concept of homogeneous therapeutic categories is defined also by the CUF (Single Italian Pharmaceutical Commission) as a group of drugs (active substances and their pharmaceutical preparations) which, in relation to their main therapeutic indications, have a common mechanism of action and are characterized by the same clinical efficacy and side-effects, although they can also have different additional therapeutic indications. A therapeutic category includes drugs composed of perfect dosage form, unit dose and number of dosage units which allows doctors to make the same therapeutic intervention, in terms of intensity and duration.

[53] Cf. F. Massimino, *Gare pubbliche di farmaci, novità applicative e aspetti critici*, in Sanità pubblica e privata No. 1/2004, pp. 63-82, note 7.

[54] AGCM, *Indagine Conoscitiva nel Settore Farmaceutico*, 1997, § 1.2, available at http://www.agcm.it/agcm_ita/DSAP/DSAP_IC.NSF/0/3a250fe3093bed4ac12564c3004594a7/$FILE/Ic14.pdf

[55] Cf. Guglielmino M., *Il mercato rilevante nel settore farmaceutico: quando è la singola specialità medicinale a determinarlo,* 2005, available at http://www.law-economics.net/public/App.%20MI%20Petrone%20c.%20Pfizer_2005.pdf

[56] Cf. European Commission, Jdgmt 96/478/CE – *Adalat*, in GU L 201 of 9.8.1996, p. 1–81 and Court of Appeal of Milan ordinanza 26 April 2005 – *Soc. Farmacie Petrone / c. Soc. Pharmacia Italia e Pfizer Italia* , in Foro it., 2005, I, 1885, (for a detailed comment of this decision see Rass. Di Dir. Farm. No. 5/2005, p. 952/968).

[57] Cf. European Commission, Jdgmt 2006/857/CE – *AstraZeneca*, in GU L 332 del 30.11.2006, p. 24–25.

[58] Cf. Court of Appeal of Milan, ordinanza 23 July 2005 – *Soc. Farmacie Petrone / c. Soc. Pharmacia Italia e Pfizer Italia*. For a detailed comment of this decision see Rass. Di Dir. Farm. No. 1/2006, p. 15/33.

[59] Cf. Conseil de la Concurrence, Jdgmt 04-D-05 of 24 February 2004, point 4, available at www.conseilconcurrence.fr/.

determine whether the investigated firm holds a dominant position in a given market; on the opposite, within the composition of tender lots choosing a group of interchangeable medicines represents a fit tool to guarantee a balance between the availability and lower prices of suitable medicines. Furthermore, in the mentioned case law, the existence of Courts' different definitions of substitute medicines shows that an aprioristic classification of drugs does not allow to identify a perfect replaceability within the medical products because it is always necessary to take into account the circumstances of rules application. With reference to tender system, the conflation of medicines on the basis of the ATC3 class – according to which all drugs designed for the treatment of the same disease are interchangeable, regardless of the active substance of which they are composed or the patent coverage – seems rather generic. Surely in the short term, this choice could trigger enormous competition between the specialties with similar but non-identical features and as a consequence it could lead to a larger containment of costs, but there are many other variables to consider. First according to reliable doctrine[60], lots which include large equivalence classes risk making products which are differentiated in terms of active ingredients, phase of life cycle, research content and existence of a patent, homogeneous in the eyes of consumers. In other words, the most innovative medicines would establish themselves more slowly in a market in which they are considered more or less equivalent to other medicines which have been available for much more time and consequently are cheaper than the former. Besides the doctors would be forced to prescribe indifferently non-identical drugs because only those have been selected.

Moreover, to tell the truth, the competitive confrontation between in-patent and off-patent drugs does not necessarily achieve a cost saving in the short run. With regard to this, it is interesting to consider specific tenders which are called "package tenders"[61]. In "package tenders" the suppliers can group some or all pharmaceuticals included in a lot and grant an initial discount on the price of the individual drug and an additional one on the price of the entire package made up of in-patent drugs and drugs with expired patents. This practice is inefficient because it is not favourable for those firms that produce only generic drugs: in fact manufacturers of generics have little opportunity to offer both in-patent and off-patent products at a competitive price. Instead the Authority recommends distinguishing lots constituted by off-patent drugs from those composed of drugs under patent protection that are considered substitutable by the scientific community. In this way: i) from the competitive confrontation between expired patent drugs, in the short run, the maximum discount on these types of drugs could be achieved and, in the long run, a lowering of price and a larger distribution of the generics at a competitive price; ii) from the competition between active substances with the same therapeutic properties but covered by patent, a larger distribution of innovative medicines and even cost savings in

[60] Cf. F. Pammolli e C. Bonassi, *Prezzi di riferimento diversi tra regioni. Un commento al comunicato Aifa n. 50 del 2007*, Editoriale CERM No. 4/2007, available at http://www.snamid.org/Prezzo%20di%20riferimento%20tra%20diverse%20regioni.pdf.
[61] Cf. AGCM, advice AS440, *Procedure di acquisto di farmaci tramite gare a pacchetto,* supra note 49 .

the short run could be achieved. Nevertheless even in this respect, some doubts arise about the selection criteria that would be fairest to apply where, for example, a tender lot was composed of a single patented molecule distributed by different manufactures connected by a co-marketing contract[62].
In general the co-marketing agreement amounts to a common interest of the contracting firms. Using this strategy, pharmaceutical companies adopt promotional policies oriented both to obtaining greater popularity of the same molecule in the medical class and also to increasing the competition with other different active substances which have the same therapeutic efficacy but are made by other companies[63]. However, while in the "ordinary" market the competitive strategies of the co-marketing firms are based both on marketing differentiation and on different prices, in public tenders the only competitive leverage between these type of companies is the sale price. Certainly the author agrees with the assertion that where there are companies in co-marketing relations, stimulating competition between patented drugs leads to lowering the price of the same[64]. However it is necessary to reflect on the fact that this type of competition is altered because the licensor and the licensee companies do not compete on an equal footing. In fact, the marketing authorisation holder will sell its molecule (or the finished product) to the licensee at a price that it considers remunerative to itself, inclusive of the costs incurred: this means that it will be very difficult for the licensee to present a more favourable bid. This problem is the result of a short-circuit in the Italian market, which was created as a consequence of an automatic acceptance by the internal authorities of trade practices such as co-marketing, without subjecting the same to a legislative model that could regulate the effects of competition. Under present conditions, the benefit of lower prices in the short term derives from price competition but it has the implicit risk of the licensee exiting from the market in the long term. However what is still not clear is whether this possible exit of licensees from the market in the long term could be classified as a loss of efficiency for the market or, on the contrary, as a sustainable sacrifice to ensure an application of the competition dynamics in which companies that are better able to organize their activities prevail[65].
With regard to the constitution of lots, a final comment is needed about the situation in which the ASL (Local Health Agency) buys truly innovative in-patent medicines, which are considered by the scientific

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[62] The co-marketing relationship is defined by doctrine as a marketing strategy whose aim is to use the powers of two or more competitors to sell the same active ingredient. First it was developed in the '80s and after the patentability of the drugs it was recognised. In fact it was created as a way for foreign multinational companies to more easily and promptly obtain marketing authorizations for their product through their Italian partners' collaboration.
This definition is extrapolated from the AGCM decision No. 7337 of 1999, in Case *Servier Italia – Istituto Farmaco Biologico Stroder*, point 2.2, available in bulletin No. 26/1999. It is one of the three AGCM decisions existing on co-marketing strategy, the others are: AGCM, decision No 6927 of 1999, in Case *Byk Gulden Italia-Istituto Gentili*, available at bulletin No. 8/2009; AGCM, decision No 6928 of 1999, in Case *Istituto Gentili-Merck Sharp & Dohme -Neopharmed-Sigma Tau industrie farmaceutiche riunite-mediolanum farmaceutici,* available in bulletin No. 8/1999.
[63] Cf. AGCM decision No. 7337 of 1999, in Case *Servier Italia – Istituto Farmaco Biologico Stroder*, point 2.2.
[64] Cf. F. Massimino, *Gare pubbliche di farmaci: novità applicative e aspetti critici*, supra note 53, p. 69, nt 9.
[65] For a critical view of co-marketing contracts see M. Sorrentino, La *strategia di co-marketing nel settore farmaceutico*, in L'impresa No. 10/1992, pp. 49-57; See A. Grandi, V. Odorici, M. Sobrero, *I gruppi strategici cognitivi nell'industria farmaceutica italiana*, in L'industria No. 2/2000, pp. 263-287; See C. Piria, *Un riesame critico del co-marketing farmaceutico (in margine ai provvedimenti dell'Autorità garante della concorrenza e del mercato),* in Rass. di diritto farmaceutico, 2000, pp. 718-735.

community as not replaceable or replaceable only with obsolete or less effective products. These types of medicines should be purchased through private negotiated procedure. In fact in these situations the principle, often affirmed also by AGCM[66], that the widest application of the tendering procedure ensures the highest degree of competition between firms operating on a market, should be debunked. The doubts about the negotiated procedure can derive from the mistrust towards the discretionary decisions of public procurement officials and not from competition reasons. In fact, in the market being analyzed – characterized by differentiated products and continuous flows of innovation – individual negotiation represents normal economic trade and as such is subjected to the conditions of natural competition[67]. Besides Article 57, II paragraph, letter b) of Legislative Decree No 163/2006[68] specifically provides for the negotiated procedure when, by way of technical or artistic nature or relating to the protection of exclusive rights, the contract may be given only to a particular economic operator[69].

3.4 – Second specific criterion, how to award the contract

Articles 53 and 55 of Directive 2004/18/EC regulating the award criteria for the bid are embodied in Italian law in Articles 81, 82 and 83 of the Procurement Code (Legislative Decree No 163/2006). According to the law, the best bid can be selected on the basis of the lowest price or the most economically advantageous bid criteria. In the first case, the bid will be considered for its price; whereas in the second case other factors are considered such as price, performance, delivery time and service, in order to reconcile economic and the qualitative aspects. According to the AGCM opinion [70] and with a view to promoting competition, the lowest price criterion tends to be more appropriate where the object of the contract is standardized; whereas in situations in which the qualitative aspects of the bid contribute to better satisfaction of the public interest, a more complex evaluation[71] would be hoped for. Besides, in order to consider the bids, IV paragraph, of Article 83, of the Procurement Code states that contractors can designate experts to draw up the criteria, weights, scores and the specifications which must be indicated in the auctions.

Unfortunately in pharmaceutical tendering, only one of the two criteria, the lowest price, is usually considered. However on the basis of a differentiation proposed in literature, the enforcement of the

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[66] Cf. AGCM, advice AS285, *Selezione delle imprese interessate al ciclo di produzione di bollini autoadesivi per i prodotti farmaceutici,* in bulletin No 46/2004; Cf. AGCM, advice AS187, supra note 39.

[67] See M. Libertini, *Organismo di diritto pubblico, rischio d'impresa e concorrenza: una relazione ancora incerta*, in Contratto e impresa, No. 6/2008 pp. 1201-1227; see also M. Libertini, *La tutela della concorrenza e i giudici amministrativi nella recente giurisprudenza*, supra note 18.

[68] The Article 57, II paragraph, letter b) of the Legislative Decree No 163/2006 implements the Article 31 of Directive 2004/18/EC.

[69] Cf. R. De Simone, *Procedura negoziata senza bando per unicità del prestatore: una deroga obbligata al principio della concorrenza*, in Lexitalia.it, June 2009.

[70] AGCM advice AS251, *Bandi predisposti dalla concessionaria servizi informatici pubblici – CONSIP S.P.A.,* supra note 39.

[71] With regard to the choice of the best award criteria see also R. Caponigro, *La motivazione della scelta del contraente negli appalti aggiudicati con il criterio dell'offerta economicamente più vantaggiosa*, supra note 22.

three existing criteria is suggested. Of note, some scholars[72] divide drugs into three distinct categories: 1) branded or un-branded off-patent drugs; 2) in-patent drugs that are less innovative either because they have been available for a long time in the market or because they constitute incremental innovations; 3) in-patent drugs with new compositions which introduce significant innovation. It is possible to apply different award criteria to each category as follows.

First, some observations on the trend of generic drugs[73] suggest that the lowest price criterion is appropriate only for making a choice within the pharmaceuticals belonging to the first category. In fact competition on price has a positive impact on off-patent molecules[74] because they can be truly considered as identical copies in terms of active substance, dosage, pharmaceutical shape, modality of release and medication. In cases like these, promoting *à la Bertrand* competition could mean encouraging an alignment of the marginal costs of production[75] and consequently a decrease in selling price and a larger diffusion of the same products[76]. Instead for drugs considered substitutes and belonging to the second category mentioned, the proposal is to use the most economically advantageous criterion. In fact, as stated above, these products are often perfect substitutes only for main therapeutic indications because they present some additional specific features. Consequently where this type of competition can be enforced, it should be based primarily on the added value that each product, or each manufacturer who supplies the product, is able to provide. According to an expert[77], in the pharmaceutical field the qualitative assessments on advantageous bids can concern: the logistic integration between the manufacturer and the purchaser's administration, the pharmacoeconomy, the equipment or the courses that are directly or indirectly aimed at the medication and other cognitive or practical support which allows public bodies to exercise their therapeutic function optimally. However to safeguard the impartiality of the choice, procurement entities must list which of the additional qualifications justified the award of the contract. In fact, European Court of Justice has ruled[78] that the contractors can choose the award criterion which is the most appropriate to the tender object, but at the same time they are obliged to indicate the assessment methods and to

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[72] The tripartition of pharmaceuticals is freely inspired by the draft: F. Pammolli, C. Bonassi, M. Riccaboni, N. Salerno, *Regolazione di prezzo, innovazione, ciclo di vita dei prodotti: per una riforma del sistema di pricing nel settore farmaceutico*, published in La regolazione del ciclo e dei prezzi dei prodotti farmaceutici e il sostegno dell'innovazione e della ricerca. Confronti europei e proposte di riforma – July 2007, available at http://www.astrid-online.it/farmaci/Paper-farm/index.htm.

[73] Cf. C. Jommi, *Il confronto internazionale tra prezzi dei farmaci: aspetti metodologici, principali risultati in letteratura e studio osservatorio farmaci*, pubblished in La regolazione del ciclo e dei prezzi dei prodotti farmaceutici e il sostegno dell'innovazione e della ricerca. Confronti europei e proposte di riforma – July 2007. available at http://www.astrid-online.it/farmaci/Paper-farm/index.htm.

[74] Cf. C. Jommi, *Value base pricing per i farmaci: quali opportunità? Quali rischi?*, 2009, available at http://www.astrid-online.it/rassegna/04-12-2009/Jommi_Value-Based-Pricing_06_11_09.pdf.

[75] Cf. F. Pammolli, C. Bonassi, M. Riccaboni, N. Salerno, *Regolazione di prezzo, innovazione, ciclo di vita dei prodotti: per una riforma del sistema di pricing nel settore farmaceutico*, supra note 72.

[76] The same opinion is expressed by the European Commission *Pharmaceutical Sector Inquiry. Final Report,* 8 July 2009, supra note 2 and by OECD Health Policy Studies, *Pharmaceutical Pricing in a Global Market*, supra note 5, p. 150.

[77] F. Massimino, *pubbliche di farmaci: novità applicative e aspetti critici*, supra note 53, p. 71

[78] Cf. ECJ of 7 October 2004, in Case C-247/02 - *Sintesi c. Autorità Vigilanza Lavori Pubblici,* in Giust. civ., 2004, p. 2893, with critical note of R.B.

explain the reason that led them to deviate from the lowest price criterion. Finally, as already specified, the drugs belonging to the third category should be excluded from the tendering process and be purchased through private negotiated procedure because they are truly irreplaceable with other kinds of products.

Conclusions

In the light of research conducted in the Italian field, the purchasing of pharmaceuticals by tendering procedure could be an effective tool both in containing public spending and, at the same time, in protecting patient health. Nevertheless this efficient result could be achieved only on the condition that procurement entities adapt public procurement rules to the specific needs of the market in question. In fact, the public agencies should pay attention to the correct application both of general criteria enforceable on all tenders such as: i) the degree of transparency in the tender process and ii) the guarantee of maximum participation; and of those criteria particularly influenced by the features of the pharmaceuticals such as: i) the correct definition of the tender lots composition and ii) the selection of the appropriate award criteria of the bid.

In particular the procurement entities should guarantee the transparency of the product selection, considering that the same rules which limit the discretion of their choices could be an incentive for the exchange of information and the collusion between competitors. Moreover in order to prevent tenders from becoming a tool of unjustified exclusion of any firm, the procurement entities should ensure maximum participation avoiding enforcing qualifications that are too restrictive for the firms which want to compete. With regard to the composition of the lots, it would be opportune to consider that including a homogeneous class of drugs in the same lot is not the most appropriate way of stimulating competition, because a homogeneous class could result in a container of products with different features in terms of efficiency, innovation and sensitivity to competition. In fact the use of this system risks encouraging a price reduction in the short run, against certain negative effects in the long run such as: i) a smaller spread of truly innovative drugs, ii) a general homogenization in the use of drugs that are equal only for the main therapeutic indications, iii) a levelling out of competition which is unfavourable to the spread of generics and the lowering of their prices. Similarly, the criteria selected for the award of the bid should not be restricted to the lowest price. In fact price competition is certainly effective for branded or un-branded off-patent drugs[79], but the same conclusion cannot be reached for in-patent drugs with different features which require a more complete and complex handling. In conclusion the author believes the observance of the listed criteria could allow tendering procurement to be an effective tool in stimulating the competition dynamics between companies. The

[79] Cf. C. Jommi, *Il confronto internazionale tra prezzi dei farmaci: aspetti metodologici, principali risultati in letteratura e studio osservatorio farmaci*, supra note 73.

hoped-for effects are: lowering of medicine prices, wider distribution of generic products, rise in competition between less innovative drugs, achievement of adequate remuneration for the truly innovative drugs, serving as a incentive to further research and allowing patients a ready availability of suitable drugs.

Finally it is important to highlight that the remarks made are the result of an analysis of Italian legislation and practices, in which tendering is used mainly to supply the pharmaceutical requirement of hospitals. The same conclusions might not have been reached if it had considered tendering procedures as a tool to supply the retail market, a hypothesis also observed in the study by ÖBIG-FP[80]. In fact a feature of the tender is to provide for a single winning bidder, which means that the exclusion of some competitors from hospital procurement could be considered a bearable compromise for the market. Whereas if the winning bidder were also the only company that could enter the retail market, as happens in Germany, further observations would be required. For example with regard to German and Dutch reimbursable medicines, the tender would also affect decisions on reimbursement, because in pharmacies, consumers can only purchase the drugs that are selected by the tendering procedures at the reimbursable price. For this reason the comments put forward have overall value, but would require further specification if the foreign markets under analysis were regulated differently from the Italian market.

[80] ÖBIG-FP, *Tendering of pharmaceuticals in Europe and EAA countries*, supra note 6.

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Essays

Essais

Ensayos

Paper n. 5

MY HOME IS MY CASTLE – BUT IS MY CASTLE TRULY MINE?

POLISH HISTORICAL IMMOVABLES AS OBJECTS OF OWNERSHIP

by

Magdalena Habdas

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MY HOME IS MY CASTLE – BUT IS MY CASTLE TRULY MINE?

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by

Magdalena Habdas♦

Abstract:

Cultural goods, in particular historical buildings and real estate, 'demand' a more complex understanding of ownership. Regardless of whether the owner is a private or a public entity, the need to protect these historical immovables in the interest of the society remains the same. There is no single category of owners, who will guarantee the proper protection and care of historical real estate. Private owners with no understanding of the limits of their right are just as undesirable as public owners (local authorities, the state), who have been known to utilize historical immovables for the benefit of their office, but without adequate protection or respect for the historical and artistic value. In all cases where ownership is affected by a public interest, the right is no longer purely private and therefore may be subject to restrictive regulation. However, common sense confirms that security of property and ownership is not in opposition to acknowledging a public element in these rights, particularly if their object is unique, as in the case of historical real estate.

Key words: historical real estate, conservation of historical buildings, ownership, public and private ownership, social element in ownership

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Introduction

In the preamble of the Constitution of the Republic of Poland,[1] the Polish Nation recognizes that we are "(...) beholden to ancestors for their labors, their struggle for independence achieved at great sacrifice, for our culture rooted in the Christian heritage of the Nation and in universal human values, (...), Obliged to bequeath to future generations all that is valuable from our over one thousand years' heritage". If Poland's over one thousand years' heritage is to be passed on to future generations, it is important to consider the characteristics of ownership as a means of holding cultural goods. It is important to realize, that since the French Revolution in 1789, the concept of ownership has evolved. In present times, states rarely accept that ownership is absolute and has no other function but to please the owner.

The purpose of this paper is to examine whether ownership of cultural real estate (historical buildings/immovables) by private individuals (natural or legal persons) should be regarded in exactly the same manner as ownership of other types of objects. Sheer intuition compels one to consider the division into public and private ownership. Bearing in mind that in constitutions of many European countries, the social aspect of ownership is emphasized, as well as its limited, rather than absolute, character, classifying privately owned cultural goods as private objects seems to be an oversimplification.

The paper is an attempt to analyze ownership of material cultural goods in Poland, in the context of historical real estate. Its aim is to show, how private ownership of historical buildings and sites is defined by public function, national heritage and identity. It is important to emphasize, that after Poland's traumatic experience with communism and the nationalization of industry and vast areas of land, the 1989 shift to a market economy was intentionally aimed at promoting private ownership of immovables and empowering private owners. However, since the return of communism is no longer a threat, the time to reconsider the role, function, and protection of historical real estate within a public context has arrived. As difficult as it may be for Poles to accept, the position of the landowner as a king of his castle must be modified, but not in order to nationalize historical buildings and violate rights of private landowners. The objective to be achieved is the protection of material heritage through mechanisms which will allow owners to see and appreciate the public element in private ownership.

The importance of the above may be illustrated by numbers. Before the start of World War II in 1939, in Poland, there were about 9 thousand inhabited palaces and 13 000 manors[2] with more or less

[1] Act of 2nd April 1997, Dz.U. (Journal of Statutes) 97, no. 78, item 321, with subsequent amendments

[2] The oldest ones in existence date back to the XVth century, they were most common in the XVIIIth and XIXth centuries. Manor houses were places of residence and centers of culture located in the rural estates of the gentry. A manor house was surrounded by a large garden and an orchard, but the estate also comprised farm buildings. After World War II, agricultural reforms were introduced by the communist state. The estates were nationalized, owners (gentry, nobility) were evicted, the estates were divided into small plots of land, and the manors were left open to looting and devastation, which was condoned

complete, original, historical interiors. Currently, that number is between 10 and 20 and the number of manors still in existence is about 3 000, most of them in a very bad state of repair or falling into ruin. Only about 30 manor houses remain in the hands of their historical owners.[3] In comparison, in the Czech Republic there are 130 palaces that survived in an original state, together with the interior fixtures, fittings, furnishings and design.[4] These numbers do not indicate, that Poland has a negligible number of historical buildings,[5] but they do show, that the state of historical immovables in Poland leaves a lot to be desired.

Ownership of material cultural goods, in particular historical buildings and sites, must be seen not only from the perspective of the owner's prerogatives, but also in the context of his duties towards the object of heritage, rather than the object of his property. Castles, palaces, manors may be privately owned, but are they indeed truly private?

Cultural property in the Polish Constitution

As has already been mentioned in the introduction, the importance of national heritage and the obligation to pass it on to future generations (so consequently, also to protect it) is contained in the Polish Constitution's preamble. This very general obligation of the Nation is expanded in the following constitutional provisions:

1. art. 5: The Republic of Poland shall (...) safeguard the national heritage;
2. art. 6 s. 1: The Republic of Poland shall provide conditions for the people's equal access to the products of culture which are the source of the Nation's identity, continuity and development;
3. art. 73: The freedom of artistic creation and scientific research as well as dissemination of the fruits thereof, the freedom to teach and to enjoy the products of culture, shall be ensured to everyone.

The first of the mentioned provisions relates to a broad term of national heritage and entails an obligation of the State to protect it. National heritage may be defined as a link between generations, that provides a sense of cultural identity and belonging to a given religious, social, or national

(or indeed planned and intended) by the communist state in order to remove all traces of nobility in Poland. For more see A. Pawlikowska – Piechotka, 'Dwory o funkcjach turystycznych [Manor houses with tourist functions]', *Ochrona Zabytkow,* 1-2 (2003), 171, 181

[3] Pawlikowska – Piechotka, 'Dwory', 171, 181

[4] W. Kowalski, 'Cywilnoprawne aspekty obrotu skradzionymi dobrami kultury [The transfer of stolen cultural goods – civil law aspects]' in J. Kaczmarek (ed) *Prwanokarna ochrona dziedzictwa kultury [Penal protection of Cutural Heritage]* (Kraków: Zakamycze, 2006), p. 59; For a historical overview of damage sustained by Polish cities in the course of the past centuries see J. Pruszynski, 'Dziedzictwo kultury i przestrzen miejska [Cultural heritage in municipal areas]', *Samorzad Terytorialny,* 7-8 (2002), 3 - 18

[5] According to the data of the National Heritage Board of Poland, there are more than 60 000 immovable monuments in Poland, out of which approximately 17 000 are residential buildings and 12 000 are religious ones. There are only 418 castles; see www.kobidz.pl

community. It comprises not only tangible objects, but also immaterial goods such as language, custom, rituals, music, etc.[6] On the constitutional level, the considered provision places an obligation to protect such heritage on the State, but not on anybody else.

Limiting this general obligation to the State only is unfortunate, particularly in the light of the fact, that a completely different solution has been adopted with respect to the environment. Article 86 of the Constitution is very clear in stating that "Everyone shall care for the quality of the environment and shall be held responsible for causing its degradation. The principles of such responsibility shall be specified by statute."[7] Considering the losses Poland's national heritage, in particular cultural goods, have suffered in the course of history, the lack of an analogous provision relating to cultural goods must be negatively assessed. It seems that such a provision would place more emphasis on the fact, that a cultural object, like a historical building, is not only an object of proprietary rights, but more importantly, it is also a part of national heritage, which everyone must seek to protect.

Moreover, the obligation of the State to protect national heritage is a very general one,[8] and there are no further constitutional provisions which attempt to make this responsibility more specific. On the one hand, this may be explained by the fact, that a constitution usually comprises general provisions, designed to set out principles that are to be later included in Acts of Parliament. On the other hand, this is a noticeable consequence of the fact, that the Polish legislator has no clear vision of the function and role of ownership as such.[9] After the fall of communism, the need to provide different levels of property protection depending on who the owner was, no longer exists. However the issue that still needs to be considered is the object of ownership and the function of that object, regardless of whether the owner is a private person or some sort of a public entity.[10]

The disappointing fact is, that the legislator did not decide to provide special constitutional protection or to adequately emphasize the significance of cultural heritage and historical property. Moreover, the legislator is under no duty to address these matters in subsequent acts of parliament.[11] This does not mean, that no such special regulations exist, but there is no common denominator that would enable

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6 Pruszynski, 'Dzedzictwo', 3

7 Luckily, a lot of the damage suffered by historical buildings is connected with environmental pollution, so protection of the environment benefits historical real estate, compare: K. Zeidler, *Prawo ochrony dziedzictwa kultury [The Law of National Heritage Protection]*, (Wraszawa: Wolters Kluwer, 2007), p. 72

8 Also see P. Dobosz, 'Pojecie dziedzictwa narodowego i jego znaczenie dla dzialan polskiej administracji publicznej wobec integracji europejskiej [The concept of cultural heritage and its significance for Polish public administration in view of European integration]', *Ochrona Zbaytkow,* 2 (2002), 121-3

9 A. Labno, 'Ochrona dobr kultury w rozwiazaniach konstytucyjnych. Rozwazania na przykladzie Konstytucji Rzeczpospolitej Polskiej z 1997 r. i wybranych konstytucji panstw obcych [The protection of cultural goods in constitutional provisions. Deliberations based on the Constitution of the Republic of Poland 1997 and selected constitutions of foreign countries]', *Humanistyczne Zeszyty Naukowe,* 10 (2006), 21-2

10 A. Labno-Jablonska, 'Nowa konstytucyjna regulacja prawa własności w Polsce [The New Constitutional Regulation of Ownership in Poland]' in A. Agopszowicz, T. Kurowska, M. Pazdan (eds.) *Zagadnienia prawa cywilnego, samorządowego i rolnego: pamięci Profesora Waleriana Pańki [Issues of Civil, Local Government and Agricultural Law: Essays in Honour of Prof. Walerian Pańko],* (Katowice: Wydawnictwo Uniwersytetu Śląskiego, 1993), pp. 36-9

11 B. Banaszak, *Prawo konstytucyjne [Constitutional Law],* (Warsaw: C.H. Beck, 2008), p. 251

public entities, particularly public decision makers, and courts to consistently understand the function of such property and to adequately protect it.

The fact that cultural heritage is a category of goods that in a moral sense belong to and benefit the society as a whole does not, in any way imply, that these goods are also commonly owned by a community. As has already been mentioned, the owners may be private persons, local authorities, or even the State itself, but there is no constitutional provision that would explicitly oblige everyone to protect objects of cultural value. When one realizes, that currently only the fate of cultural objects that have been entered in the register of monuments can be properly monitored and protected by public authorities, the lack of a distinct constitutional provision introducing everyone's responsibility to protect national heritage is acutely perceptible.[12]

Apart from art. 5 of the Constitution, national heritage is also taken into account in art. 6 s. 1 and art. 73, although the legislator has not been consistent and instead of referring to national heritage, refers to products of culture[13] (cultural goods). Although these two terms are not synonymous (it would seem that cultural heritage has a wider scope than cultural goods or cultural property), they are often used interchangeably. It is rather obvious, that these two provisions are a natural extension of art. 5, since if the State is to safeguard national heritage it is also logical, that such protection is aimed at making national heritage accessible to interested parties.[14] It is not however clear how the constitutional instruction to provide conditions for the people's equal access and enjoyment of the products of culture is to be carried out. There are no special provisions which allow for such access and enjoyment, if the historical object in question is in private ownership.

The Polish Constitutional Tribunal has recently attempted to explain the State's obligation of ensuring enjoyment of cultural goods. In the view of the Tribunal, a provision of the Polish Protection and Care for Monuments Act 2003 (PCM)[15] that required a landowner, who planned to carry out construction works concerning a building registered as a monument, cover all costs of archeological research (if conducting it was necessary to protect the monument) was unconstitutional.[16] The Tribunal held, that such duties are, according to art. 5 of the Constitution the sole obligation of the State. Since such costs are usually substantial, most landowners will not be able to cover them, thus the public will be deprived

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[12] See J. Pruszynski, *Dziedzictwo kultury Polski. Jego straty i chrona prawna. Tom II [Polish Cultural Heritage. Losses and Legal Protection. vol. II]*, (Kraków: Zakamycze, 2001), pp. 360-2; A. Labno-Jablonska, K. Skotnicki, 'Wprowadzenie do rozważań nad koncepcją własności w europejskich konstytucjach ostatniej dekady XX wieku [An introduction to deliberations on the concept of property in European constitutions of the XXth century's last decade]' in K. Skotnicki, K. Winiarski (eds.) *Własność i jej ograniczenia w prawie polskim [Ownership and its Limitations in Polish Law]*, (Częstochowa: Akademia im. J. Długosza, 2004), p. 27

[13] Official translation of the Constitution available at: http://www.sejm.gov.pl/prawo/konst/angielski/kon1.htm

[14] Labno, 'Ochrona', 20

[15] Dz.U. 03, no. 162, item 1568, with subsequent amendments

[16] A criticism of the provision when it was still in force was presented by W. Szafranski, 'Uwagi o nowelizacji ustawy o ochronie zabytkow i opiece nad zabytkami [Remarks about the amendments of the Act on the Protection and Care for Monumets],' in W. Szafranski (ed) *Wokol problematyki prawnej zabytkow i dziel sztuki [The legal issues concerning monuments and works of art],* vol. I, (Poznan: Wydawnictwo Poznanskie, 2007), pp. 174-8

of the enjoyment and access to cultural property (art. 73 and 6 s.1 of the Constitution).[17] This judgment further confirms, that the very general content of the above mentioned provisions does not in practice allow to apply them independently of art. 5 of the Constitution.

It is interesting to compare the above Polish provisions with the Italian Constitution.[18] The important starting point is that the latter contains clear regulations on the nature of property. In art. 42 s.1 it provides that property may be public or private (a distinction missing, for understandable, historical reasons, from the Polish Constitution) and that economic goods may belong to the state, to public bodies, or to private persons. Additionally, private ownership is recognized and guaranteed by laws determining the manner of acquisition and enjoyment and its limits, in order to ensure its social function and to make it accessible to all (art. 42 s.2). This reflects the social function of property, which compels one to acknowledge, that when collective and individual interests collide, the former ones will prevail. Thus the social function of property denotes a collection of limitations which the state imposes *ab initio*, in order to keep the powers of property owners under control in the interest of the society as a whole.[19]

In this context, Italian statutory law is consistent when it distinguishes a category of property, which is privately owned, but serves a public purpose/use, namely environmental and cultural heritage property. Private owners of such properties (particularly immovables) are subject to conservation requirements, pre-emption rights of public entities in the event of a sale, etc., because such properties are viewed as public in the sense, that they serve the community. Regulations concerning this type of property have been united in the Cultural Heritage Code 2004. Additionally, in art. 9 of the Italian Constitution it is stipulated that the Republic protects the landscape, which has the effect of placing various additional duties on private owners of immovables. The Italian Constitutional Court has been consistent in holding, that these duties may not be indemnified, as they are a derivative of the community interest that is inherent in the property itself.[20]

In contrast to the above, the German Constitution[21] does not refer to national heritage or cultural property at all.[22] However, ownership is a right strictly connected with social responsibility. The famous phrase of art. 14 s. 2: "Ownership (property) entails obligations", (*Eigentum verpflichtet*) supplemented by: "Its use shall also serve the public good", leaves no question as to the legal position of an owner, particularly if the object of ownership forms a part of national heritage. The German Constitution does not define ownership, as this is the role of the German Civil Code (BGB), however the legislator

[17] Judgment of 8 Oct. 2007, K 20/07, OTK-A 2007/9/102

[18] Adopted on 22nd December 1947, with subsequent amendments (http://servat.unibe.ch/icl/it00000_.html)

[19] G. Alpa, V. Zeno-Zencovich, *Italian Private Law* (Routledge-Cavendish, 2007), pp. 119-122.

[20] Ibid., pp. 124-125

[21] That is: the German Basic Law (Grundgesetz für die Bundesrepublic Deutschland – the so called Bonn Constitution) from 23rd May 1949

[22] Except for art. 73 (1), 5a: The Federation has exclusive power to legislate in the matters of the protection of German cultural items against being moved abroad.

cannot shape this right in such a way, that it would entail no responsibilities. Consequently, statues which influence the exercise of ownership (environmental law, planning law, protection of cultural property law) are seen as a natural ingredient of property.[23] Therefore, when §903 BGB defines ownership, it refers to limitations stemming from the law and rights of others and emphasizes its strongly social nature.[24] Moreover, German courts have been known to rely on art. 14 s. 2 of the German Constitution to indicate, that an owner must refrain from anti-social uses of his property and even perform positive acts that a reasonable owner would take in the absence of relevant provisions.[25]
Therefore, in German legal reality, the lack of a constitutional provision on the protection of cultural heritage does not seem to have negative effects. As a matter of fact, Germany is known for the society's understanding and the political will to preserve monuments and historical buildings. It is seen as an investment that not only creates jobs but also shapes a responsible attitude towards social resources.[26] The necessary protective legislation in the area of planning, conservation, style and the identification of historical sites is therefore an accepted indicator of the social responsibilities that owners, particularly of historical buildings and monuments, must fulfill.
The above comments indicate, that provisions concerning the protection and significance of national heritage vary in constitutions of different countries. They also demonstrate, that the reasons for adopting different approaches to this matter are strictly connected with the concept of property itself. It seems that countries with a visible public or social component within the notion of property, or at least with a clear understanding of the co-existence of public and private ownership, have an easier task when it comes to emphasizing the unique character of owning cultural property. Poland is not one of those countries, as the issue of public and private property as well as 'borderline' or 'mixed' cases remain an uncomfortable area of law, due to past experiences.

Ownership of cultural goods

Since the Polish Constitution addresses cultural goods in a rather general manner, it is necessary to consider the general provisions on property in the context of cultural goods. The highest authority for the existence and protection of ownership is provided by the Polish Constitution. Firstly, in art. 20 it is stipulated, that a social market economy, based on the freedom of economic activity, private ownership, and solidarity, dialogue and cooperation between social partners, shall be the basis of the economic system of the Republic of Poland. This provision is located in the first chapter of the Constitution, which concerns the principles of Poland's socio-economic system. The purpose of an

[23] M. Raff, *Private Property and Environmental Responsibility: A Comparative Study of German Real Property Law,* (The Hague, London, New York: Kluwer Law International, 2003), p. 171 *et seq.*
[24] G. Roberts, *An Introduction to German Law,* (Baden-Baden: Nomos, 2006), p. 270
[25] M. Raff, *Private,* pp. 174-175
[26] C. P. Echter, 'Preservation in Germany and the Study on Cultural Assets in Europe', *German Journal of Urban Studies,* occasional paper (2002), 8-9; http://www.difu.de/english/occasional/preservation-cultural-assets.shtml

express reference to private ownership is justified by the need to accentuate the fact, that Polish economy is to be based on private means of production and not on public ones, like it was in the communist era. This does not eliminate the existence of public ownership. It does, however, exclude the possibility of building an economy based predominantly on public ownership of means of production.[27]

Secondly, in art. 21 it is emphasized that the Republic of Poland protects ownership and the right to inherit (s. 1) and that expropriation is allowed only for public purposes and with just compensation (s. 2). In this context it is also necessary to mention two other constitutional provisions, relating to possible limitations of basic constitutional freedoms and rights. According to art. 31 s. 3, restrictions on enjoyment of constitutional freedoms and rights may only be imposed through an Act of Parliament (statute), if they are necessary in a democratic state to ensure public safety or order, protection of environment, health and public morals, or freedoms and rights of other persons. Such restrictions may not constitute an infringement of the essence of a given right or freedom. Additionally, in art. 64 it is stipulated that everyone has the right to ownership, other property rights and to the right of succession (s. 1). Protection of the above is granted to everyone on an equal basis (s. 2). Restrictions of ownership may only be imposed through an Act of Parliament (statute) but they may not violate the substance of ownership (s. 3).

The above provisions concern the right of ownership and relate to all kinds of goods, whether movable or immovable, historical or not, tangible or intangible. It should also be noted, that for constitutional purposes, the term ownership is understood not only in its narrow, technical, law of real rights sense, but also as a wider notion that is closer to the term 'property',[28] particularly as defined in art. 1 of Protocol no. 1 to the European Convention on Human Rights.[29] Nevertheless, ownership, has not been constructed as an absolute right that stands no limitations. Conversely, the Constitution expressly refers to restrictions of this right in art. 31 s. 3 and in 64 s. 3. These restrictions are possible, as has been consistently confirmed by the Polish Constitutional Tribunal,[30] only if two conditions are met. The first one requires that the imposed limitations be necessary in a democratic state to ensure public safety or

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[27] See the Polish Constitutional Tribunal judgment of 7th May 2001 (k 19/00), OTK 2001/4/82

[28] L. Garlicki, *Polish Constitutional Law. An Outline [Polskie prawo konstytucyjne. Zarys wykladu]*, (Warszawa: Liber, 2008), pp. 112 - 113; E. Skowronska-Bocian, in K. Pietrzykowski (ed.) *The Civil Code. Vol. I. Commentary [Kodeks cywilny. Tom I. Komentarz]*, (Warszawa: C.H. Beck, 2008), pp. 548 - 549; S. Jarosz-Zukowska, 'Prawo do wlasnosci – własnosc jako prawo podmiotowe [The right to ownership – ownership as a right] in B. Banaszak, A. Preisner (eds.) *Prawa i wolnosci obywatelskie w konstytucji RP [Rights and Freedoms of Citizens in the Polish Constitution]*, (Warszawa: C.H. Beck, 2002), p. 258; Labno-Jablonska, Skotnicki, 'Wprowadzenie', p. 21; Aldona Domanska, Anna Domanska, 'Własność jako element społecznej gospodarki rynkowej [Ownership as an element of social, market economy] in K. Skotnicki, K. Winiarski (eds.) *Własność i jej ograniczenia w prawie polskim [Ownership and its Limitations in Polish Law*, (Częstochowa: Akademia im. J. Długosza, 2004), p. 35.

[29] See M. Carss-Frisk, *The Right to Property. A Guide on the Implementation of Article 1 of Protocol No. 1 to the European Convention on Human Rights,* (Strasbourg: Council of Europe, 2001), p. 6

[30] See S. Jarosz-Zukowska, 'Konstytucyjne przeslanki dopuszczalnosci ograniczen prawa wlasnosci [Constitutional conditions of restricting the right of ownership]' in L. Garlicki, A. Szmyt (eds.) *Szesc Lat Konstytucji Rzeczpospolitej Polskiej. Doswiadczenia i Inspiracje [Six Years of the Polish Constitution. Experiences and Inspirations],* (Warszawa: Wydawnictwo Sejmowe, 2003), p. 136

order, protection of environment, health and public morals, or freedoms and rights of other persons. The second one prohibits limitations that violate the substance of ownership. There is no direct reference to the protection of national heritage or cultural goods, and yet the State's obligation to safeguard this heritage cannot be realistically fulfilled without statutory restrictions placed on private (but equally public) owners of cultural goods.

The only sensible interpretation is to accept that restricting ownership in order to protect freedoms and rights of other persons also encompasses the freedom expressed in art. 73 of the Constitution, that is the freedom to teach and to enjoy the products of culture.[31] Consequently, ownership may be limited if it is necessary to protect third parties' freedom of enjoying cultural goods.[32] Another option is to classify restrictions designed to protect cultural goods as ones justified by the need to ensure public safety or order. The *ordre public* clause is very broad and encompasses issues such as the protection of socially and constitutionally acknowledged values, like national heritage.[33] This rather indirect, but legally plausible, mechanism does allow for restrictions of ownership to protect cultural goods, but leaves the impression of forced or extensive interpretation. Moreover, the difficulty in applying art. 31 s. 3 to restrictions of cultural goods' ownership has lead to doubts concerning the legality of numerous, and often onerous, responsibilities imposed by the PCM.[34]

The constitution also stipulates, that restrictions of ownership cannot violate the substance (essence) of this right. According to the Constitutional Tribunal, the essence of a right is its core or nucleus, without which a given right could not exist, whereas additional elements of a right may be modified or shaped in different fashions, without changing the identity of the right in question. With respect to ownership this nucleus denotes two spheres: a positive one (*ius possidendi, ius utendi, ius fruendi, ius abutendi, ius disponendi*) and a negative one (the owner may enjoy his right to the exclusion of all others), but it is also necessary to consider whether the ownership of a given thing in a given context (factual situation) has lost the ability to fulfill its function.[35] The Tribunal also indicated, that art. 31 (3) of the Constitution contains a principle of proportionality. This principle denotes that the legislator may only utilize restrictions which are adequate to the goal that is to be achieved and that limit the right in the smallest possible extent. The measures employed by the legislator may not be excessive to the goals to be achieved.[36] Finally, some restrictions of ownership may not necessarily be unconstitutional *per se*, but may be unconstitutional because of the context in which they function (e.g. a compensation mechanism has been introduced, but it is not proportional to the actual restriction of a right).

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[31] M. Drela, *Wlasnosc zabytkow [Ownership of Monuments]*, (Warszawa: C.H. Beck, 2006), p. 22

[32] Compare Pruszynski, *Dziedzictwo,* p. 362-5

[33] Polish Constitutional Tribunal judgment of 7 Feb. 2001, K 27/00, OTK 2001/2/29 and of 12 Jan. 1999, P 2/98, OTK 1999/1/2

[34] Jarosz-Zukowska, 'Konstytucyjne', p. 145

[35] See judgment of 25 May 1999, SK 9/98, OTK 1999/4/78

[36] Judgment of 12 Jan. 1999, P 2/98, OTK 1999/1/2

The fact that ownership is not an absolute right is further emphasized in the Polish Civil Code (PCC).[37] Ownership is the most extensive right to property that one can enjoy, but in Polish law (like in most contemporary legal systems) it is not an unlimited, absolute right.[38] In art. 140 PCC, where the right of ownership is defined, the legislator stipulates, that owners have entitlements within certain limits. Art. 140 PCC continues that an owner may, within the limits specified by statutory law and the principles of community life and to the exclusion of other persons, use a thing in accordance with the socio-economic purpose of his right. In particular he may collect fruits and other income from the property as well as dispose thereof, all within the mentioned limits.

This concept of ownership, limited by statutes, principles of community life, and the socio-economic purpose of the right, implies, that when the law in force 'limits' the owner, it is not in fact a restriction of his right, but a manner of indicating where the right ends. In other words, a manner of shaping the right of ownership. The problem of ownership limits, has been a contentious issue in Polish academic writing and different opinions have been presented as to whether these limitations should be considered as, for example, internal or external, *ex lege* or *ex officio*. Other classifications of these limits have also been proposed.[39]

It will suffice here to refer to most commonly presented views. As has already been mentioned, ownership is not *ius infinitum,* therefore J. Wasilkowski expressed the opinion, that since ownership is conceptualised as having limits, all statutory restrictions are merely a means of shaping the right, in accordance with its object as well as the holder of the right.[40] A similar opinion was expressed by W. Panko, who emphasized, that ownership performs a social function and therefore particular responsibilities contained in specialized legislation are not a restriction of the right, but its element.[41] The limits, understood as the borders, of ownership are not predetermined once and for all, but change according to the changes in society, economy, the law, and the purpose of the object in question.[42] In this way, ownership is a flexible right,[43] and its limits, identified by the legislator, particularly the limit of

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[37] Dz.U.64, No.16, item 93 with subsequent amendments

[38] E. Gniewek, *Prawo rzeczowe [The Law of Real Rights]* (Warszawa: C.H. Beck, 2008), p. 56; judgment of the Polish Supreme Court of 9 July 2008, CSK 52/08, LEX no. 510986

[39] See R. Mikosz, 'Ograniczenia wlasnosci na przykladzie prawa gorniczego [Limitations of ownership based on mining law]', *Problemy Prawne Górnictwa,* 5 (1982), 35-58; W. Bugajski, 'Przepisy o zakladaniu na cudzych nieruchomosciach urzadzen wodno kanalizacyjnych, gazociagowych, energetycznych i telekomunikacyjnych, a tzw. sluzebnosci ustawoowe [Provisions on installing water, sewage, gas and telecommunications lines in the context of statutory easements]', *Palestra,* 12 (1966), 50-64; for a concise presentation of different views expressed in literature also see M. Drela, *Wlasnosc.* p. 112-25

[40] J. Wasilkowski, 'Pojecie wlasnosci w swietle kodeksu cywilnego [The notion of ownership in the civil code]', *Państwo i Prawo,* 12 (1965), 826-7

[41] W. Panko, *Wlasnosc gruntowa w planowej gospodarce przestrzennej. Studium prawne. [Land Ownership in a Planned Spatial Economy. A Legal Study],* (Katowice: Wydawnictwo Uniwersytetu Slaskiego, 1978), pp. 36-7

[42] A. Wasilewski, *Administracja wobec prawa wlasnosci nieruchomosci gruntowych [The Administration and Land Ownership],* (Krakow: Wydawnictwo Uniwersytetu Jagiellonskiego, 1972), pp. 19-20

[43] For a critical opinion of ownership's definition in PCC see B. Ziemianin, K.A. Dadanska, *Prawo rzeczowe [The Law of Real Rights],* (Warszawa: Wolters Kluwer, 2008), pp. 43-4 who point out, that the definition was formulated in 1964, in a completely different political and economic system; its purpose was to legitimize the State's intervention and control, and therefore now it must be perceived as obsolete.

socio-economic purpose, allow to view a given right of ownership in the light of its object, holder, and possible interests of the society.[44] This right is shaped by civil and administrative law provisions, which not only specify *non facere* or *pati* obligations, but also, particularly with respect to cultural goods, introduce obligations of active behaviour (*facere*).[45] A similar view is expressed by J. Ignatowicz and K. Stefaniuk,[46] A. Stelmachowski,[47] S. Rudnicki and G. Rudnicki.[48] Consequently, the legislator may give ownership various shapes, depending on the object of the right, its holder (private person or public entity) and the function or purpose of that object. There is, however, a condition: regardless of the particular shape ownership takes, it must retain its core, its essence.[49] Ownership cannot be an empty right - *nudum ius.*[50] This is why, the Polish Constitution does not allow for restrictions, which would effectively reduce ownership to a lesser right.

The mentioned limits of ownership are to be identified with respect to a particular object and the holder of the right. As a consequence, owners of cultural goods are subject to detailed provisions concerning the transfer, use, and conservation of these objects. Regardless of who the owner of cultural property is, that person (physical or legal, public or private) must realize that the socio-economic purpose of ownership is not only to satisfy the needs of the owner, but also to evidence the history, achievements, culture of a given nation.[51] Historical buildings or other cultural objects do not cease being things in terms of the law of real rights, however their ownership is shaped by their unique function. Differences in the right of ownership are visible not on the level of the holder of the right, but on the level of the object of the right. This is the precise reason for differences in regulations concerning the ownership of land and other things,[52] of material and immaterial goods,[53] and consequently of goods possessing historical/cultural value and those that do not.

It would seem from the above, that the notion of ownership in Polish law is flexible enough[54] to fully reflect the unique character of historical real estate. Since ownership is shaped not only by limits

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[44] T. Dybowski, 'Zasady wspolzycia spolecznego i spoleczno gospodarcze przeznaczenie prawa, a prawo wlasnosci [Principles of community life and the socio-economic purpose in the context of ownership]', *Nowe Prawo,* 6 (1967), p. 731-3

[45] T. Dybowski, *Ochrona wlasnosci w polskim prawie cywilnym,* (Warszawa: Wydawnictwo Prawnicze, 1969), pp. 64 75

[46] J. Ignatowicz, K. Stefaniuk, *Prawo rzeczowe [The Law of Real Rights],* (Warszawa: Lexis Nexis, 2009), p. 66

[47] A. Stelmachowski, 'Tresc i wykonywania prawa wlasnosci [The Content and Exercizing Ownership]' in T. Dybowski (ed.) *System prawa prywatnego. Prawo rzeczowe – The System of Private Law. The Law of Real Rights*, volume 3 (C.H. Beck: Warsaw 2007), p. 239

[48] S. Rudnicki, G. Rudnicki, *Komentarz do kodeksu cywilnego. Księga druga. Własność i inne prawa rzeczowe [The Commentary to the Civil Code. Book Two. Ownership and Other Real Rights]* (Warszawa: Lexis Nexis 2008), pp. 31-3

[49] A. Stelmachowski, 'Tresc', p. 239; E. Skowrońska Bocian, in K. Pietrzykowski (ed.) *Kodeks cywilny, tom I. Komentarz [The Civil Code, vol I. Commentary]* (Warszawa: C.H. Beck, 2008), pp. 556-7

[50] For more see S. Grybowski, 'Struktura i tresc przepisow prawa cywilnego odsylajacych do zasad wspolzycia spolecznego [The Stricture and content of provisions referring to principles of community life]', *Studia Cywilistyczne,* VI (1965), 68 *et seq.*

[51] M. Kierek, 'Ograniczenia prawa wlasnosci w swietle ustawy o ochronie dobr kultury [Limitations of ownership in the context of Protection of Cultural Goods and Museums Act]', *Annales UMCS,* vol. XII (1965), 62-3

[52] This is particularly clear in common law systems, where law relating to land developed separately from law regarding other things, see T Murphy, S Roberts, T. Flessas, *Understanding Property Law* (London: Thomson, Sweet&Maxwell, 2004), pp. 38-9

[53] W. Panko, *O Prawie Wlasnosci i Jego Wspolczesnych Funkcjach,*(Katowice: Wydawnictwo Uniwersytetu Slaskiego, 1984), pp. 106-7

[54] Flexibility of ownership was emphasized by Wasilewski, *Administracja,* p. 21

introduced in specialized legislation, but also by principles of community life and the socio-economic purpose of the right, then it should be rather straightforward to conclude, also by reference to German practice (see point 2 of this paper), that an owner must refrain from anti-social uses of his property and perform positive acts that a reasonable owner of historically relevant real estate would take, even in the absence of relevant provisions.

However, J. Pruszynski notices, that an owner of a cultural good is not abusing his right when his use of that object does not bring cultural benefits to the society as such.[55] He also states, that in relation to historical immovables it is very difficult to determine the socio-economic purpose of ownership. Such immovabels, due to changes in history, society and economy, are almost always utilized contrary to their original destination and historical function.[56] These arguments are not completely correct. Firstly, although the use of a cultural object by its owner does not have to bring cultural benefits to the society, the PCM does provide, that in certain situations, the owner must make his property available to others (see point 4 below). Secondly, the contemporary use of a historical building will rarely coincide with the historical use, but that is not required by the socio-economic purpose of ownership. It is obvious, that no one will expect the owner to keep animals inside a palace or house, as it was once practiced or to run a barn or a factory in the middle of an urban setting. The socio-economic purpose denotes a use that takes into account the historical value of the immovable and should prevent the owner from taking actions, which although not formally forbidden by legislation (e.g. PCM) are nevertheless undesirable when cultural value is taken into account. This statement, although general, has its practical importance, since not all historical buildings are registered and although they are still subject to the PCM, the protective measures that may be employed by the conservation authority are limited.

Monuments and sites as objects of ownership

In the preceding sections of this paper an overview concerning the regulation of ownership in Polish law was presented in order to show, that although constitutional regulation of national heritage is not completely satisfactory, the definition of ownership is flexible enough to include a public element. These remarks must be supplemented by a more direct reference to the already mentioned PCM which regulates the protection and care for monuments. The latter are defined as immovables or movables, their parts or collections, which:

1. are a product of or are connected with human activity,
2. are evidence of a past era or event,
3. should be maintained in the interest of the society or due to their historical, artistic or scientific value (art. 3 point 1 PCM).

[55] Pruszynski, '*Dziedzictwo*', p. 363-4
[56] Ibid., 364-5

Consequently, PCM regulates not only monuments which have been entered in a special register, but all monuments, i.e. objects which possess the features listed above.[57] Nevertheless, the scope of the required protection and care is wider with respect to registered monuments.[58] The PCM, which is a relatively new act (2003), has adopted a solution which differs from its predecessor, the Protection of Cultural Goods Act 1962,[59] where as a rule only registered objects had the status of protected cultural goods.[60] This mechanism, was modeled on French regulations, which even after the introduction of a new act concerning cultural heritage in 2004,[61] still provide protection to those objects, which have been registered (classified).[62] A similar approach has been adopted in the Netherlands.[63] The French legislator has decided to protect only those objects of national heritage, which he knows exist. This rational premise has allowed the French to create a cohesive system of listing cultural goods and to vary levels of protection, depending on the type of the listed object.[64]

The Polish legislator differentiates between the protection of monuments, and the care/guardianship over monuments. The first notion relates to tasks of the public administration, which are aimed at protecting the monument, sometimes even from the actions of its owner. These authorities have four basic forms of protecting the monument, namely: 1) listing it in a register of monuments 2) classifying it as a monument of history 3) creating a cultural park 4) including protection of monuments in the local development plan/zoning (art. 7 PCM).

The second notion relates to the owner of a monument, who is obliged to care for it (guard it). In particular, this obliges the owner to maintain conditions which allow to:

1. carry out scientific research and prepare relevant documentation,
2. undertake conservation, restoration or construction works,
3. safeguard and maintain the monument and its surroundings in the best possible state,
4. use the monument in a way which protects its value,
5. disseminate knowledge about the monument and its significance for history and culture (art. 5 PCM)

These duties are only exemplified by the legislator, therefore the owner should realize, that he may also have other duties, which are inextricably woven into the ownership of cultural goods through the general clauses contained in art. 140 PCC. Since according to PCM, a monument is not only an object listed in an appropriate register, but an object of historical value (see above), all owners of such objects

[57] Drela, *Wlasnosc',* p. 48; Zeidler, *Prawo ochrony,* p. 49
[58] Zeidler, *Prawo ochrony,* p. 49, 52
[59] Act of 15 Feb 1952, Dz.U. 99, no. 98, item 1150, with subsequent amendments
[60] Kierek, 'Ograniczenia', 70-1
[61] *Code du patrimoine*
[62] Drela, *Wlasnosc,* p. 102, Kierek, 'Ograniczenia', 70-1
[63] See K. Lubina, 'Protection and preservation of cultural heritage in the Netherlands in the 21st century,' *Electronic Journal of Comparative Law,* vol. 13.2 May (2009), 4
[64] A. Dobrzyn, 'Ochrona dziedzictwa kultury we Francji [The protection of cultural heritage in France],' *Ochrona Zbytkow,* 3 (2007), 85

must perform the duties mentioned above. They are of particular relevance when one considers immovables, which frequently require conservation work or other maintenance. Such work is usually necessary just to prevent them from further deterioration.

Registering a monument as a listed building significantly alters the legal position of his owner,[65] who is now subject to much more detailed regulations and specific requirements, than he would be, if the monument remained unlisted. The registration may be done *ex officio*, by the conservation authority or on the basis of a motion filed by the owner of the immovable (art. 9 s. 1). Registration may include the monument's surroundings and geographical or historical name. Consequently, the ownership of other immovables, even those which are not monuments, is also influenced by the act of registration.

Once a building has been listed, conservation authorities have various legal instruments to impose additional duties on the owner.[66] It is not the purpose of this paper to present these in detail. It will suffice to mention that the owner of a listed immovable must: receive permission to convert the building for commercial uses (art. 25 PCM), inform the conservation authorities of danger or damage of the monument (art. 28 PCM), allow entry for purposes of scientific research (art. 29 and 30 PCM), obtain permission for any and all conservation, restoration or construction works (art. 36). Needless to say, in order to obtain the necessary permissions, the owner also has to prepare and maintain specified documentation.

The conservation authority has the power to enter and control the state of a listed building (art. 38 PCM), may suspend any conservation, restoration or construction works carried out in violation of or without the necessary permissions and demand that the monument be brought back to its previous state (43-45 PCM). Conservation authorities may also demand that the owner of a listed building carry out conservation works if this is necessary to protect the monument from destruction or substantial damage, order these works to be carried out at the cost of the owner, with the claim secured by a mortgage on the immovable (art. 49 PCM), or temporarily seize the immovable in order to prevent its destruction or substantial damage (art. 50 s. 3 PCM). In the latter situation, if removing the threat of destruction or substantial damage is not possible, the listed immovable may be expropriated by the State or the local authority of *rei sitae* (art. 50 s.4 point 2 PCM), according to the principles set out in the Management of Real Estate Act 1997 (MRE).[67] These principles involve administrative proceedings, which include mandatory negotiations. Only unsuccessful negations justify instigating formal expropriation, which is compensated on the basis of the market value of the immovable (see art. 112 *et seq.* MRE).

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[65] Jarosz-Zukowska, 'Konstytucyjne', p. 145-6

[66] Compare B. Ruszkiewicz, 'Ochrona nieruchomosci zabytkowych jako przyklad ingerencji Panstwa w sfere prawa wlasnosci [The protection of immovable monuments as an example of the State's interference in the right of ownership],' *Gdanskie Studia Prawnicze,* vol. XXI (2009), p. 108-13

[67] Act of 21 Aug. 1997, Dz.U.04, no. 261, item 2603, with subsequent amendments

The above illustrate, that registration of a monument is connected with substantial financial obligations. This is particularly true, if the building to be listed is in a bad state of repair, since after registration, the owner becomes automatically obliged to undertake at least the most expedient conservation works.[68] The owner is not, however, obliged to restore a historical building to a condition of full repair.[69] The Principal Administrative Court has emphasized that a decision to list a building must take into account all relevant circumstances and registration must be justified in the light of the constitutional principle limiting instances of permissible ownership restrictions.[70] Unlike in French law, where listing a building *ex officio* may be connected with the payment of compensation to the owner,[71] in Poland such instruments are not in place. However, owners of listed buildings may apply for financial aid either to the State or the local authority and obtain from 50% to 100% of costs connected with carrying out necessary conservation, restoration or construction works.[72]

As far as unlisted immovables are concerned, it is necessary to point out, that the conservation authority may suspend any conservation, restoration or construction work for up to two months if it is decided that the building in question shall be listed *ex officio* (art 46 PCM). Additionally, establishing a cultural park or providing protection through a local development plan will influence all owners of historical immovables, whether listed or unlisted. These instruments may introduce, within the relevant area, restrictions on permissible construction works, business activities, use of land, advertisements and shop-signs, etc (art. 17 PCM). The legislator does allow for compensation[73] if such limitations have caused restrictions on use and consequently a loss in value. Compensation is paid on the basis of a valuation report prepared by a certified real estate appraiser.

In this context it is important to note that the value of a historical building is very closely connected with its utility. The more useful a historical building will be to today's society, the more chances it has of surviving in a good state of repair. Utility is the best guarantee for the continued existence of historical buildings and sites.[74] Ones which are utilized by the owner and/or the community are

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[68] R. Pietruk, 'Obowiazki i prawa wlascicieli oraz posiadaczy zabytkow [The Obligations and roghts of owners and possessors of monuments],' in A. Gryszczynska, B. Koniczna (eds.) *Ochrona zabytkow militarnych Helu [The Protection of Military Monuments of the Hel Penninsula],* (Torun, Warszawa: TNOiK, 2006), pp.60-1

[69] Ibid., p. 63

[70] I SA 233/99, ONSA 2000/4/162 as cited by Jarosz-Zukowska, 'Konstytucyjne', 145-6 and Ruszkiewicz, 'Ochrona', 110

[71] Drela, *Wlasnosc,* p. 259

[72] M. Rymer, 'Rola jednostek samorzadu terytorialnego w systemie ochrony zabytkow – analiza wybranych problemow [The role of local authorities in protection of monuments – selected legal issues],' in A. Gryszczynska, B. Koniczna (eds.) *Ochrona zabytkow militarnych Helu [The Protection of Military Monuments of the Hel Penninsula],* (Torun, Warszawa: TNOiK, 2006), pp.34-5;

[72] M. Laczamanska, 'Ochrona nieruchomosci zabytkowych [Protection of historical immovables],' in H. Kisilowska (ed) *Nieruchomosci, Zagadnienie prawne [Immovables. Legal Issues],* (Warszawa: Lexis Nexis, 2009), p. 612-13

[73] Ibid., p. 29-30

[74] A. Kadluczka, 'Rewaloryzacja kamienicy mieszczanskiej – wartosc artystyczna, a wartosc uzytkowa w swietle pryncypiow konserwatorskich [Revitalization of urban tenement houses – artistic value and use value in the light of conservation rules],' *Rzeczoznawca Malopolski,* 5 (2009), 10

referred to as 'living' monuments,[75] although this term also has a more technical meaning and denotes monuments which are not ruins.[76] This principle is also expressed in the Venice Charter 1964,[77] where it is stated that:

- the intention in conserving and restoring monuments is to safeguard them no less as works of art than as historical evidence (art. 3), and
- maintaining monuments on a permanent basis is essential to their conservation (art.4).

Therefore the Charter emphasizes that the conservation of monuments is always facilitated by making use of them for some socially useful purpose. Such use, although desirable, must not change the lay-out or decoration of the building. It is within these limits only that modifications demanded by a change of function should be envisaged and may be permitted (art. 5).

This very delicate balance, between the necessary modifications and the need to keep the original features, makes a historical building a rather complex object to sell. The purchaser on the one hand, takes into account the use value, permissible modifications and their costs, but on the other hand is often 'seduced' by the artistic, historical, aesthetic value of the building and succumbs to its prestige against his better judgment.[78] Pre-emption rights of the of the commune (local authority) apply to a sale of a listed historical immovable, but only if this claim is entered in the land register kept for the immovable (art. 109 MRE). The sale of State or local authority immovable monuments is connected with a 50% reduction in price (art. 68 MRE). Still the market for historical immovables in Poland is a difficult one, since, as has been demonstrated above, their ownership is connected with numerous obligations and responsibilities. The latter quickly materialize, as most historical real estate on the market is in a bad state of repair and requires immediate action. Moreover, the Polish legislator provides one level of protection[79] regardless of the value and use of the monument in question. Frequently, this makes utilizing historical immovables of a lesser historical/artistic value unnecessarily difficult.[80] In contrast, the French have regulations providing different levels of protection.

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[75] For more on monuments' use value see K. Zeidler, 'Wartosci zabytku jako kategoria normatywna [Various values of a monument as a legislative characteristic],' in W. Szafranski (ed) *Wokol problematyki prawnej zabytkow i dziel sztuki [The legal issues concerning monuments and works of art],* vol. II, (Poznan: Wydawnictwo Poznanskie, 2008), pp. 45-6

[76] M. Laczamanska, 'Ochrona,' p. 593

[77] International Charter for the Conservation and Restoration of Monuments and Sites, International Council on Monuments and Sites, http://www.international.icomos.org/charters/charters.pdf

[78] M. Bogdani, P. Drelich, 'Wszystkie kamienice sa zabytkowe, ale niektore bardziej [All urban tenement houses are historical, but some more than others],' *Rzeczoznawca Malopolski,* 5 (2009), 55

[79] A similar solution is adopted in the Netherlands, see Lubina, 'Protection', 12; in contrast, the French have regulations providing different levels of protection depending on the clssification of the cultural good, see Dobrzyn, 'Ochrona,' 80 *et seq.*

[80] Zeidler, 'Wartosci,' 47

The public element in private ownership – concluding remarks

The Polish legislator refers to national heritage and cultural goods. Although the latter are often translated as cultural property, the term is closer to the French *les biens culturel* or the Italian *beni culturali*. The difference goes beyond the question of translation, as cultural goods are objects of proprietary rights. Placing emphasis on the object of the right, rather than the right itself is of paramount importance where objects of national heritage are concerned.[81] L.V. Prott and P.J. O'Keefe state, that the term 'cultural property' does not incorporate the duty to preserve and protect objects and other manifestations of cultural heritage,[82] and yet the very purpose of identifying this heritage is to pass it on to future generations. This requires restrictions to be imposed on owners of objects that form a part of national heritage, since it is " (...) unique and precious and it cannot be renewed."[83]

As can be seen from previous sections of this paper, cultural goods themselves 'demand' a more complex understanding of ownership. Regardless of whether the owner is a private or a public entity, the need to protect these goods in the interest of the society remains the same. Poland's history is particularly indicative of the fact, that there is no single category of owners, who will guarantee the proper protection and care of cultural goods. Private owners with no understanding of the limits of their right (which is not shaped as an infinite, absolute right) are just as undesirable as public owners (local authorities, the state), who have been known to utilize historical immovables for the benefit of their office, but without adequate protection or respect for the historical and artistic value.[84] Indeed, when public entities are owners (particularly the State or local authorities) there is a perceptible lack of a true economic interest, guarded by an active owner.[85] Additionally, this abstract organization functions within two spheres, namely the *imperium* and *dominium*, which may cause further misunderstandings concerning its role as an owner.[86]

Ownership is naturally associated with the right to exploit, alienate and exclude others and this is its most common, although distorted, perception.[87] Nevertheless ownership and property, apart from having an element of liberty, also have a public ingredient. As Chief Justice Waite noticed back in 1877: "When a person becomes a member of society, he necessarily parts with some rights or privileges

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[81] National heritage also encompasses elements, which are not material objects, but this paper concerns only material cultural goods, in particular historical immovables.

[82] L.V. Prott, P.J. O'Keefe, 'Cultural heritage or cultural property?,' *International Journal of Cultural Property,* 1 (1992), 307

[83] Preamble of the South African Heritage Resources Act 1999, for more see M. Beukes, 'A tug of war between heritage conservation and property rights: some success at last for heritage conservation – City of Cape Town v. Ouderkraal Estates (Pty) Ltd. [2007] JOL 20887 (C),' *International Journal of Cultural Property,* 16 (2009), 68 - 72

[84] Pruszynski, *Dziedzictwo,* 359 – 60 and J. Pruszynski, 'Ochrona prawna zabytkow nieruchomych [Legal protection of immovable monuments],' *Panstwo i Prawo,* 12 (1974), 80

[85] D.H. Cole, *Pollution and Property. Comparing Ownership Institutions for Environmental Protection* (Cambridge University Press 2002), p. 39

[86] M. Bednarek, 'Koncepcja wlasnosci w dobie transformacji ustrojowej w Polsce [The concept of ownership in an era of political transformation in Poland],' *Kwartalnik Prawa Prywatnego,* 4 (1993), 468

[87] Prott, O'Keefe, 'Cultural,' 310-11

which an individual not affected by his relations to others might retain."[88] Consequently, in all cases where ownership is affected by a public interest, the right is no longer purely private and therefore may be subject to restrictive regulation.[89]

Moreover, this public element is decisive in shaping the right of ownership, even when there are no specific legislative limitations. A particularly controversial matter concerns the image of a historical immovable. In Poland this issue has not been widely commented on,[90] but private owners of historical buildings (palaces, manor houses) have been known to claim exclusive rights to the image of their immovable. I personally know of a case (in early stages of litigation) in which a private owner of a palace is claiming a violation of his ownership by the local authority, which in an advertisement of the geographical area, showed an image of the castle. Although it should not be questioned, that a private owner has exclusive rights to his object of ownership and that he alone is entitled to take fruits it brings (e.g. income), he cannot exclude others from looking at and seeing an immovable, which is a part of the landscape, the urban setting, the general image of the city/village/rural area. His right of ownership should be viewed through the socio-economic designation contained in art. 140 PCC, and this corresponds with the historical building's function to be a part of a larger urban or rural setting. The public element in the right of ownership of a historical building is easily discernible and unless someone is using the image for commercial purposes, objections of the owners are unfounded. The issue becomes complex when one attempts to explain what commercial purposes denote. Showing a palace as part of the area of a given region should not be treated as such use, however selling postcards with that image may be a more delicate matter. Still I am of the opinion, that postcards with an image of a historical building that may be obtained by taking a picture when passing by or over (in a helicopter) the immovable do not violate the right of ownership, because privately owned historical immovables are a part of national heritage. If, however, these images are obtained when sightseeing or by trespassing, this would indeed be a violation.

Polish regulations concerning ownership and historical immovables do contain elements which clearly indicate the public element of this right. Due to past experiences, claiming that historical immovables are a type of public property, would do more harm than good, particularly since many of them had been damaged or brought to a state of a complete ruin, when the communist State exercised its public ownership. Instead of attempting to divide ownership into private and public, when in most cases the division is anything but clear, and choosing which is better,[91] it would be more constructive to view this issue from a different point of view. Communism has proven, that public is not a better option for

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[88] Quote taken from P. Kens, 'Liberty and the public ingredient of private property,' *The Review of Politics,* 55 (1993), 106-7 and his analysis of the dual nature of property in the case of *Munn v. Illinois* (1877)

[89] Ibid., 107

[90] See M. Drela, Wlasnosc, pp. 155 *et seq.*

[91] D.A. Krueckeberg, 'The difficult character of property,' *Journal of the American Planning Association,* vol. 61, issue 3 (1995), pp. 301-3

private, and democracy has shown, that private is not always a better version of public.[92] Common sense confirms, that security of property and ownership is not in opposition to acknowledging a public element in these rights, particularly if their object is unique, as is the case with historical immovables.

[92] Compare A. Gambaro, 'Public vs. private land property or complex regimes of rights on land,' in M.E. Sanchez Jordan, A. Gambaro (eds) *Land Law in Comparative Perspective,* (The Hague, London, New York: Kluwer Law International, 2002), p. 3, 6

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NEW FRONTIERS OF PHARMACEUTICAL LAW YOUNG RESEARCHERS WORKSHOP*: A SUMMARY

by

Francesco Panetti♦

The *Dipartimento di Studi giuridici* of the Università del Salento, Lecce, in association with *Opinio Juris in Comparatione* and the British Institute of International and Comparative Law (BIICL), Product Liability Forum, held on May 6th–7th, 2010 the Young Researchers Workshop "New frontiers of pharmaceutical law". The Workshop was intended to stimulate the debate and promote Young Researchers' ideas and work on pharmaceutical law topics such as ethical issues, market approval processes, civil liability (product liability and compensation schemes), antitrust and intellectual property. The discussion highlighted how this legal field, which originally stems from general principles of private and public law, is now experiencing a thorough process of specialization and partial isolation, only partially mitigated by the globalization of the pharmaceutical market.

This Workshop was opened by Dr. Duncan Fairgrieve, Director of the Product Liability Forum of the BIICL. Through the lense of comparative law (both horizontal and vertical), the speaker addressed the audience on the relationship between civil liability and *ex ante* regulation tools, highlighting the coordination problems that give rise to the risk development defense and US-style preemption in pharmaceutical law.

Stemming from these ideas, Marco Rizzi's presentation entitled "Regulating risks in pharmaceutical law: the need of an optimal interplay between products safety and products liability" opened the first panel of the workshop, dedicated to the connections between health regulation and policy. Rizzi called for a theoretical model of pharmaceutical products safety in which regulation and liability operate complementarily, as they are supposed to achieve the same goal of protecting consumers. He proposed a move forward from the traditional separation between public and private law (a suggestion that many other participants will share along the debate), and a reshaping of pharmaceutical law around the empirical necessities of patients. "Relevant knowledge" is deemed to be the key notion in this respect.

The analysis started with some comparative remarks about the divergences and similarities between the U.S. and the European drugs regulatory and liability regimes.

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♦ Scuola Superiore Sant'Anna, Pisa

As for the former, the discussant highlighted how the International Conference on Harmonization is trying to soften the differences between the two legal orders. However, a complete harmonization is still a long way off, and this is even more the case for tort law, because of the differences still existing between the European Member States legal regimes despite the implementing of the EC Directive no. 374/1985. To make an important example, U.S. do not apply the European concept of "development risk", but rather make reference to the vague notion of "state of the art".

In the second part of his presentation Marco Rizzi made the case for bridging a tighter link between regulation and product liability, and expressed his concern for the opposite direction that the U.S. legal system is rather taking in this respect. He showed how the "preemption" doctrine - that is the idea that FDA approval of labeling preempts conflicting or contrary State law - has been gaining momentum in the area of drugs litigation, at least until the 2009 U.S. Supreme Court decision in the case *Wyeth vs Levine* apparently – but not in the discussant's opinion – overruled it.

However, Marco Rizzi's claim was that both scenarios, the European and the American, still consider the two regimes separate rather than complementary. The discussant concluded by mentioning the Italian regime as an example of a system that might work properly in making them interact. Article 2050 of the Italian Code, in fact, seems to protect effectively consumers without unreasonably sacrificing the interests of the producers.

Starting from the influenza A H1N1 case, Anniek de Ruijter's paper gave a detailed insight of the role that public health policies play within the EU political and constitutional system. In particular, the Author highlighted the constitutional implications of the European response to the pandemic emergency, getting to the conclusion that Europe relied excessively on informal instruments of cooperation and denied parliaments a proper role of control, therefore violating the basic principles of a democratic order.

In the first part of her discussion, the Author described the creation of a European institutional system for the protection of EU citizens' health. The speaker started from the 1998 Treaty of Amsterdam reforming the EC Treaty Article 152, under which institutional networks for the surveillance and control of communicable diseases could finally be implemented. Always in 1998 the European Network for Communicable Diseases moved its first steps and ended up covering two main pillars: surveillance network and the European Early Warning and Response System, whose scope was alerting national health authorities in Member States whenever an international outbreak required European coordination. The last phase of the process was the extension of the Health Security Committee mandate (created in 2001 after the September 11th terrorist attack) to cover generic health emergencies and to prepare a united European response in case of a flu pandemia.

In the second part of the relation the Author addressed the history of the EU response to the 2009 pandemia, paying a more specific attention to how the European regulations on vaccines were adapted to the emergency, both from the point of view of the authorization procedures and product liability.

Finally, the legitimacy of the whole EU emergency procedure came into question. The informal structure of the Health Security Committee was deemed to violate the *rule of law* and democracy principles, as the Committee members, responding to the sole respective national health departments, had the power to create and propose extensive measures with an extreme impact on the lives of EU citizens without being subject to any effective legal constraint. As the Speaker pointed out, the same decision of declaring that a pandemic was ongoing was taken on the complete discretion of the Committee: neither the National nor the European Parliament could play any role in this respect. What is more striking, the European procedures in case of outbreak of communicable diseases might also seriously impact on citizens' fundamental rights: emergency measures might restrict the free movement of people and goods, and the exchange of information between national health systems might result into a violation of patients' right to privacy; even the decision to prioritize certain groups for vaccination might have constitutional implications with regard to the right to access health care. For all of these reasons, the H1N1 pandemic experience represents an important opportunity to reconsider the whole European response to epidemic threats.

Following Marco Rizzi's opinion, Francesco Quarta as well strongly advocated for a deeper involvement of private actors in monitoring the costs connected to drug prescriptions.

The discussant started from highlighting the tight connection that links drug costs to what is traditionally considered the main purpose of tort law, that is making the victim whole: tort victims, in fact, at least those resulting with health damages, are likely to use damage awards mainly to buy medicines or to cover other medical expenditures. Nonetheless, centralized systems like Italy *de facto* exclude private citizens from playing any role in the control of drugs costs; this is not the case in the US, where the Department of Justice incentives private parties to bring suits against drug companies whenever they detect anticompetitive conducts, such as raising pharmaceutical prices by promoting off-label use. What is more important, these so called "qui-tam" plaintiffs may be able to recover up to 25 % of the obtained proceeds.

Therefore, the Author assumed that these "Private Attorney General" actions might be profitably exported to Europe without any risk of violating the European legal tradition. He concluded by making the case for a complete reconsidering of the public/private divide, and expressing his hope that the democratic emergency that often brings Parliaments to outsource regulation to alleged "independent agencies" could rather be overcome by reconsidering the intersection of private litigation and public goals.

The second Panel of the Workshop, entitled "Specific issues in pharmaceutical law", was opened by Dr. Peter Feldschreiber from the MHRA, who gave an in-depth and thorough presentation on "Causality in medicine law" from the dual perspective of scientific and legal causation.

In the first paper of the session Isabelle Chivoret addressed the topic of causality in product liability cases, and used the French case law on damages deriving from vaccines against Hepatitis B as an example of how Courts might weigh scientific evidence differently in establishing causal connections between conducts and torts. The Author reported a contrast on the point between the French *Cour de Cassation* and *Conseil d'Etat*: while the first in 2003 relied on the absence of scientific certainty about the nexus between the vaccine and the disease to exclude the responsibility of pharmaceutical companies, the second used factual presumptions based on a case-by-case analysis to get to the opposite solution. The Author supported the position expressed by the *Cour de Cassation*, and expressed her belief that causation should reflect scientific knowledge and should not be based on purely empirical presumptions.

The public/private divide that was already at the centre of Francesco Quarta's analysis on "private attorney's actions" and Marco Rizzi's proposal on the regulation of risks in pharmaceutical law, came back to the fore with Francesca Ferrari's presentation dedicated to nanomedicine issues.

Francesca Ferrari's work addressed three main points: first, she explained what nanomedicine is and what kind of legal questions it gives rise to; second, she argued that nanomedicine is a typical situation where a precautionary approach is needed, and draw a comparison between this field and the European legislation on GMO (genetically modified organisms), arriving at the conclusion that the European system is overly grounded on regulatory functions; third, she criticized this solution as not taking into full account the necessity of a proper balancing between prevention and compensation in the social acceptance of the new risks.

The Author at first pointed her attention on the fact that, despite the new challenges connected to the practice, there is still no piece of legislation explicitly dedicated to nanomedicine on the European level. This happens because nanomedicine is incorrectly referred to as a new enabling technology and not as a new model of healthcare tool, without considering that nanoproducts are expected to blur the rigid distinction between drugs and medical devices. Moreover, even if the risks connected to the practice are still uncertain, this was not enough for Europe to adopt in this case as well, under the precautionary principle, the pre-market approval regulation already in force in the GMO field. The discussant's explanation for that was that nanomedicine issues cut across too many disciplines and industrial sectors, making it impossible to arrange a comprehensive set of specific rules. This means that nanomedicine is, and in the future is likely remain, regulated through dispositions already in place for other sectors, as long as they are sufficiently flexible to be adapted to its specificities. Is this the only possible solution? The Speaker replied with a clear no. What is missing here is a clear liability rule that

permits to overcome the risk that the development risk defence, under the EU Products Liability Directive, broadens too much its scope of action. The Speaker's conclusion was that precautionary actions cannot be reduced to a choice among different legal solutions, but should rather be seen as a complex framework that takes into account all the possible conflicts that might arise in the area.

Also addressing the general issue of regulation of uncertain risks, Albina Mulaomerovic focused on pharmacovigilance in Canada, noting the non-compulsory nature (at least for professionals) of this "phase IV". From a comparative perspective, she questioned whether such a voluntary practice is in line with other models (such as that of the EU), while advocating a revisiting of the federal law.

Opening the third panel dedicated to IP and Competition Law issues, Anna Lisa Bitetto's contribution dealt with the controversial practice of parallel imports in the pharmaceutical sector, that is, following the Discussant's definition, «the unauthorized distribution across borders of goods protected by intellectual property rights in the receiver nation».

Parallel imports present highly controversial features both from a legal and an economic perspective. EC law has traditionally contrasted firms trying to prevent parallel imports from distributors, as this is likely to result in a partitioning of the European market contrary to the principles set by the EC Treaties. Furthermore, it is unclear from an economic point of view whether parallel imports, by reducing prices for retail distribution, do actually enhance the welfare of consumers, or rather disincentivise R&D investments to their detriment. The Author gave short account of the different economic positions on the point and went on to make extensive reference to EC case law, and mainly to the *Bayer*, *Glaxo*, and *Syfiat* cases. Finally, the Author quoted an analysis on the economic impact of parallel pharmaceutical trade in the European markets, showing that there is no evidence of a "race to the bottom" of prices, but rather a "convergence to the top"; she concluded by signalling the importance of balancing incentives for innovation with free access to drugs, especially for the needs of underdeveloped countries.

Chiara Sammarco's work was focused on the effects of purchasing medicines through tendering procedures as a way to stimulate dynamic competition in the pharmaceutical market.

As can be gleaned from an Austrian Institute of Research survey on the topic, a significant number of EU members use tendering as a procedure for purchasing medicines. As for Italy, pharmaceuticals are purchased through public tenders in order to reach two goals: to ensure the needs of hospitals are met and to deliver drugs to patients in home care or discharged from hospitals. In both cases, the aim is to ensure the maximum availability of pharmaceuticals at the lowest price. The German case also deserves a more specific mention, as Germany is the only country where the public price of drugs is fixed by private companies and not by public regulatory entities.

The Discussant went on by mentioning the four factors that might be taken into account in order to make tendering in the pharmaceutical sector more efficient: transparency, maximum participation, attention to the composition of tender lots and to the sums awarded for contracts.

As for transparency, the Author highlighted the trade-off between enforcing non discriminatory procedures and avoiding parties to collude, as it might happen when the conditions offered are clearly stated and known to the other participants.

The composition of tender lots was deemed to represent the problematic core of the practice. Advice from the Italian Competition Authority (AGCM) suggested that tendering objects shall be neither expanded nor artificially restricted, and should be carefully designed in technical and economic terms but without making reference to any specific brand or patent (regarding the Italian case, some useful guidelines can be found in the case law, and mainly in a 2003 Emilia Romagna Regional Administrative Court decision[1]). The Speaker's conclusion on the point was that including in the same lot a homogeneous class of drugs does not represent the most appropriate tool in order to stimulate competition, as it might create all-inclusive and undistinguished containers of medicines with different efficiency and innovation potentialities.

Finally, the Discussant suggested that lowest price should not represent the only criteria for determining the award, especially for in-patent drugs, which require a thorough and extensive comparative selection.

Panel III ended with Antonio Del Sole's presentation entitled "The legal protection of biotechnological inventions". The Discussant focused his contribution on the EC regulations referring to the patentability of biotechnological inventions, by making a more specific reference to the EC Directive 98/44/EC and to the Directive Chapter II, covering "Scope of protection" issues. What is at stake here is whether a biotechnological genetic patent protects all the possible uses of the patented genetic sequence, or rather the sole specific purpose the patent was originally allowed for. The text of the Directive looks rather obscure in this respect, as Articles 8 and 9 and Article 5 seem to point respectively in the two opposite directions indicated above. However, in the Author's opinion Article 5 should prevail and therefore biotechnological patents should be kept "purpose-bound", as the AG conclusions in the case C-428/08, *Monsanto Technology LLC c. Cefetra BV and others* further confirmed. The opposite solution would be in contrast with what the Discussant called the "exchange principle" between the inventor and society, according to which the legal order protects (for a limited amount of time) the inventor's exclusive right on the patented product, and the inventor in exchange acknowledges to the scientific community the opportunity of studying and further implementing his discovery.

[1] TAR Emilia Romagna no. 549/2003.

A presentation from Dr. Agnese Querci entitled "Clinical trials on vulnerable human subjects" opened the fourth and last session of the Workshop, dedicated to "Professions and bioethics".

The starting assumption of the Discussant's analysis was that clinical trials should be differentiated according to parameters such as the ability of persons involved. Trials on people affected with mental or physical disabilities might therefore be problematic because of the patients' incapacity of expressing a free and informed consent; in the case of minors, consent might be given by the parents and the minor together, but a proper balance between the two seems hard to establish. However, the necessity to conduct such trials might still arise in emergency situations.

In this respect, the EC Directive 2001/20/EC allows the inclusion in clinical trials of incapacitated adults with the only condition of the legal representative's consent: the Italian d. lgs. No. 211/2003, instead, adds a "state of necessity" requirement (the therapy is needed in order to save the life or avoid critical damages to the person involved). Moreover, the long time that is needed to designate the guardian under Article 408 of the Civil Code further enhances the rigidity of the Italian solution. In the Speaker's opinion, another option would be listing by law those who can allow trials in case of emergency (consort or partner *more uxorio*, relatives) following the legislation on legal transplants. The cases of minors, pregnant women and vaccine testing should be regulated specifically. As a final remark, the Discussant restated the importance of letting patients freely express their consent to tests in the best possible way, without any undue psychological influence and not just in the absence of physical constrictions.

Luca Nocco and Benedetta Guidi focused their attention on the legal and medico legal aspects of the debate concerning the off-label prescription of drugs, that is «the administration of a registered medicine or medical device that is not included nor disclaimed in the product information». The two discussants' long analysis addressed a large amount of topics: among them, we remember the Italian case law regarding the doctors' professional autonomy, with a more specific reference to the liability issues connected to the prescription of drugs; the reasons that justify the off-label prescription of medicines; the so-called Italian "Di Bella" case; the Italian rules and procedures on off-label prescriptions; some comparative remarks between the Italian and the American case.

Off-label use of drugs is regulated in Italy by two pieces of legislation, law no. 94/1998 and law no. 244/2007. The two provisions are not easy to reconcile: the first requires off-label employments to be in compliance with common knowledge and scientific opinions, while the second adds the availability of favourable data deriving from phase two clinical experimentations. Recommendations from the Italian National Bioethics Committee make the point even more unclear: not only may a doctor be authorised, but he may even be bound to use off-label prescriptions in state of necessity, whenever there might be a realistic possibility of using therapies already known and accepted by medical science. The medical deontological code as well, in its last 2006 version, only states that non conventional

practices must be held under the direct professional responsibility of medical doctors. An expressed and informed consent from the patient is also generally required.

The Discussants moved on to describe the scarce Italian case law on the topic. According to a 1997 decision from the Private Law Division of the *Corte di Cassazione*, new therapies should be allowed only after careful clinical experimentations. However, in 2008 the Criminal Law Division tackled the issue more broadly, stating that doctors may be held liable for off-label prescriptions whenever they do not accurately evaluate the patient's physical conditions, and, what is more important, whenever they suggest treatments which are not useful in curing the specific disease they are called on to evaluate: the odd conclusion is that off-label treatments are allowed as long as they obtain better results than on-label ones.

As for the U.S. case, the Authors assumed that off-label prescription of drugs is generally acknowledged both by the Federal Drugs Administration and by the Courts. According to a widespread opinion, U.S. doctors are not even required to inform patients that treatment is off label, as failure to inform does not constitute malpractice in itself. In any event, doctors would not be held liable for failure to warn about any undemonstrated risks, even those they should have been aware of.

The conclusion is that the Italian system leaves far less freedom to physicians in prescribing off-label treatments. However, the Discussants' belief was that «freedom to prescribe drugs cannot transform itself in an unrealistic ambition, based on experimentalism and empiricism, with the tendency to lead to a culpable complaisance».

The fourth session continued with the Aurélie Mahalatchimy's presentation dedicated to issues regarding advanced therapy medicinal products (ATMP), that is to say medicinal products based on human genes, cells and tissues. The main scope of the analysis was to explore the problematic relation between the topic and the general bioethics principles, and more specifically to describe how the EU institutions, despite not being competent to regulate ethical standards as such, handle such controversial issues on a legislative level with the aim of creating a more complete political union.

The Speaker started from giving a detailed account of the European legal framework related to the topic. As medicinal products, ATMP are covered by the EC Directive 2001/83/EC, but also by the more specific EC Regulations no. 1394/2007 and no. 726/2004. Furthermore, the EC Directive 2004/23/EC regulates various activities connected to tissue and cells, such as their donation, procurement, testing and distribution.

The analysis went on by describing the ethical role the European Parliament tried to play during the process of adoption of the aforementioned Directives. In particular, some of the parliamentary amendments aimed at banning human cloning research, or at least to provide Member States with an explicit right to prohibit the use of particular cells, such as germ cells, foetal and embryonic cells.

Furthermore, the Parliament proposed that all uses of particular tissues and cells should respect some minimum quality and safety standards.

However, the Commission rejected most of the EP proposals, and especially the one on the prohibition of research of human cloning, as it supposedly felt outside the scope of the EC Treaty Article 152 on human health protection. As a consequence Member States are left with a wide action margin, which means that, according to the subsidiarity principle, States can prohibit every use of human tissues and cells, with the only limit being that legal measures shall not represent «*a means of arbitrary discrimination or a disguised restriction on trade between Member States*» (proportionality principle).

However, this is not to say that ethical aspects are completely out of the reach for the EU legislation. The main reference is to be made to the EU Charter of Rights and to the principle stated therein of human dignity, but also to the principles of voluntary and unpaid tissue and cell donations, consent, non profit basis of procurement of tissues and cells that are all expressed as recommendations in the Directive 2004/23/EC. Furthermore, ethical assumptions infiltrate binding and non binding norms indirectly related to ATMP, such as the decisions for the adoption of European support programmes for scientific and technological research, or even the Article 3 of the Directive 98/44/EC on the legal protection of biotechnological inventions, which denies the patentability of those products whose commercial exploitation would be contrary to the "public order" or "morality". The Speaker's conclusion is that the effect of such provisions should not be underestimated, as it is likely to play an important role in what she called the European "governance by dominium".

Some interesting comparative remarks with the Italian case described by Luca Nocco and Benedetta Guidi can be taken by Francisco Miguel Bombillar Saenz's paper about the Spanish legislative regulations on the "compassionate exemption" in the use of drugs.

The formula refers to three different medical treatments that may save the life of patients suffering from severe diseases and not having a satisfactory therapeutic alternative: *a)*, "compassionate use" of drugs, that is using drugs in the clinical research stage even without being part of the clinical trial; *b)*, "foreign drugs", that is access to drugs approved in other countries other than Spain; *c)*, "off-label" use, that is access to drugs used in conditions other than those provided in their data sheet. The three practices are now covered by the Spanish Royal Decree 1015/2009, enacted in June 2009 with the aim of speeding up procedures and guaranteeing safety to patients. Until that moment, Spanish patients in the above-mentioned condition had to follow a long and painful three-steps procedure: after they had given their informed consent to the treatment, the doctor, the Centre Director and the AEMPS (the Spanish Medicines Agency) were competent to approve or refuse the compassionate use for every single case, each of them repeating evaluations that, in the Author's view, should have been left to the patient's discretion (e.g. the benefit/risk connection of a given treatment). The new legislation, instead,

provides patients with two different and patient-friendly procedures: individual access authorizations and temporary use permits.

The second appears as the most relevant option, as it exonerates medical centres from applying for individual clearances for each patient «*in cases of drugs that are at an advanced stage of clinical research* (…), *whenever it is planned to be used on a significant group of patients*» (article 9 RD 1015/2009), under the conditions established by the AEMPS. AEMPS is also entitled, under article 13 of the Decree, to use recommendations in the off-label use: in this respect, the Agency shall consider, between the other factors, whether the use «*entails a significant health care impact*», that is, as the Author critically pointed out, whether it increases public pharmaceutical expenditure.

Finally, the Author explained how the new automated procedures provided for the submission of applications will supposedly speed the process up further. He concluded by giving some remarks on the administrative law issues connected to the topic, paying a more specific attention on how patients might challenge a denial from the AEMPS under the doctrine of "legitimate interest".

News

Annonces

Noticias

Federazione Regionale Ordine
Medici e Chirurghi della Sardegna

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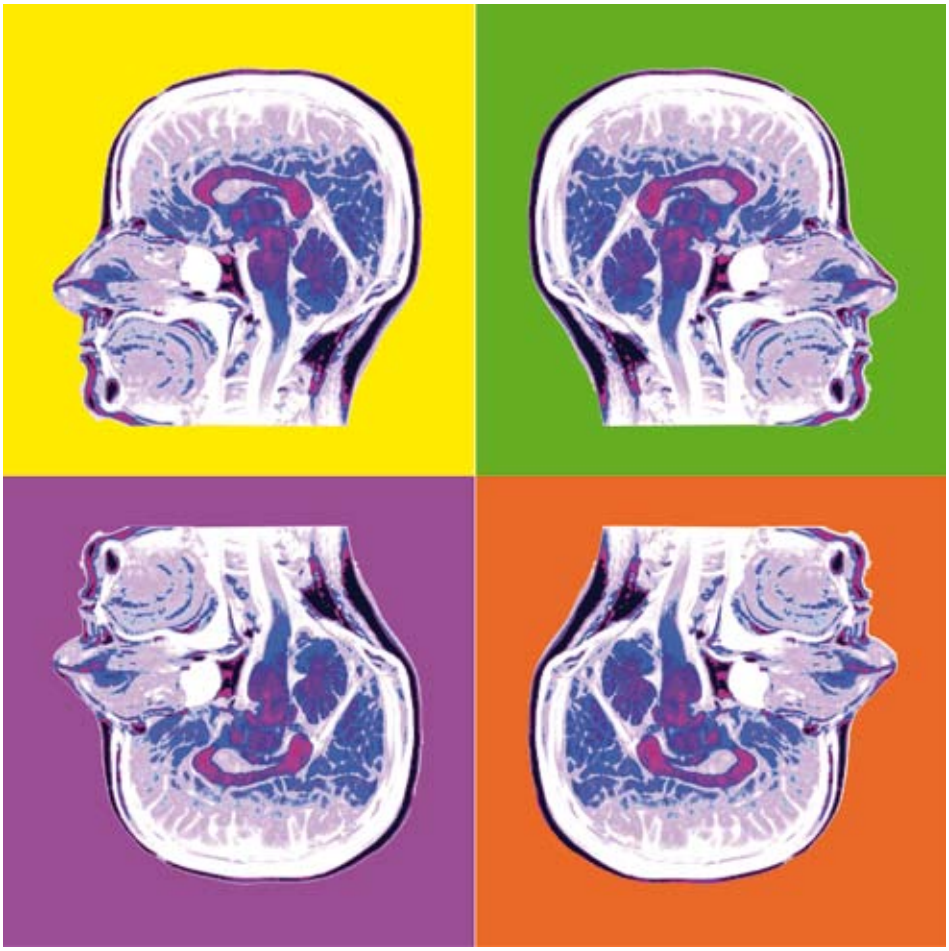
International Workshop

SU GOLOGONE SYMPOSIA

Lo stato vegetativo: evidenze scientifiche, dilemmi etici, filosofici e legali/*The Vegetative State: Medical Facts, Ethical, Philosophical and Legal Dilemmas*



Date: **5-6-7 October 2010**

Sede/Venue: Su Gologone Resort Oliena ****

Nuoro - Sardinia - Italy

con il contributo

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Mi piacerebbe condividere alcune riflessioni su come la bioetica promuove il dialogo tra le scienze e la cultura umanistica, parlando un po' del mio lavoro come medico-eticista che collabora con i neuroscienziati che studiano le gravi lesioni cerebrali e i meccanismi di recupero. Se avrò successo in questo viaggio da pioniere, lo spero, vi convincerò che le lesioni cerebrali possono insegnarci molto su noi stessi. E ciò non è qualcosa a cui ero preparato a credere come studente in medicina, quando ero più certo delle cose di quanto non sia ora.

"I would like to share some reflections on how bioethics fosters dialogue between the sciences and humanities by talking a bit about my work as a physician-ethicist collaborating with neuroscientists studying severe brain injury and mechanisms of recovery.If I am successful in this Pilgrim's Progress, I hope I will convince you that the injured brain can teach us much about ourselves. It is not something I was prepared to believe as a medical student, when I was more certain of things than I am now."

Prof. **Joseph J. Fins**

Chief of the Division of Medical Ethics at Weill Cornell Medical College Professor of Medicine, New York USA

Chairman

Dr. **Luigi Arru**
Presidente OMCeO Nuoro & Chairman FNOMCeO center for research and studies on medical profession Italy

Scientific Committee:

Dr. **Aldo Amantini**
Former Member Società Italiana Neurofisiologia Clinica Firenze Italy

Dr. **Amedeo Bianco**
President FNOMCeO Italy

Prof. **Remo Bodei**
Professor of Philosophy University of California Los Angeles

Prof. **Francesco Busnelli**
Professor of Civil Law, Professor at Scuola Superiore di Studi Universitari e di Perfezionamento S. Anna of Pisa - The European Group on Ethics in Science and New Technologies, Italy

Prof. **Carlo Casonato**
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Prof. **Giovanni Comandé**
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Prof. **Steven Laureys**
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Centre for Biomedical Ethics and Law – Professor Medical Law Leuven Belgium

Prof. **Paolo Vineis**
Chair in Environmental Epidemiology Imperial College London UK

Dott.ssa **Anna Ticca**
Director Dept. Neurology ASL 3 San Francesco Nuoro

Special thanks to Julie Wilkinson of Manchester Metropolitan University

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Ordine degli Avvocati di Nuoro

Scuola Forense
di Nuoro

5 ottobre 2010 - Day 1

15.00 **Saluti benvenuto/*Greetings and welcome***

Saluto Autorità

Amedeo Bianco
Presidente FNOMCeO Italia

Luigi Arru
Presidente OMCeO Nuoro - Coordinatore Centro Studi FNOMCeO Italia

Giovanni Comandé
Professore Diritto Privato Comparato Scuola Superiore Sant'Anna Pisa Italia

Delimitare le frontiere: aspetti medici ed etici dei pazienti in stato vegetativo/Mapping the field: medical and ethical aspects of PVS

15.30 **Quali evidenze in medicina e loro interazione con l'etica/*Questioning evidence in medicine and its interaction with ethics***

Paolo Vineis
MD, MPH, FFPH Chair in Environmental Epidemiology, MRC/HPA Centre for Environment and Health School of Public Health Imperial College London, UK

16.00 **L'esplorazione dello stato di coscienza mediante metodiche di RMNf/ *Using fMRI to detect conscious awareness***

Adrian Owen
MRC Cognition and Brain Sciences Unit; University of Cambridge, UK

16.30 **È possible modificare la prognosi delle gravi cerebrolesioni acquisite? /*Can we modify the prognosis of severe brain injury?***

Cesare Vittori
Coordinatore Neuro-SIAARTI - Direttore Neuro Anestesia e Neuro Rianimazione Università di Siena, Italia

17.00 **Discussione/*Discussion***

17.30 **Pausa/*Break***

18.00 **Valutazione comportamentale dei disturbi cronici della coscienza: obiettivi, standard e limiti/ *Behavioral Assessment of Disorders of Consciousness: Aims, Metrics and Limits"***

Joseph T.Giacino
PhD, FACSM,
Director of Rehabilitation Neuropsychology, Spaulding Rehabilitation Hospital/ Harvard Medical School, Boston, MA, USA.

18.30 **L'errore diagnostico nei disturbi della coscienza: un problema irrisolvibile?/*Misdiagnosis in DOC: an insoluble problem?***

Aldo Amantini
Servizio Neurofisiopatologia Azienda Ospedaliera Universitaria Careggi, Firenze - Italia

19.00 **Discussione/*Discussion***

6 ottobre 2010 - Day 2

Preparando il terreno: problematiche legali, mediche ed etiche/ Tilling the ground: legal, medical, and ethical conundrums

9.30 **Disturbi della coscienza: una nuova classificazione basata sul neuroimaging funzionale?/*Disorders of consciouness: a new classification based on functional neuroimaging?***

Steven Laureys
Department of Neurology Liège University. Hospital Head, Coma Science Group Senior Research Associate, Belgian National Funds for Scientific Research Cyclotron Research Centre University of Liège Belgium

10.00 **Aspetti giuridici del fine vita tra natura e artificio /*Legal aspects of an end of a life between the natural and the artificial***

Francesco Busnelli
Scuola Superiore di Studi Universitari e di Perfezionamento S. Anna of Pisa - The European Group on Ethics in Science and New Technologies, Italy

10.30 **Storia Naturale dei disturbi cronici della coscienza/*The Natural History of chronic disorders of consciousness***

Anna Estraneo
Unità di Neuroriabilitazione per Disordini della coscienza - Fondazione Salvatore Maugeri – IRCCS – Telese Terme

11.00 **Discussione/*Discussion***

11.30 **Pausa/*Break***

12.00 **Quando, come e perchè lo stato di coscienza è moralmente rilevante: esempio dal danno cerebrale/ *When, How and Why Consciousness Morally Matters: Examples from Brain Damage'***

Guy Kahane
Deputy Director, Oxford Uehiro Centre for Practical Ethics and of Oxford Centre for Neuroethics, Philosophy Faculty, University of Oxford UK

12.30 **Meccanismi neuronali alla base del recupero spontaneo e "indotto" dello stato di coscienza / *Common circuit mechanisms underlying spontaneous and induced recovery of consciousness"***

Nicholas D. Schiff
M.D Director of the Laboratory of Cognitive Neuromodulation Associate Professor of Neurology and Neuroscience? Weill Cornell Medical College New York USA

13.00 **Discussione/*Discussion***

13.30 **Pranzo di lavoro/*Working lunch***

15.00 **Aspetti di fine vita in una prospettiva comparativistica /*End of life issues: a comparative view***

Carlo Casonato
Diritto Costituzionale Comparato Università Trento (Italy)

15.30 **Quali cure palliative per i pazienti in stato vegetativo?/*Which palliative care for vegetative state patients?***

Danila Valenti
Direttore Hospice Maria Teresa Chiantore Seràgnoli Bologna, Vice presidente Società Italiana Cure Palliative Italia

16.00 **Aspetti di fine vita: rifiuto e rinuncia ai trattamenti e obblighi del medico/** ***End of life issues: refusal and withdrawal of treatment and the duty of the physician***

Andrea Nicolussi
Ordinario di Diritto Privato – Università Cattolica del Sacro Cuore di Milano - Comitato nazionale bioetica

17.00 **Discussione/*Discussion***

17.30 **Pausa/*Break***

18.00 **Alla ricerca della coscienza come diritto civile: lezioni dall'estero/** ***The Pursuit of Consciousness as a Civil Right: Lessons from Abroad.***

Joseph J. Fins
Chief of the Division of Medical Ethics at Weill Cornell Medical College Professor of Medicine, New York (USA)

18.30 **Neuroimaging e la sospensione dei trattamenti di sostegno vitale nei pazienti in stato vegetativo/** ***Neuroimaging and the withdrawal of life-sustaining treatment from patients in Vegetative State***

Adrian Owen dialoga con / *discuss with* Hon.Justice **Barkett** *and* Hon.Justice **Ann Power** *and* Hon.Justice **Amedeo Santosuosso**

Moderatori/*Chairmen*

Ernesto D'aloja
Istituto Medicina Legale Università di Cagliari, Italia

Giovanni Comandé
Scuola Superiore Sant'Anna Università Pisa, Italia

19.30 Discussione/***Discussion***

7 ottobre 2010 - Day 3

Stati di coscienza e processi decisionali: dentro o fuori le aule del tribunale?/States of consciousness and decision-making: in or out of the courtroom?

9.00 **"Stati di coscienza: aspetti cognitivi ed etici"/*State of consciousness: cognitive and ethical issues***

Remo Bodei
Professor of Philosophy University of California Los Angeles, USA

9.30 Indicazioni per uso appropriato dell'idratazione nutrizione artificiale: principi fondamentali e raccomandazioni/***Appropriate Use of Artificial Nutrition and Hydration - Fundamental Principles and Recommendations***

Maurizio Muscaritoli
Professore Associato di Medicina Interna Dipartimento di Medicina Clinica dell'Università La Sapienza di Roma - Former President SINPE

10.00 **Sospensione dell'idratazione e nutrizione artificiale in pazienti in stato vegetativo persistente: leggi europee attuali e proposte per il futuro/*Terminating artificial nutrition and hydration in persistent vegetative state patients: Current and proposed European laws***

Herman Nys
Centre for Biomedical Ethics and Law – Professor Medical Law Leuven Belgium

10.30 **Discussione/*Discussion***

11.00 **Pausa/*Break***

11.30 **Dal caso di Karen Quinlan a Eluana Englaro: I pazienti in stato vegetativo e la giurisprudenza/ *From Karen Quinlan to Eluana Englaro: the vegetative state patient in the courts***

Moderatori/*Chairmen:*

Ernesto D'aloja
Istituto Medicina Legale Università di Cagliari, Italia

Giovanni Comandé
Scuola Superiore Sant'Anna Università Pisa, Italia

Relatori/*Speakers:*

Rosemary Barkett
Hon. Justice, U.S. Court of Appeals for the 11th Circuit

Ann Power
Hon. Justice, European Court of Human Rights

Amedeo Santosuosso
Consigliere presso la Corte d'Appello di Milano

13.00 **Discussione/*Discussion***

17.00 ***Theatre session with jazz interludes.***
(Concerto organizzato in collaborazione con Ente Musicale di Nuoro)

Quodlibet

Consciousness, awareness, conscience in the vegetative state: tentative interdisciplinary dialogues

Coordina/*Co-ordinator:* **Giuliano Giubilei** *Vicedirettore TG3*

Partecipano/***Participants:***
Giurista/*Jurists:* **Giovanni Comandé**
Filosofo/*Philosophers:* **Remo Bodei**
Medico/*MD:* **Aldo Amantini**
Politico/*MP Senator:* **Ignazio Marino**
Politico/*MP Senator:* **Giuseppe Saro**

Segreteria organizzativa/*Organizing Secretariat:*

Kassiopea Group, Via Mameli 65, 09124 Cagliari
Tel +39 070 651242 fax +39 070 656263

Iscrizioni/*Registration:*

simonacasu@kassiopeagroup.com

Quota d'iscrizione/*Registration Fee:*

Euro 250 *(IVA inclusa/VAT included)*

Per ulteriori informazioni inerenti la registrazione e la prenotazione alberghiera si prega di contattare la Segreteria Organizzativa Kassiopea Group o di visitare il sito web: **www.kassiopeagroup.com**
For detailed information regarding registration and hotel booking please visit our website www.kassiopeagroup.com or contact us directly.

Sede/*Venue:*

Su Gologone Resort Oliena **** Nuoro - Sardinia Italy
http://www.sugologone.it/

Su Gologone é situato ad un ora di macchina dall'areoporto di Olbia e a 2 ore dagli Areoporti di Cagliari e Alghero. Un servizio navetta sarà disponibile a tariffe speciali per gli iscritti al Symposia.
Sardinia is reachable from the main european and italian airports. Su Gologone is one hour from Olbia Costa Smeralda Airport. and 2 hours from Cagliari Elmas (South Sardinia) and Alghero Airport (North East). A shuttle service with special fees is granted to all workshop partecipants from the main sardinian airports.

Hotel Accommodation:

Hotel Su Gologone**** tel. +39 0784 287512
Hotel Sandalia*** Via Einaudi, 14 Nuoro +39 0784 38355
Euro Hotel*** Via Trieste 62, Nuoro +39 0784 34071
Hotel Paradiso*** Via Aosta 44, Nuoro +39 0784 232782

The official carrier is: Meridiana

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grafica: luigi manca

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