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Paper n. 1

JUDICIAL EQUITY AND THE "MILD" ETHNICISATION OF ITALIAN LAW

by

Raffaele Aveta

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JUDICIAL EQUITY
AND THE "MILD" ETHNICISATION OF ITALIAN LAW

by

Raffaele Aveta♦

Abstract:

The article examines the recent changes occurred in the Italian legal framework, after the bursting of ethnic and multicultural factors. In particular, the reflection is focused on the action of the judicial power, which, when called upon to resolve a wide range of practical disputes, has demonstrated a remarkable aptitude for recognising the "thought of difference" in the regulation of inter-subjective relationships. This hermeneutic procedure has indeed turned out to be a valuable instrument in reinterpreting traditional legal categories and transcending the mechanical application of private international law, plugging normative gaps.

In the Italian system it is possible to identify three main ways in which culturally-sourced law enters the judicial system: the subjectivisation of the *regula iuris*; the commixture/linking of institutes and/or legal categories; and the valorisation of extra-normative elements. The relationship between these channels of communication is particularly complex and does not follow a general rule, inasmuch as the relative constitutive factors often overlap, giving way to a variegated record of case histories. These different means of communication seem to be informed by a single principle, general in character, capable of acting as a fluidifying agent in the choice of the solution most fitting to each individual case: the principle of reasonable equity. The approach and encounter between equity and reasonableness generates a structure of interpretative solutions which are suitable for the resolution of the many issues in pluralistic society within the unity of the system. The analysed case laws are illustrative of this tendency and lay the foundations for the construction of a full-blown model for the governance of multiculturalism in Italy. Thanks to its proper qualities, this model is distinguished from those of other European nations and contributes to a process of "mild ethnicisation" of the Italian judicial system.

Key words: multiculturalim - immigration law - judicial equity – equity – ethnicisation - italian law - immigration - principle of reasonableness - public order – repudiation - family law – islam - cultural defense - equality of treatment – minorities - cultural rights - intercultural democracy - human rights

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1. Introduction 2. The subjectivisation of the *regula iuris* 3. The co-mingling / linking of institutions or legal categories 4. The evaluation of extra-normative elements 5. The misguided understanding of justice 6. The reasonableness of distinctive criteria 7. Equality of treatment between co-nationals and foreigners 8. The grounded "creolisation" built into the Italian model and the role of comparative law

Introduction

1. In recent years Europe has seen a significant rise in immigration from outside the EU. Men and women coming from diverse geographic and sociocultural contexts have brought to European society customs and habits different from those of the majority of the existing population. The eruption of new cultural factors onto a homogeneous scene underpinned by "shared and undisputed fundamental values"[1] drawn from the western tradition has generated significant changes in many aspects of social life. In certain areas, from the economy to culture, multicultural and multi-ethnic co-existence has formed the basis for valid reforms and has offered opportunities for reflection, enriching the European spirit of the new millennium. However, it has also provoked conflicts and opened up debates to which there are no easy answers, giving "new content to ancient questions of political and legal theory".[2]

The legal world has become a sensitive interpreter of these tensions, not only as a result of certain special legislative measures on issues related to multiculturalism, but also thanks to the actions of the judiciary which, when called upon to resolve a wide range of practical disputes, has demonstrated a remarkable aptitude for recognising the "philosophy of difference"[3] in the regulation of inter-subjective relationships. This hermeneutic procedure has indeed turned out to be a valuable instrument in reinterpreting traditional legal categories and transcending the mechanical application of private international law, plugging normative gaps.

In the Italian system it is possible to identify three main ways in which culturally-sourced law enters the judicial system: the subjectivisation of the *regula iuris*; the commixture/linking of institutes and/or legal categories; and the valorisation of extra-normative elements.[4] The relationship between these channels of communication is particularly complex and does not follow a general rule, inasmuch as the relative

1 F. Belvisi, *Società multiculturale, diritti, Costituzione. Una prospettiva realista*, CLUEB, 2000, p. 10.

2 See A. Facchi, *I diritti nell'Europa multiculturale. Pluralismo normativo ed immigrazione*, Editori Laterza, 2001, p. V. The author lists some of the most obvious issues under discussion: "from nationality to forms of political participation, from ownership and the guarantee of fundamental rights to the relationship between minorities and majority, between community and individual, between universalism and relativism, between positive law and traditional or religious norms".

3 "Philosophy of difference" defines that which, starting from the feminist currents at various levels and in different areas reassessed the identities of minority groups.

4 This tool is used mostly by the judges of the Court of Justice and the ECHR, but often with different outcomes when dealing with issues of identity. Observance of established mechanisms of interpretation and the need to reach compromises among different state guidelines sometimes prevents the High Courts of Europe from having complete freedom to manoeuvre.

constitutive factors often overlap, giving way to a variegated record of case histories. There is no lack of cases and rulings in which it is possible to note the use of all these infiltrating mechanisms running alongside the rights of immigrant populations.

These different means of communication seem to be informed by a single principle, general in character, capable of acting as a fluidifying agent in the choice of the solution most fitting to each individual case: the principle of reasonable equity. The approach and encounter between equity and reasonableness, both understood in a non-technical sense with reference to the equal balancing of interests and to their intrinsic justifiability, generates a structure of interpretative solutions which are suitable for the resolution of the many issues in pluralistic society within the unity of the system.

The cases illustrated in the following pages are illustrative of this tendency, and lay the foundations for the construction of a full-blown model for the governance of Italian multiculturalism. Thanks to its proper qualities, this model is distinguished from those of other European nations and contributes to a process of "mild ethnicisation" of the local judicial system, according to a pattern which currently appears decidedly to provide an alternative to the legislative power, but which in the medium- to long-term should influence "public policies" and the substance of parliamentary measures.

The many judgments handed down by the Italian courts on the reasonableness of distinctive criteria among co-nationals and foreigners confirm the presence in the Italian judicial framework of a principle of reasonable equity, by nature able to induce, through its pervasiveness, a phenomenon of judicial circulation among like-minded sectors.

2. The first analytical factor relative to the subjectivisation of the *regula iuris* has the greatest capacity to intersect with others while still maintaining its autonomy and individuality provided by the traditional "individualisation" in the law applied in a judiciary system inspired by Roman law. According to the classic dynamic of a trial, giving value to the specific elements of each particular case constitutes an ineluctable operational element in the hermeneutic method. The application of general rules to the multiplicity of cases suggested by normal practice passes for a subsumption of the concrete case under the abstract one, through the reconstruction of the event which is the object of judgement and of the qualifying elements of the action proposed by the parties. This procedure of "concretising" the law takes on new connotations in the resolution of problematic cases thrown up by cultural pluralism. The retrospective judgement on the constitutive facts of substantive law or on the fact of the crime is strongly conditioned by the analysis of those people who have some significance within the trial and by the identification of their individual profile.

Respect for individuals and for "culturally characterised" groups introduces into the logic of the trial a factor which could influence (much more than in the past) the assessment of facts and their legal status. Examples drawn from legal reports in recent years show many court cases in which judges, unable to

apply private international law, or not having precise criteria for linkage with foreign laws or practices, base the *ratio* of the defendant on the connotations of the person being addressed, while judgement based on factual matters is relegated to a complementary role.

The reversal of the fact-subject relationship, or attenuation of its traditional pattern, allows the court to reconstruct normative facts according to equitable profiles, which take into due account personal factors and identities of those involved in the trial.

The story of a young Rom woman is emblematic in this regard: she was discovered begging with her underage child.

The Italian Supreme Court has had recourse to subjective analysis in order to understand which law to apply, relegating the crime contested by the judge of first instance and by the Naples Court of Appeal from enslavement to domestic abuse[5]

The inability to reconstruct an objective element for a crime under article 600 of the penal code[6] (hereafter c.p.) in the reconstruction made by the Supreme Court leads to the identification of some causes of subjective exclusion: the parent-child relationship, the subject's ethnic community of origin and/or her conditions of economic marginality, the temporary nature of the begging from which are also evidenced considerations about the personality of the defendant. The judges assume in particular that begging restricted to certain hours of the day does not constitute "so complete a denial of the freedom and human dignity of the child as to suggest that it is in a state of complete servitude."

A probabilistic hypothesis also covers the possibility that the mother, after begging, "in the remainder of the day (...) takes care of her children, trying to adequately meet their needs and allows them to play and meet other children". The parental relationship seems to strengthen this argument, distinguishing the behaviour of the mother who (for reasons of cultural or economic hardship) is engaged in begging with the help of a child "from the conduct of those who buy a child or toddler and continuously use him/her for begging, collecting" their earnings, neglecting their needs and desires and using them "basically as a res from which maximum economic advantage should be gained".

The Court continues, in an *obiter dictum* which is not irrelevant to the proceedings, by saying that the boundary between the legitimate use of parental authority and its abuse appears rather tenuous in cases where "the demand for charity is a condition of traditional life deeply rooted in culture and mentality" of some ethnic communities, such as Rom people[7]. However, those who drafted the ruling indicate that

5 Court of Cassation, judgment no. 44516 of November 26 2008, Penal sect. V.

6 See art. 600 c.p.: "*Chiunque esercita su una persona poteri corrispondenti a quelli del diritto di proprietà ovvero chiunque riduce o mantiene una persona in uno stato di soggezione continuativa, costringendola a prestazioni lavorative o sessuali ovvero all'accattonaggio o comunque a prestazioni che ne comportino lo sfruttamento, è punito con la reclusione da otto a venti anni. La riduzione o il mantenimento nello stato di soggezione ha luogo quando la condotta è attuata mediante violenza, minaccia, inganno, abuso di autorità o approfittamento di una situazione di inferiorità fisica o psichica o di una situazione di necessità, o mediante la promessa o la dazione di somme di denaro o di altri vantaggi a chi ha autorità sulla persona* (…)".

7 Probably the judgment of the Court of Appeal would be been equally rejected, also without recurring to cultural factors. However, the use of such elements is noteworthy and is indicative of a trend which is taking place. In fact the cases, where the Italian courts firmly makes the rule subjective, are even more frequent. There are a lot of examples. A case which has

even in the case of culturally motivated conduct, criminal prosecution is unavoidable where it "jeopardizes fundamental rights guaranteed" by the Constitutional Charter. This mode of interpretation, based on the subjectivisation of the law, seems to be driven by the desire fairly to balance individual and social needs. Further, this approach makes it possible to avoid, (as with others issued in similar cases by the Italian courts) "an exasperated criminalization of the conduct of adults, whose condition is already well marked by social and economic marginality"[8] while simultaneously anchoring behaviour considered deviant for children, within the framework of domestic abuse.

Thus an equitable model takes shape, which is sensitive to social issues and is a substantial shift in the way criminal cases are considered under article 572 c.p[9], reintroducing under the concept of abuse "any action or lack of action that causes extensive suffering and distress to children"[10], regardless of the perception of the victim and of the intentions of those involved in their exploitation.[11]

The failure to analyse these two factors allows the relevant previous case law to be superseded,[12] avoiding the temptation to justify practices and behaviours that, although inspired by a different "perception of family morality",[13] affect the proper physical and psychological development of

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aroused a lot of clamour in the public opinion is that concerning the incident of the young Fatima, hit and maltreated by his relatives of Islamic faith for her behaviour considered not pursuant with the precepts of her family. The Court of Cassation, in this case, has confirmed the absolution of the respondent on the element ascertained by the Court of Appeal, "it did not subsist the entire proof that the violent behaviours were habitual (...) to the detriment of the daughter, but the proof of just three episodes in the space of the life. Moreover, these were all justified by the girl's behaviours, which were considered improper and thus not expressing the necessary requirement of "will, overcoming and content". The connection established between the violent behaviour and the worthiness, differently arguable, of the daughter's behaviours seems questionable at least. This kind of subjectivist justification is not found, for example, in a following judgment of the Cassation, which has considered configurable the maltreatment offence in family, even in cases where "the harmful acts" have been alternated with periods of normality. In all probability, in the first judgment the Islamic familiar context has played a relevant role in the discharge of the respondents. For an analysis of the judgments: Court of Cassation, judgment no. 31510 of 2 October 2007, Penal sect. V; Court of Cassation, judgment no. 26571 of 27 June 2008, Penal sect. VI. A wary doctrine warns against a little cautious use of cultural factors by the judges and queries if this genre of reflections has "any utility or it is not a stone thrown into a quite enough muddy pond". On this point see: A. Simoni, *La qualificazione giuridica della mendacità dei minori rom tra diritto e politica*, in *Diritto, immigrazione e cittadinanza*, 2009, I, p. 99.

8 For a reconstruction of other relevant cases see M. Bouchard, *Dalla famiglia tradizionale a quella multietnica e multiculturale: maltrattamenti ed infanzia abusata in dimensione domestica*, in *Diritto, immigrazione e cittadinanza*, 2000, I, p. 19.

9 See art. 572 c.p: "*Chiunque, fuori dei casi indicati nell'articolo precedente, maltratta una persona della famiglia, o un minore degli anni quattordici, o una persona sottoposta alla sua autorità, o a lui affidata per ragione di educazione, istruzione, cura, vigilanza o custodia, o per l'esercizio di una professione o di un'arte, è punito con la reclusione da uno a cinque anni* (…)".

10 See the text of the judgment of the Court of Appeal, ruling no. 44516 of November 26 2008, Penal sect. V.

11 Previously, the Supreme Court identified as essential elements for the configuration of the crime of mistreatment "that the victim suffers an attack on her or his moral, cultural heritage, (...) the feeling of being unjustly harassed physically and morally which results in (...) a state of suffering resulting in humiliation, suffering, distress and feeling hated (...) an attack on moral heritage caused by vexatious intent or an attitude of contempt". See: the Court of Cassation, no. 11376 of 7 October 1992, Penal sect. I in *Giurisprudenza italiana*, 1993, II, p. 582.

12 The progressive toughening of Supreme Court's position on the exploitation of children in a multicultural context clearly emerges when recent judgments nos. 44516 of 2008 and 3419 of 30 January 2007 are compared. In the latter it is clearly stated that "offense against property protected by art. 572 c.p. comes about when the victim is caused to suffer (...). As to the subjective element, a specific purpose for the conduct of the offender is not required, only sufficient awareness and wilfulness such as to determine that the victim is in a state habitual and continuous suffering". These elements are deliberately neglected in ruling no. 44516 of 2008.

13 P. Morozzo della Rocca, *Stato di abbandono, ordine pubblico ed esercizi di multiculturalismo giudiziario*, in *Minori e Giustizia*, 2006, I, p. 7.

children.[14] The solution identified in ruling no. 44516 highlights how giving value to individual elements brings about the emergence of equitable interpretations which can adjust the regulatory framework to the real, subjective facts to be found in the case, without undermining the foundations of the system and while incorporating cultural facts into the choice of law suitable to the case in question.

3. Another way for the insertion of ethnocultural legal elements into the framework of Italian law is the *reductio ad unum* between legal categories of different origins. The phenomenon becomes very real when a judge is faced with case studies in which different legal orders interact and overlap. In the pursuit of applicable substantive law, the courts use connective criteria developed by private international law unless they determine to situations which conflict with the basic principles of the legal system. The article 16 of Law no. 218/95 rules on the inapplicability of foreign laws "if their effects are contrary to public order".

The difficulty of defining this concept, its content and its limits, is revealed as a central issue in multicultural contexts where "networks of legality"[15] conflict in their definitions of what is right, and situations of incompatibility/conflict between regulatory systems emerge with increasing frequency.[16]

In these circumstances, reference to traditional national legal schemata proves to be an effective tool of persuasion capable of leading the *quaestio iuris* and "eccentricity" of foreign models into the framework of state legislation. The adoption of this mode of interpretation, which is suitable for more frequent use within civil law, allows the re-definition of the same co-ordinates of the concept of public order and a limitation of the cases in which it can operate.

Some recent rulings in case law relating to matters "of an Islamic nature falling under national law"[17] confirm this adoption and bear witness to a cognitive process which is gradually moving away from a purely formalistic approach to the characterization of foreign institutions, and is adopting a method of "pragmatic" assessment of non-native legal categories, inspired by equitable considerations which can mitigate the impact on public order and redirect possible conflicts into the prevalent regulatory framework. The objective of ensuring the protection of the "vulnerable", primarily women and

14 In the Italian system there have been decisions of this type which have aroused lively debate in public and in the text books. There is well known ruling made by the court of Turin, which released the parents charged with the abuse of young Romanian gypsies who had been used for begging. The judge did not consider the case relevant to article 572 c.p. given that inducement to beg is not proof of abuse when "this happens in a context of family harmony and affection, in the absence of physical violence and in the moral framework of a joint effort for survival", so that - continues the Judge - "the child may well live through the begging without the suffering that the very idea of [begging] causes the average Italian citizen to imagine. The text of the judgment can be read in *Minori e Giustizia*, 1998, II, p. 165.

15 The expression is used by B. de Sousa Santos, *Toward a New Legal Common Sense*, Butterworths, 2002, p. 437, who identifies in legal pluralism and in interlegality one of the characteristics of our age where "a multiplicity of networks of law (...) require" individuals "to make constant transitions and transgressions."

16 On the concept of public order and its latest applications see: P. Lotti, *L'ordine pubblico internazionale. La globalizzazione del diritto privato ed i limiti di operatività degli istituti giuridici di origine estera*, Giuffrè, 2005.

17 R. Clerici, *La compatibilità del diritto di famiglia musulmano con l'ordine pubblico internazionale*, in *Famiglia e Diritto*, 2009, II, p. 198.

children is driving these guidelines which will ensure "a degree of freedom within reasonable limits for the continuity of the personal status of individuals"[18] and support the possible co-mingling of regulations.

In the case of a Moroccan *Kafalah*, for example, the analysis of the motivations within ruling no. 19734,[19] by which the Supreme Court[20] considered the institution of Islam to be a relevant factor for the purposes of reuniting families, shows not only an openness to a different cultural model, but also the willingness to ground it in the overall regulatory structure. In this particular case, given its exceptional nature, the Administration[21] had ruled out any possibility of analogous extension of article 29 of Legislative Decree no. 286/98.[22] In order to overcome this ruling, the Supreme Court judges could have appealed to international law and, in particular, to the New York Convention on the Rights of the Child, which recognises the *kafalah* as an adequate mechanism for the protection of abandoned children.[23] The legitimisation offered by article 20 would contend the automatic recognition of the relationship between *makfull* and *kafil* in the Italian legal system without need for further investigation.[24] Moreover and by the same token, adherence to the Hague Convention of October 5th 1961 requires Italy to recognize and apply "measures to protect minors in their country of residence",[25] except in cases where they are contrary to public order.

This kind of contrast must be "clear and deep enough to undermine the principles that govern the state itself, without issues of mere detail being allowed to become prominent".[26] The essence of the *kafalah*, which "meets the need to provide a family which is recognized as suitable for abandoned children,

18 See, R. Clerici, *La compatibilità del diritto di famiglia*, op. cit., p. 201.

19 This is the most recent judgment passed by the Supreme Court on *kafalah* following ruling no. 7472 of March 20 2008, with identical content. Recently the Court of Brescia (Decree of August 3, 2009) annulled the decision to refuse an entry visa for family reunification as requested by a legally residing foreigner for her nephew (or grandchild) entrusted to her under the *kafalah* act.

20 Supreme Court ruling no. 19734 of July 17 2008, Civil sect. I.

21 In this case it was the Ministry of Foreign Affairs.

22 Art. 29 of Legislative Decree no. 286/98 extends family reunification to the following relationships only: parent-child, adoption, fostering and guardianship.

23 Article 20, para. 3 which states: "1. Every child temporarily or permanently deprived of his/her family environment, or who, in its own interest, cannot be left in that environment, is entitled to special protection and assistance from the State. 2. Member States provide for such a child substitutive protection, in accordance with their national legislation. 3. Such substitutive protection may be expressed particularly by means of accommodation in a family, by *kafalah* of Islamic law, by adoption, or if necessary by placement in suitable children's institutions. In selecting one of these solutions full account will be taken of the need for some continuity in the child's education as well as his/her ethnic, religious, cultural and linguistic origin".

24 See for example the Juvenile Court of Reggio Calabria, judgment October 10, 2006, in *Famiglia e minori*, 2006, II, p. 86.

25 See: M. Orlandi, *La kafalah di diritto islamico e il diritto al ricongiungimento familiare: un interessante pronuncia del Tribunale di Biella*, in *Il diritto di Famiglie e delle Persone*, 2007, IV, p. 1860, which adheres to the analysis made by the Court of Biella in its ruling of April 26, 2007 that "the Convention in question, to have been fully implemented and translated into domestic law, finds for Italy the application of *erga omnes*, or irrespective of the foreign State's agreement". The ruling can be read in *Il diritto di Famiglie e delle Persone*, 2007, IV, p. 1823. Against the application of the Hague Convention of 1961 given that "Morocco is not a party to this Convention", see: R. Clerici, *La compatibilità del diritto di famiglia*, op. cit., p. 209, footnote 112.

26 Court of Biella, judgment of April 26, 2007, in *Il diritto di Famiglie e delle Persone*, 2007, IV, p. 1824.

without creating legitimate parent-child ties"[27] and the checks guaranteed by Moroccan law on the suitability of the *kafil* and the interests of the child[28] should "exclude, in the abstract and in essence, the possibility that the *kafalah* can be considered an institution in conflict with domestic public order".[29]

The adequacy of the *kafalah* as a substitute means of protection for abandoned children finds additional backing in the Hague Convention of 19th October 1996 on co-operation in matters of parental responsibility and the protection of minors. This Convention, "applicable to article 3, paragraph e) on measures relating to "*le placemént de l'enfant dans une famille d'accueil ou dans un établissement, ou son recueil légal par kafalah ou par une institution analogue*",[30] although not yet mandatory for Italy[31] requires, "as a matter of international law, not to preserve conduct contrary to it."

The reference to international treaties and a not formalistic reading of the rules on family reunification[32] could have allowed the Supreme Court to fully absorb the importance placed by the pursuant on the unsuitability of *kafalah* compared to other state institutions.[33]

The reconstruction made by the Supreme Court is, however, internal to the legal system and seems to underpin a clear desire to apply a "normalization" to the institution of Islam within the Italian legal system, identifying similarities with the mechanisms provided by national laws regarding child protection.

The directive of the "judge of the laws" (i.e. the constitutional judge) in the 2003 judgments nos. 198 and 295 is primarily about the protection of children as the supposed main interest, compared "to the defence of national territory and the containment of immigration".[34] With that in mind, the judges point out that a ruling which excludes *kafalah* as a protocol for reuniting families would "penalise (...) all children from Arab countries, illegitimate, orphaned or otherwise in a state of neglect for whom (...) it

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[27] Court of Biella, ibid, p. 1825.

[28] Moroccan law on *kafalah* provides for the Judge to oversee compliance with the interests of the child. Inspections by the Authority find no conflict with public order. According to the Supreme Court there is still room for doubt about the compatibility of Islam with Italian law only in cases where "*kafalah* is used exclusively for negotiation in the absence of any monitoring from the authorities on the suitability of the trustee and the reality for the need to entrust". On the distinction between judicial and consensual *kafalah* see: R. Gelli, *La Kafalah tra esigenze di tutela del minore e rischi di aggiramento della disciplina dell'immigrazione*, in *Famiglia e diritto*, 2008, VII, p. 679.

[29] Court of Appeal of Florence, Decree of February 2, 2007, in *Diritto, immigrazione e cittadinanza*, 2007, IV, p. 139. In this case, the Florentine Court emphasized that ratification by Italy, like Morocco, according to the New York Convention, excludes conflict with domestic public order. The potential paradox is highlighted in the textbooks: A. Vanzan e L. Miazzi, *Kafala e protezione del minore in Italia*, in *Diritto, immigrazione e cittadinanza*, 2004, II, p. 82; recently see: J. Long, *La Kafala: un risorsa sociale per i bambini e per le famiglie di religione islamica in Italia?*, in *Minori e giustizia*, 2007, II, p. 171.

[30] Art. 3 para. e of the Hague Convention of 19 October 1996. The quotation is taken from the Court of Biella, cit. p. 1826.

[31] The Convention signed by Italy and not yet ratified, is "intended to come into force in our system following the decision of the European Union Council of June 5, 2008 authorizing certain Member States to ratify the Convention." See R. Clerici, *La compatibilità del diritto di famiglia*, op. cit., p. 207.

[32] For a detailed reconstruction of the relevant case law see the ruling of the Court of Biella, cit. p. 1814.

[33] The Administration maintains that *kafalah* can lead to none of the relationships in art. 29 of Legislative Decree no. 286/98 (of parentage, custody, adoption and guardianship), given "its purely negotiatory nature".

[34] The Court rules out the circumvention of immigration laws given the "complex and multifaceted process of authorisation which (prior to the consular authority authorising the one-stop shop for immigration and visa issue) concludes with the issuing of residence permits for family reasons." On this point see: R. Gelli, *La Kafalah tra esigenze di tutela*, op. cit., p. 680.

represents the only institutionalised form of protection provided by Islamic law".[35] The *vulnus* on the principle of equality provides further evidence which can ensure adequate coverage of subsequent constitutional reasoning on the legal status of *kafalah*, located halfway between custody and adoption.

Further, the analogous extensibility of the rules laid down in article 29 of the Consolidation Act on immigration is necessary for the identification of typical characteristics of different institutions. Judges point out that the *kafalah*, shares with the national fostering system the absence of a legitimizing and other effects on the child's civil status; it also has, in common with Italian adoption law, a stability-giving characteristic inasmuch as "(although revoking is permitted), it extends until the child reaches adulthood".[36]

References and analogies in a pattern of debate and discussion have promoted compatibility between regulatory systems and dispelled the uncertainties and doubts that the Supreme Court had expressed a few years before in ruling no. 21395,[37] whose substantial scope - expressly remarked upon by judges - was limited to the particular trial[38] underlining *kafalah*'s elements of similarity and contiguity with pre-adoptive custody.

This further appeal to juridical categories which are well-known in the national tradition turns out to be a valuable source of complementarity which can forefront the needs of minors and "the substance of institutes over legal form via which these needs become apparent"[39]Comparative research remains, however, limited to the legal functions of the examined legal particles, regardless of their characterization and place in the context of the general principles of their respective laws. Further, the Supreme Court, unlike other European courts,[40] shows a total disregard for the verification of the compatibility of *kafalah* with the structural principles of family law procedure,[41] which constitute in several other countries, conversely, an insurmountable obstacle to the recognition of Islam where the reuniting of families is concerned.

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[35] Supreme Court, ruling no. 19734 of July 17, 2008, Civil sect. I.

[36] Supreme Court, ibid.

[37] Supreme Court ruling no. 21395 of November 4, 2005, Civil sect. I.

[38] On the express intention of minimizing the extent of ruling no. 21395 see: L. Miazzi, *Riconosciuta la funzione dell'istituto a protezione del minore*, in *Guida al diritto*, V, 2008, p. 45.

[39] Court of Biella, cit. 1822. M. Orlandi stresses the need to assert a fundamental approach in the comparison between institutions, La *kafalah di diritto islamico*, p. 1854, he writes "given the importance of children's rights which are at stake, a particularly rigid approach does not seem useful, nor is the formal verification of the exact correspondence between national and foreign institutes; it seems more appropriate to solidly test whether the foreign institutions produce substantially similar effects to ours." In executing this check there are errors and contradictions such as the assimilation of *kafalah* to adoption or pre-adoptive custody.

[40] With reference to the views emerging in various European countries see: MC. Foblets and A. Dundes Renteln, *Multicultural Jurisprudence*, Oxford and Portland Oregon, 2009; R.D. Grillo (et al.), *Legal Practice and Cultural diversity*, Ashgate, 2009; S. Aldeeb and A. Bonomi, *Le droit musulman de la famille et des successions à l'épreuve des ordres juridiques occidentaux*, Schulthess Polygraphischer Verlag, 1999.

[41] Amongst the relevant principles equality between spouses plays a central role. The vulnerability of the principle of equality between spouses is obvious when considering that the husband has the power to decide the establishment of *kafalah* for their children.

Indifference to this analysis allows a fair solution to be reached which can incorporate into state tradition a family model[42] of affection and solidarity for children from Arab countries who live in difficult conditions.

The recognition, made recently by the Cagliari Court of Appeal, of a divorce ruling made in Egypt under Islamic repudiation[43] law is based on the same assumptions of equality and "decontextualised comparison". The procedure, known as *talaq*,[44] which allows the husband to unilaterally dissolve the marriage[45] and symbolises the "discomfort that certain Islamic institutions feel towards western social conscience",[46] was declared effective within Italian law through the compression of the concept of public order.[47]

The notion, put forward to protect the complex of values "that characterise the fundamental ethical and social structure of the national community in a given time in history"[48] must - according to the Cagliari judges - be reduced to "its core," "to the principles that are really indefeasible and fundamental"[49] to the legal system.[50]

This core content cannot disregard the assertion of the essential rights of defence, as required by article 65 of Law 218/95. In the case here under review, the Court of Appeal emphasizes that repudiation ensures a safeguarding of the adversarial principle since, under Egyptian law, *talaq* does not qualify as "simply a monitoring process, in which the plaintiff is limited to express - in a purely assertive manner - his claim of dissolution, but is structured as a complex procedure, "in which the possibility for the wife to intervene ensures the irreversible dissolution (...) of the sharing of lives and affection between spouses, and regulates the economic rights"[51] of women.

Given these considerations, no element of conflict with public order arises in the Court, whose scope overrides the fulfilment of the requirements "of Egyptian law for the validity and irrevocability of the divorce".[52]

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[42] The traceability of *kafalah* within the family model has been recently highlighted by R. Gelli, *La Kafala di diritto islamico: prospettive di riconoscimento nell'ordinamento islamico*, in *Famiglia e diritto*, 2005, I, p. 62.

[43] Court of Appeal of Cagliari, ruling no. 198 of May 16, 2008. The ruling is available on www.immigrazione.it.

[44] In Egypt the procedure of *talaq* is regulated by law no. 125/1920 and subsequent amendments.

[45] For a reconstruction of *talaq* in the Islamic legal system see: F. Castro, *Il modello islamico*, Giappichelli, 2007.

[46] C. Campiglio, *Il diritto di famiglia islamico nella prassi italiana*, in *Riv. di diritto internazionale privato e processuale*, 2008, I, p. 43.

[47] The ruling seems particularly innovative. Previous Italian case law has in fact always ruled out the validity of a repudiation occurring abroad because it is contrary to public order. For an appraisal of relevant judgments see C. Campiglio, *Il diritto di famiglia islamico nella prassi italiana*, op. cit., p. 64.

[48] The public order which the court refers to is international public order, as distinguished from internal public order. For a discussion of the concepts see: F. Angelici, *Ordine pubblico e integrazione costituzionale europea*, Cedam, 2007 e P. Lotti, *L'ordine pubblico internazionale*, op. cit..

[49] The quotation in this judgment is taken from the Court of Appeal of Cagliari, cit.

[50] The Court highlights that "under art. 10 of the Hague Convention of June 1, 1970, which applies in this case, the State Party may refuse to recognise a divorce or separation only if they are manifestly incompatible with public order."

[51] The quotation in this judgment is taken from the Court of Appeal of Cagliari, cit.

[52] Court of Appeal of Cagliari, judgment no. 198 of May 16, 2008, para. 2.8.

Even the detailed description of the procedure of *talaq* seems designed with the objective of pointing out the similarities and analogies with the typical elements of a dissolution of marriage in the Italian system, noting, for example, the parallels between the effects of the repudiation declared only once by the pursuant and in the absence of his wife, with the "separation of bodies under western law".[53]

As with the *kafalah*, judges tend, in their reconstructions, to apply a "normalization" of Islam, abstracting it from all the general principles governing the law of "the *forum*" and giving substance to the concept of public order.

The legal system unanimously places in that category all "fundamental principles of the (...) Constitution or other rules which, while finding no place in it, nevertheless meet the need for basic and universal protection of human rights" or which govern the "regulatory order such that breaking them results in overturning the basic values of the entire regulatory structure".[54] This judicial process is very much in contrast with the silence of the Court on the compatibility of *talaq* with the principles of equality and non-discrimination "between the sexes and between spouses, which are derived from (...) the Constitution and numerous international instruments".[55] The Court of Cagliari's referral to the *khola*, which, under Egyptian law grants the wife the right unilaterally to dissolve her marriage, even without the consent of her husband, cannot be considered sufficient for the purposes of compliance with the principle of equality between the sexes. The procedure actually appears very different from the *talaq* and in any case infringes the rights of women[56] and violates "the principle which forbids the dissolution of marriage on the initiative of a free and unmotivated spouse"[57] present in the Italian legal system.

Thus the value judgment on how *talaq* conforms to the criterion of public order turns out to be extremely weak, highly decontextualised, and can be justified solely on considerations of equity concerning the situation of married couples (both remarried) and the children of the pursuant. The concern over avoiding "lame" situations, even those not emerging directly from the text of the

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53 In both cases the marriage continues and its effects still remain suspended.

54 The citation in this judgment is from: Supreme Court ruling no. 22332 November 26, 2004, sect.: work. For a complete overview of the case law on this point see: E. de Feis and F. Tomaseo, *Contrarietà all'ordine pubblico del divieto islamico di riconoscere figli naturali,* in *Famiglia e diritto*, 2007, XII, p. 1118.

55 R. Clerici, *La compatibilità del diritto di famiglia*, op. cit., p. 202. A. Sinagra also points out the contrast:, *Ripudio-divorzio islamico ed ordine pubblico italiano*, in *Il diritto di Famiglia e delle Persone*, 2007, I, p. 163. Respect for the principles of moral and legal equality between spouses has been used by Italian case law in other situations of conflict with Islamic law, as, for example, in the case of polygamy. On the not always happy results produced by this approach to the rights of polygamous women see: C. Campiglio, *Matrimonio poligamico e ripudio nell'esperienza giuridica dell'occidente europeo*, in *Riv. di diritto internazionale privato e processuale*, 1990, I, p. 63.

56 In this case, the woman has no right to reconsider and "the husband must return the dowry and other gifts that she had offered and is not entitled to any gifts of consolation, as happens in the case of *talaq*" See: A. Barbu, *Compatibilità del ripudio-divorzio islamico e ordine pubblico italiano*, on www.immigrazione.it. What distinguishes the two institutions is mainly the lack of motivation, while under *talaq*, the husband can dissolve the marriage without any explanation, for women dissolution is possible only in specific cases.

57 R. Clerici, *La compatibilità del diritto di famiglia*, op. cit., p. 202.

judgment, may have encouraged judges to allow the Egyptian decision on divorce to be transcribed (through a reductive interpretation of the concept of public order) into the register of the civil State.[58]
This approach undoubtedly opens an effective conduit between standards from different legal systems, but its replicability in the long term will in many cases depend on the ability of judges to find a reasonable balance between the need to promote the acceptance of a non-prejudicial vision of foreign institutions and the protection of individual rights.

4. The appeal to equity or rather to a fair balance between conflicting legal dynamics and values can lead to promoting the use of meta-judicial elements, traditionally unrelated to judicial decisions, in the judicial process.[59]
Sociological analysis, legal anthropology, ethnology, psychology and the history of religions are just some of the new disciplines that figure as complementary criteria in the formation of *ratio decidendi*; they often also figure as tools for giving direction and decision making.[60]
This sometimes fruitful, often extremely dangerous contamination finds its basis in the recognized and widespread need to preserve the cultural identity of individuals or, in the case of a crime being committed, in the opportunity to take into account (when imposing sanctions) of the influence on the subject of his/her original ethnocultural context.
Respect for the principle of equality does require the reconstruction of individual and collective profiles of the individual in order to give substance to the notion of equality.[61] This approach, popular in European courts, frequently results in the singling out of different legal *status* differentiated on an ethnocultural basis, with identification of fundamental "declinable" rights and the construction of pockets of unequal law which produce dangerous gaps in the legal framework. Promoting meta-judicial elements is in most cases the necessary logical precursor for these transformations. An interpretative trend, though difficult to reduce to a set uniform pattern, seems directed by a common ideological basis

[58] On the possible consequences of rejecting the application see: A. Barbu, *Compatibilità del ripudio-divorzio islamico*, op. cit., footnote 12.
[59] See: A. Facchi, op. cit, p. VII, who emphasizes that "the legal community is increasingly finding itself involved in cases in which they must deal with the compatibility between standards and behaviour of religious or community origin and governing legal regulations. It is no coincidence that the science of law, while maintaining the boundaries attaching to its methodological tradition, is extending its interests to phenomena outside state law, which until recently were left to sociologists of law, in order to search for concrete solutions to deal with the current social/legislative mix".
[60] It is a process that has some affinity with extra-systemic interpretation.
[61] A. Bernardi, *Modelli penali e società multiculturale*, Giappichelli, 2006, p. 41, appropriately highlights that "at national and international level, there seems to be a juridically founded process of coexistence through acceptance of details, through which what might be called 'the culture of diversity' or at least 'the idea of tolerance' becomes progressively stronger". Testifying to this are articles 3, 6, 19, 21 of our Constitution, articles 8, 9, 10 11, 14 of the European Convention on Human Rights and art. 2 of Protocol 1 thereof, articles 10 & 20-26 of the Charter of Fundamental Rights proclaimed in Nice". Through these laws, continues Bernardi, a kind of "right to diversity" gains substance, which tends to permeate of its own accord the very principle of equality". On the idea of a genuine right to cultural identity, see the recent: C. Ricci, *Diritti fondamentali, multiculturalismo e diritto alla diversità culturale: appunti a margine della Convenzione Unesco sulla protezione e promozione della diversità culturale*, in *Riv. I diritti dell'Uomo: cronache e battaglie*, 2007, I, p. 49.

which identifies, in its quest for equality, the teleological horizon of the solutions devised at jurisdictional level. This search for equality brings about different results, sometimes in line with fundamental rights, more often in conflict "with the principles and values accepted by international and domestic sources of law".[62]

An interesting example of the first case is provided by a recent ruling in the Court of Cremona which acquitted an Indian Sikh of the alleged crime of unlawful possession of a weapon and potentially harmful objects[63]: he had left his home with a traditional dagger used in the *kirpan*[64] ritual. In order to maintain an appropriate balance between the need for public safety and religious freedom, the Court has to evaluate the merit of the defendant's behaviour in light of the precepts and symbols present in the Sikh religion.

The obligation for the followers of Sikhism to wear the *kirpan* as a symbol of resistance to evil makes this conduct not punishable, insofar as it is considered lawful because it is a peculiar manifestation "communicative of religious identity"[65] The principle is then established that carrying in public an implement which in theory could be harmful to people, may not be considered an accessory to a crime if it constitutes a symbol which is religious in nature.

Article 19 of the Constitution which recognises "everyone's right to profess her or his faith freely in any form, individually or collectively, to promote it and to carry out its practices in private or in public, provided that the rituals are not contrary to good custom", guarantees, according to judges, an adequate regulatory support to the proposed solution; this is confirmed by the provisions of article 18 of the Universal Declaration of Human Rights[66] and article 9 of the law ratifying the Convention for the Protection of Human Rights and Fundamental Freedoms.[67]

In support of its line of argument, the Court of Cremona also cites ruling no. 30322, *Multani v. Commission scolaire Marguerite-Bourgeoys*,[68] pronounced by the Supreme Court of Canada which, addressing a similar issue, came to the conclusion that "the carrying of the *kirpan* within schools is considered as

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62 A. Bernardi, *Modelli penali*, op. cit., p. 43. The author refers to "radical forms of recognition" of cultural otherness "which could trigger dangerous reactions of social rejection" and a dangerous legal conflict with human rights.

63 The offence comes under art. 4 of Law no. 110/1975.

64 Court of Cremona, ruling of February 19, 2009. For an initial comment on the ruling see: G. Gatta, in *Osservatorio di diritto e processo penale*, in *Corriere del Merito*, 2009, IV, p. 399.

65 Court of Cremona, cit.

66 Art. 18 of the Universal Declaration of Human Rights states that: "Everyone has the right to freedom of thought, conscience and religion, this right includes the freedom to change religion or belief, and freedom of expression alone or in community, in public and private, to manifest one's religion or belief in teaching, practice, worship and observance of rites".

67 Art. 9 of the ECHR states: "1. Everyone has the right to freedom of thought, conscience and religion; this right includes the freedom to change religion or thought, as well as the freedom to manifest one's religion or thoughts individually or collectively, in public or in private, through worship, teaching, practices and performance of rituals. 2. Freedom to manifest one's religion or thought cannot be subject to additional restrictions beyond those required by law and are necessary in a democratic society for public safety, protection of public order, health or public morals or the protection of the rights and freedoms of others." The full text of the Convention can be read at: www.unhcr.it.

68 For a review of this case see: F. Astengo, *La Corte Suprema del Canada afferma il diritto di portare a scuola il coltello dei sikh*, at www.associazionedeicostituzionalisti.it. The judgment may be viewed at: http://csc.lexum.unmontreal.ca/en/2006/2006scc6/2006scc6.html.

per se allowable (surprisingly), showing how, in order to restrict a right protected by the Charter, the threat must be present and real (and not based on mere dislike or concern) and that the means chosen to limit it are proportionate to the pursued objective".[69]

The Italian judge highlights the way in which the Canadian solution "is based on the symbolic nature of the Sikhs' dagger, also stressing the background of the fundamental Canadian value of multiculturalism".[70] Respect for this sociological and philosophical theory (now part of the broad heritage of Western democracies) seems to permeate the subsequent statements of the judge who, in an *obiter dictum* worthy of particular interest, broadens the explanatory potential of the judgment well beyond the bounds of this case. Criminal unlawfulness within incriminating conduct is, for example, excluded, even in (hypothetical) cases where the object in question falls within the framework of article 699, paragraph 2 of the c.p. (illegal carrying of weapons), on the premise that the right guaranteed by article 19 of the Constitution is exercised under article 51 c.p. as a cause of justification.[71]

This potential ruling is perplexing because it appears to depict an exoneration based on exercising a right to "unlawful acts of a cultural nature"[72] that sets recognition of the so called cultural defences as standard. Unconditionally accepting cultural defences, something which has clearly grown alongside the importance of giving value to extra-normative factors in judicial reasoning, is undoubtedly the most dangerous result of multiculturalism. In the Anglo-Saxon world, where the theories were first developed,[73] the use of cultural exemption has generated quite a few practical issues of application.

The possibility of envisaging special treatments on an ethnocultural basis defines a clear divergence of legal systems which has serious consequences for their practical effect and stability. The circulation of cultural defences in continental Europe has given rise to the same difficulties. Their use in law, often without prior and proper doctrinal input, has encouraged offhand use and allowed the emergence of debatable solutions where the extra-normative, cultural element has caused all other technical and legal considerations to be overridden.

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[69] Court of Cremona, judgment of February 19, 2009. The citation of foreign criminal judgments, which is particularly innovative in the Italian legal landscape, is a direct consequence of the clash between constitutional rights, a conflict that fuels the possible duplicity inherent in the rules, forcing the court to resort not only to extra-normative measures, but also extra-systemic reasoning. For a discussion of the dissemination of extra-systemic reasoning in recent jurisprudence, see: S. Bartole, *Il ricorso al diritto comparato in tema di diritti umani, fra vincoli giuridici e mediazioni culturali*, in *Diritti umani e diritto internazionale*, 2007, II, p. 229; A. Lollini, *La circolazione degli argomenti: metodo comparato e parametri extrasistematici nella giurisprudenza costituzionale sudafricana*, in *Diritto pubblico comparato ed europeo*, 2007, I, p. 479.

[70] Court of Cremona, ruling of February 19, 2009. For the latest on the theory relating to Canadian multiculturalism: G. Gentili, *La dottrina canadese in tema di diritti*, in *Diritto pubblico comparato ed europeo*, 2008, IV, p. 1872.

[71] The Court of Vicenza by Decree of January 28, 2009 also acquitted an Indian Sikh who left his home with a dagger used in ritual: he had been charged with carrying objects intended to offend or carrying illegal weapons. In this case the G.I.P. closed the prosecution without "placing emphasis on the religious reason for carrying the *kirpan* dagger, but excluding it from classification as a weapon since it has no blade"

[72] A. Bernardi, Modelli penali, op. cit., p. 117.

[73] On this point see the important essay by A. Dundes Renteln, *The Cultural Defense*, Oxford University Press, 2005.

5. In Italy the acceptance of cultural defences is a very limited phenomenon, although there have been cases in which the analysis of extra-normative factors has favoured solutions "based on an attitude of great and extraordinary sympathy for certain offenses caused by cultural factors". There are some well-known judgments from the Courts of Turin, Venice and Naples on female circumcision, begging and abandoned children based on the Courts' beliefs concerning acquittal or disculpation on extra-legal grounds linked to the ethnic and cultural background of the accused.[74]

There is a tendency to the "equitable clemency", which, in some measures taken by the Italian courts, is openly expressed. In a decision taken by the Court of Genoa in November 2003 the author points out for example that: "in regard to crimes against the family, while parties who, by nationality and therefore by culture, religion, education and underlying values come from institutional and social contexts which are quite different from those of the host State jurisdiction to which they are subject, it is appropriate for the judge to raise questions over the possible influence of this background data on deeds committed in Italy; this in order to complete her/his knowledge of the objective and subjective elements that form the basis of her/his decision."[75] Such a shareable logical premise must, however, be properly pondered in order to prevent a misguided sense of justice from leading to the validation of practices and actions which, while having a defined cultural pattern, are not justifiable within the established regulatory framework. There are cases where the equitable powers of judges become elements of instability in the legal system, causing social conflict and complicating the development of legal mechanisms and values between indigenous and immigrant populations. In this sense, for example, it seems difficult to accept the ruling given by the Justice of the Peace in L'Aquila, condemning the behaviour of an Egyptian (Muslim) who had beaten and threatened an acquaintance who had taken advantage of his absence to talk with his wife.[76] In applying sanctions, the judge confirms that "s/he cannot ignore the personality of the accused, influenced by the culture of his place of origin (Cairo), and therefore that s/he can cite provocation as mitigation."

The granting of extenuating circumstances on the basis of a vague cultural disposition in the absence of a genuine cultural offense[77] constitutes an excessive emphasis on equity, which legitimizes offensive conduct which infringes personal rights and disproportionately broadens the scope of relevant factors in the proceedings. The general preventive function of criminal law turns out to be extremely weakened, and the principle of equality becomes distorted, laying the foundations for rendering

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[74] For a framework of the relevant case law see: F. Basile, *Immigrazione e reati "culturalmente motivati",* CUEM, 2008.

[75] For the full text of the judgment and a brief comment see: S. Sergio, *Il credo religioso va tenuto presente per le attenuanti generiche*, in *Diritto e giustizia*, 2004, XI, p. 89 e ss.

[76] L'Aquila Justice of the Peace, July 1, 2008, unpublished. From the findings of the proceedings it seems that the accused had complained about the misconduct of the assaulted person "who had entered his house when he was not there the day before (...)".

[77] On the reconstruction of the elements necessary to identify a cultural offense see: C. De Maglie, *Società multiculturale e diritto penale. La Cultural defense*, in *Studi in onore di Giorgio Marinucci*, Giuffrè, 2006, p. 226.

vulnerable other areas of basic, individual self-interest such as the right not to have one's body impinged upon.

Compared to artificial rights created by the system, it may appear easier to understand the attitude of bias towards ethnic minorities, or more generally, immigrants. An example of this is clearly shown in ruling no. 44048/08 of the Supreme Court which acquitted a Macedonian citizen accused of aiding and abetting illegal immigration by smuggling his twelve year old daughter into Italy.[78]

The Supreme Court did not consider the act to be a crime as it believed that the immigrant had acted out of necessity, to avoid abandoning his daughter in their country of origin.[79] This judgment is worth analysing because, while not directly involving the incriminated individuals' cultural profiles, it clearly shows two phenomena which are significant in relation to the subject of the investigation.

The first is about the mutation of the intrinsic characteristics of legal categories in the structuring of legal rights on a subjective basis, while the second involves the sensitive theme of the gradual assertion of rights which would otherwise be punishable, depending on the various individuals involved. With reference to the first phenomenon it can be observed how, in the case under review, the concept in article 54 c.p.[80] is used in ways which alter its traditional characteristics. Further, the case is relevant to some essential points which are also defined in article 2045 of the Civil Code: the "need to save one's self or others from real danger of serious personal harm", the unintentional nature of the alleged harmful event and its inevitability.

These last two items are difficult to trace in this case where the immigrant (although constrained by precarious economic conditions) voluntarily chose to leave his country of origin in a situation which can only potentially be described as inevitable. The transformation of "necessity" from the category of involuntary inevitability, the real scope of which should be established to protect all those individuals involved in court proceedings, to the category of abstract possibility, represents a significant innovation and a substantial alteration of a traditional legal *species*. This is one of many examples of flexible adaptation of Italian law to the variety of cases imposed by immigration law, a solution that unfailingly gives rise to doubts and misgivings. The "equitable clemency" has become, in the case under review, an instrument which can not only circumvent the rules for the protection and safeguarding of national borders, but above all which can determine different treatment for a crime, according to whether it is committed by co-nationals or by foreign immigrants. Abetting illegal immigration is thus no longer a

[78] Supreme Court ruling no. 44048 of November 26, 2008, Penal sect. I. The Macedonian citizen had already been acquitted by the Court of Trieste in 2007, but the prosecutor had appealed on the assumption that the father could have avoided the psychological damage to the child with "the decision to remain in Macedonia or leave his wife and child in the country of origin pending a new application for family reunification". For comment on ruling no. 44048 see: N. Folla, *Introdurre nello Stato il minore, in assenza di autorizzazione, non integra favoreggiamento dell'ingresso illegale se sussiste lo stato di necessità*, in *Famiglia e diritto*, 2009, IV, p. 366.

[79] The foreigner, with a regular job in Italy, had already been reunited with his wife and with one of his two children.

[80] Art. 54 c.p. establishes that "people are unpunishable, who are forced to commit a crime by the need to save themselves or others from danger of serious harm, danger that is not self-inflicted or otherwise avoidable, provided that the deed is commensurate with the danger (...)".

neutral fact: it loses its repressive character to become a case with subjective and humanitarian overtones. The alteration of the lawmakers' intentions is unequivocal, even if it has been brought on by the aim of escaping a literal interpretation of the regulatory apparatus which is overly burdensome to the foreign immigrant.[81]

In the same way, there are also many cases of preferential treatment based on extra-normative elements, non technical in character, such as in the doings described by the Supreme Court in 2001 ruling no. 42289 where a non-European witness's failure to report a rape is justified by her being one of a group of foreign nationals in a country which is not always friendly towards them".[82] This mode of judicial reasoning, regardless of the case under review, is very dangerous because it appears to be based on the firm conviction that different rights and duties may derive from different sets of values, even in situations negatively affecting the fundamental rights of the individual.

6. The Italian Supreme Court seems to be fully aware of the risks associated with the ongoing attribution of value to extra-normative elements in judicial reasoning and, in recent court rulings, it has ruled out the possibility of placing emphasis on the different connotations of individual agents in cases involving violence and abuse of authority in family relationships.

While cultural motives in particular are coming under analytical scrutiny in court, they are nevertheless subordinate to individual rights: any form of legal inequality between foreign nationals and immigrants is being rejected. The Supreme Court has made it clear that, especially in cases which have relevance to the constitution "the ethical and social traditions of those who are present on State-controlled soil (...) can only be practised only outside the ambit of influence of the penal system."[83]

Ruling no. 46300, December 2008, clearly and precisely reconstructs this directive and offers interesting ideas for a discussion aimed at understanding how Italian multiculturalism is taking shape with regard not only to criminal law but also to matters relating to civil law and private international law.[84] The case concerns a North African Muslim citizen, accused of abuse, kidnap, rape and violation of his family assistance obligations. The accused, in going to the Supreme Court, gave only one reason for escaping punishment: a violation of article 606, paragraph 1, section e of the c.p., given that the judge had

[81] P. Morozzo della Rocca, *Il diritto dell'immigrazione ed i malintesi sensi (degli obblighi) dell'integrazione*, in *Corriere Giuridico*, 2009, IV, p. 443, stresses "(...) if found guilty of the alleged crime, not only would the law impose a prison judgment on the parent, but, because of a questionable but sometimes implemented administrative practice, the revocation or refusal of the request for renewal of a residence permit may also be enforced under the combined provisions of art. 4, paragraph 3 and art. 5, paragraphs 4 and 5 of the Consolidation Act on immigration; the subsequent expulsion of the foreigner would result in very serious consequences for him/her and the family".

[82] Supreme Court ruling no. 42289 of November 26, 2001, Penal sect. III.

[83] Supreme Court ruling no. 179, May 29, 2009, Penal sect. VI. In this ruling, the Supreme Court reiterated that, especially in family matters, the principle of "compulsory use of criminal law: whereby those who are on State-controlled soil, whether co-nationals or foreigners, are bound by it" must always prevail.

[84] Supreme Court ruling no. 46300 December 16, 2008, Penal sect. VI.

"concluded penal proceedings on the basis of value assessments which were exclusively based on an ethnocentric bias, lacking in any motivation"[83] relating to the subjective element of the alleged offenses. The applicant considers in particular that his conduct should be seen "within the context of the concept of family which is typical of the social group to which he belongs" and should be disculpated, based on the notions that he, as a "citizen of the Muslim religion, has of family life and marital powers due to him as head of the household".[85]

The Supreme Court does not accept a defence based on the principle laid down in article 5 c.p. which, even when read with the interpretation dictated by the Constitutional Court, cannot be affected by special considerations and perceptions based on the merits or demerits of individual conduct. The Court also emphasises that the role of "cultural mediator that doctrine attaches to criminal judges" cannot be called upon in court and that "it can never be implemented outside of or against the rules which, in our system, set limits of permitted conduct".

The reference to fundamental rights under articles 2 and 3 of the Constitution is - in the opinion of the Supreme Court - an "impassable barrier against the introduction into civil society, either in law or in fact, of habits, customs and practices, which are antithetical to the history of the results achieved over the centuries in terms of the affirmation of inviolable, individual rights, whether the individual be a co-national or a foreigner". Quite apart from statements of principle, the drafters of judgment no. 46300 are at pains to suggest a tripartite schema intended for general use in cases of cultural or culturally-oriented crimes: (i) "looking after victims' rights" regardless "of whether or not they consent to the violation of rights considered to be inappropriate to them", (ii) "guarantees to the accused (..) in the search for truth and in applying the law" and finally (iii) "a personalised conviction (…) with sanctions to be sought and identified in accordance with the principle of the legality of judgments".

This wording allows for the adjustment of a punitive response to the specific needs of individual cases within a spirit of equity which has its grounding in the system produced by article 25 of the Constitution and with reference to a "case by case", "situation by situation" form of justice, described in the ruling as the "natural task of the judge". The individualisation of the judgment should nevertheless not be completely separated from an examination of the individual agent, including a possible assessment of extra-legal factors, while still remaining within the legislative system.

Achieving a balance between the objectivity of the laws and the subjectivity of the case is a matter for the judge's estimation, who must apply his/her equitable powers in a reasonable manner. Two very recent court decisions on the new crime of illegal entry and residence within the state seem to take inspiration from these premises, which testify to the penetration and diffusion within the Italian judicial system of a complex system of equity based on an individualisation of the law and gradualisation in its application, according to right reason. This system forms the basis not only of cases where Italian law is

[85] Ibid.

adapted to or in response to ethno-cultural law, but also constitutes a central mechanism in cases where there seem to be possibilities of inequality in law between individuals, classes or groups. Precisely by following this hermeneutic practice, a Justice of the Peace in Recco decided s/he should not apply the provisions of article 10 bis of Legislative Decree no. 286/98[86] to an illegal immigrant "because of lack of substance"[87] and because of the subjective conditions of the accused who was found to have no criminal record (…) and who was engaged in a legal, albeit irregular activity." The Ligurian judge in question based his reconstruction on article 34 of Legislative Decree no. 274/2000 which allows for the non-application of penal action when, "with regard to the interests to be considered, the little substance in the damages, or in the danger arising from it, as well as its rarity and the level of guilt" do not appear to legitimise the handing down of the usual sanction.[88] The arguments raised allow for the identification of a reasonable solution within the legal apparatus and on the basis of elements within the case, (i.e. an examination of the facts and the damages or the danger incurred) and subjective considerations.[89] Following the same line of reasoning, the Criminal Court of Pesaro also criticized the rule which places penal importance on the status of irregular migration, and asked the Constitutional Court to rule on its legality.

The fact underlying the Pesaro judge's action is the absolute inability to locate justifying elements, with a "legal-constitutional rationale",[90] in the innovation brought in by Law no. 94/2009 which, overriding the previously-established model of administrative expulsion[91], criminalises an individual situation beyond the committing of material acts. The reasoning is very simple: "the indiscriminate imposition of penal sanctions on foreigners who remain illegally on State-controlled soil arbitrarily assumes that they

[86] The new crime of illegal entry and residence in the territory of the Italian Republic was introduced by art. 1, c. 16 a) of Law no. 94/2009, published in the Official Gazette no. 170 of 24/07/2009.

[87] The quotations are from unpublished judgment given by Justice of the Peace of Recco, September 2009.

[88] Many authoritative commentators have stressed the danger that, by handing over the new offense under art. 10 bis of Legislative Decree no. 286/98 to the jurisdiction of a Justice of the Peace, the honorary character of the judiciary may be distorted and placed in conflict with its "conciliatory nature" and setting up "a subsystem of sanctions not consistent with general principles of law and with fewer guarantees than the established system for the crimes of illegal detention which are subject to the knowledge of the court". The quotation is from a letter sent by the Head of State to the Chairman of the Cabinet (Prime Minister) and the Presidents of the Chambers during the promulgation of the law on "Measures relating to public safety". The full text of the letter can be found at: www.federalismi.it.

[89] Equity is defined as a choice between rules within the system, rather than as an abstraction within a single rule of the best solution to the given case.

[90] Court of Pesaro, Penal sect. order of August 31, 2009, p. 7. The text of the ordinance is from www.immigrazione.it.

[91] In an appeal a few days before the approval of new rule 22, prominent jurists pointed out, among other things, how the introduction of the crime of illegal entry and residence within the state constitutes an unnecessary criminalization of a subjective situation which poses no real danger, whose "sphere of application (...) is designed to overlap completely with that of the administrative penalty, which shows the complete irrationality of this new crime". The full text of the appeal can be read on: www.giuristidemocratici.it. The magistrate of Pesaro has also argued the futility of criminal sanctions provided by art. 10 bis of Legislative Decree no. 286/98 destined to remain "practically devoid of specific effects against the majority of irregular immigrants, since almost no one would be able to pay the heavy fines envisaged, from 5,000 to 10.000 Euros, or to usefully pay the penalties commensurate with such sums".

all pose a danger to society" in open violation of articles 3 and 27 of the Constitution which, conversely, require a concrete ascertainment of criminal responsibility with reference to the individual.[92] The principle of reasonableness in its many expressions "(rationality of purpose, adequacy of means to ends, proportionality, and substantial respect for the basic values of the Constitution)"[93] is being blatantly violated. The only effect with any degree of rationality that the Pesaro judge manages to identify in the new law is the radical exclusion of any form of solidarity with the immigrants, around whom a curtain of indifference and hostility has been raised. Further, the expectation of penal sanctions brings with it the notion of "complicity in crime under article 110 c.p. for all those who express towards the "illegal immigrant" real and factual solidarity by receiving and helping her/him to find food and lodging and to engage in activities for her/his subsistence"[94] and entails the legal obligation to report matters to the authorities for any public official or for people working in the service of the public who, because of their role or in the course of their duties, become aware of an immigrant's irregular status.[95]

Having identified these premises, the Court points out how this law affects society, changing it from one "which welcomes" to one "which excludes"[96] certainly endangering "the basic principle of human and social solidarity which the Constitution, by contrast, holds as a primary value to achieve and promote".[97]

The reference to solidarity as a legal value in the text of the ordinance seems, in truth, rather vague, referring rather to an abstract principle founded in natural law and identifiable in the duty of every human being to receive and help, with good grace, "poor persons in dire need".[98] The tendency towards natural law seems also to account for the Pesaro judge's thinking regarding the compatibility of article 10bis with principles concerning immigration which are widely recognised at an international level.

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[92] Besides which, the Constitutional Court ruled out, in the same ruling no. 78 in 2007, that "the non-possession of a qualifying title allowing residence in the territory of the state" may in itself be "symptomatic (...) of a particular social dangerousness."

[93] Court of Pesaro, cit., p. 10

[94] Ibid. The Court of Pesaro notes, cit., 7, how contravention with a fine, though ineffective for illegal immigrants, is however "very effective against all the other" regular citizens or foreigners.

[95] The obligation to report arises under the requirements of articles 361 and 362 c.p.. Health and education professionals are excluded from the list of persons required to report illegal immigrants. However, the Court of Pesaro cit, 8, points out that such exemptions "relate only to restricted areas of life and are not sufficient to give illegal immigrants real security in terms of access to these services, as this would still imply that their status would come to the surface and be visible. The many formalities, such as the obligation to declare place of residence to the PS when a young illegal immigrant is hosted by a boarding school, for example, are tantamount to the crime being reported".

[96] The court describes the perverse effects of the new incriminatory law in social relations, highlighting the danger of the spread of the "popular mentality of strong hostility to any kind of diversity".

[97] Court of Pesaro, cit., p. 8.

[98] A universal value that can be grounded, the Court of Pesaro points out, in both secular and religious values. Court of Pesaro, cit., p. 7.

The judge, after having shown how international acts and conventions identify a migrant, even one who has not been regularised, as a subject worthy "of the utmost respect in her or his quest for more humane living conditions (...) who will certainly have to submit to the laws of individual states, intended to verify if his or her actual immigration is legalisable, but who cannot be considered, by definition, a criminal",[99] postulates the existence "of an absolute birthright, that a citizen of the world has, to share with all other men and women ownership of the land and the right to enjoy it for a free and dignified existence".[100]

The reference to this primal right is accompanied by quotations from several extra-normative texts, by a statement from the UN High Commissioner for Human Rights[101] by an appeal from famous personalities and religious and lay charities and even by a passage from the Gospel of Matthew which reports the words of Christ.[102]

This type of referencing, which often comes up in judgments of the European Court of Human Rights[103] and U.S. federal courts,[104] is something absolutely new to the Italian law scene, in which judges rarely resort to such a quantity and quality of extrajudicial factors to support their constructions.

The need to demonstrate the unfoundedness of legal categories on the basis of ethnicity is probably what leads judges to make use of cases and extra-normative references.

However, it is conceivable that the reference to an extra-systemic reasonableness, linked to natural rights, or taken from factors external to the law books, could be the start of a broader interpretative trend, which Italian judges will look to in order to resolve cases brought about by ethnocultural rights or which involve weak or otherwise disadvantaged individuals, such as, precisely, immigrants.[105]

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[99] Court of Pesaro, cit., p. 7. The court considers the criminalization of migrants to be excessive, stressing that "the international conventions and laws of the states generally try to reserve regulatory and administrative sanctions for the stage of attempted immigration and the investigation of its acceptability, because they are more suited to 'mildly' governing what is a highly complex global phenomenon, itself an expression and a consequence of, the poverty and oppression that is widespread in large parts of the world, the cause of which is often traceable through history to former colonial states and, more recently, the neo-colonial system of economic exploitation of poor countries".

[100] Court of Pesaro, cit., p. 9.

[101] The Pesaro judge, with reference to the right of every human being to seek, even in countries other than her/his own, food and decent living conditions, cites the words of the High Commissioner for refugees who on June 18, 2008, after approval by the European directive on rejections and ejections declared: "it is time to grant the same benefits to those who live with the threat of extreme poverty, hunger and disease, especially epidemics; dangers which they have the right to try to escape". Court of Pesaro, cit., p. 9.

[102] This is the summary of a document which refers to the Church's social doctrine, based on the words of Christ: "I was a stranger and you took me in" (Matthew 25, 35). The relevance of elements of a religious nature in judicial decisions must be properly contained so as not to endanger the lengthy process of secularization and secularism achieved by the European legal systems.

[103] For example, there are many extra-juridical references, within the judgments of the European Court of Human Rights on the subject of immigration.

[104] The most interesting sections in this regard are undoubtedly those relating to affirmative action and discrimination against homosexuals.

[105] Even the inter-systemic link allows the Court to show the irrationality of the new legislation art. 10 bis which does not try to justify absence determined by just cause, governed instead by article. 14 para. 5 b of the Consolidation Act on immigration, generating an obvious "unequal treatment of persons charged with similar allegations". See Court of Pesaro, cit., 10. Even the President of the Republic, in a letter to the President of the Cabinet and the Presidents of the Chambers during the promulgation of Law no. 94/2009 showed strong concern for "the fact that the new theory

7. The interesting judgment of the Pesaro judge documents the impossibility of drawing distinctions between individuals without reasonableness and encapsulates the trend in Italian law to temper and to prevent, thanks to this legal principle, the spread of irrational hypotheses of unequal law into the system. All the most recent and innovative juridical interventions running counter to discrimination against non-EU citizens have chosen reasonableness as a guiding criterion. The rooted, stable presence of this hermeneutic criterion in the framework of Italian law constitutes not only a barrier against the drift towards discrimination, which is increasingly widespread in legislative and administrative practices, but also, as is clear from the previous pages, a contributory factor in the construction of the physiognomy of Italian multiculturalism.

Some very recent examples of legal cases will confirm the spread into the system of various interpretation techniques based on reasonable equity thinking; these techniques could also be used in future to resolve legal issues posed by ethnic and cultural rights and to deal with legal regimes which are differentiated among individuals involved in court proceedings.

The driving forces which the Constitutional Court has expatiated on in recent years are characterised in particular by a great expansive force and an inherent predisposition towards extension by analogy.

The "judge of the laws" has thus selected measured reasonableness and "the weighty criterion of constitutional values", thanks to its "meta-normative nature (...) and its empirically pivotal role in any principle: it is as if this figure were an integral, structural part of any such principle".[106]

These features enable the Court to use its reasonableness and its subprincipals,[107] both independently and in connection "with a positive procedural instrument"[108] to interpret the law in a developmental mode and to meet the needs of differentiation which are imposed by modern society.[109.]

Regarding equality between co-nationals and foreigners, the principle in question is frequently expounded in the assessment of equality or in the prospect of a *tertium comparationis*, i.e., in "comparison

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of undue detention does not try to justify absence determined by just cause" maintaining that such unjustified absence is hardly compatible with the jurisprudence of the Constitutional Court (Case no. 5 / 2004 and no. 22/2007). On this point see: De Napoli, *La L. 94/09 e il reato di immigrazione clandestina: implicazioni giuridiche e potenziali risvolti nel campo sociale*, in www.immigrazione.it.

[106] M. Cariglia, *L'operatività del principio di ragionevolezza nella giurisprudenza costituzionale*, in *La ragionevolezza nel diritto*, M. La Torre A. Sword (ed.), Giuffrè, 2002, p. 198. The author gives reasonableness a central role in maintaining a proper balance between the powers of the state, abandoning Montesquieu's thesis and embracing "that of Neustadt who considers the power of the State, alone and executed by three bodies, each required to interact with the others, while respecting their autonomy, but with a view to and the ultimate purpose of achieving a properly functioning system".

[107] On the constitutional elements of the canon of reasonableness see: F. Modugno, *La ragionevolezza nella giustizia costituzionale*, Editoriale Scientifica, 2007.

[108] Meaning a normogenetic function of the principle of reasonableness M. Cariglia, op. cit., p. 184.

[109] On this point M. Cariglia, op. cit., p. 199 writes: "Reasonableness summarizes and expresses (...) in the most effective way the Constitution's uniqueness, how it is ahead of society and politics, soliciting and promoting internal dynamics, but also demanding constant orientation towards more widely experienced needs". Fulfilment of the need for legal certainty is safeguarded by the close relationship between reasonableness and reason.

with a similar (…) standard (...), so that where unlawfulness is claimed, there is a foil within the system and the unlawfulness has a functionality which carries a guarantee of internal coherence".[110]

The phenomenon is similar to the one described in the preceding pages regarding the mixing and linkage of institutions and/or legal categories, where systematic rationality is a decisive factor in resolving the dispute. And finally there are cases in which the Court directly censures the "inherent irrationality" of contested measures.

This dual level of conceptual analysis, which foregrounds reasonableness both as an autonomous principle summarizing the ancient aspiration for equitable justice[111] and as a hermeneutic criterion of interpretation encompassing a variety of interpretative techniques, emerges clearly in decisions concerning the allocation of social benefits to non-EU immigrants.

Already in 2005 the Constitutional Court had to "make it clear that any differential treatment must meet criteria of reasonableness to be assessed in relation to the purposes and functions of the objective actually pursued by the legislator".[112] In the case in question, the Court's reasoning focused on a law local to the Lombardia Region, which recognized the right to free public transport for people who have become totally incapacitated because of civil reasons. This promotional measure expressly excluded foreign nationals residing in the region. The Court, in accepting the complaint of unconstitutionality raised by the Court of Prato, does not find within the contested regulatory structure "any specific, transparent and rational justifying cause such as to explain, on a constitutional level, the reasons given for the measure".[113] Nationality is an altogether arbitrary criterion, inappropriate in establishing a correlation between "the positive condition of eligibility for the benefit (...) and other specific requirements (100% disability and residence) on which recognition of the condition depends and which define its *ratio* and function".[114] The constitutional judge reverses the argument put forward by the

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110 C.R. Riva, *Droga e immigrazione: il diritto penale ingiusto, i suoi giudici e i suoi studiosi*, in *Critica del diritto*, 2005, II, p. 229 identifies in the *tertium comparationis* an "internal anchor" that "permits the Court to counter accusations of excessive political discretion, because doing so simply extends a criterion which already exists, rather than basing it exclusively on principles external to subjective regulations".

111 An equitable justice with boundaries defined by constitutional values and their balance.

112 See: A. Caligiuri, *L'accesso ai benefici di natura assistenziale dei cittadini extracomunitari soggiornanti in Italia*, in *Diritto, immigrazione e cittadinanza*, 2009, XI, p. 64.

113 Constitutional Court ruling no. 432 of December 2, 2005, excludes not only the possibility of discriminating between Italian citizens and foreigners regarding the enjoyment of fundamental human rights, but imposes, even outside of that core, limits on the discretionary power of the legislature, which "is allowed to introduce different schemes regarding the treatment of individuals involved in court proceedings only in the presence of a case law which is not clearly irrational or, worse, arbitrary". For comment on the judgment see: Arconzo G., *Il processo costituzionale, la ragionevolezza, l'illegittimità consequenziale. Note a margine della sentenza n. 432 del 2005*, in *Giurisprudenza italiana*, 2006, XII, p. 2253.

114 Constitutional Court, ibid. On this point M. Cuniberti., *L'illegittimità costituzionale dell'esclusione dello straniero dalle prestazioni sociali previste dalla legislazione regionale*, in *Le Regioni*, 2006, II, p. 523, stresses that the Constitutional Court considers residence in the Lombardia region "a reasonable criterion for differentiation, in as much as it highlights the relationship between the individual and the territory within which s/he intends to exercise his/her right to move freely (...): the political link between the subject and the national community represented by nationality, does not, on the other hand, appear to be proportionate and appropriate to the purposes of the primary regulation, and thus reference to it in order to limit the number of recipients of the benefit, over and above the intentions that may have

Lombardia region's defence counsel and rules that choices made with regard to service provision, even when they go beyond "essential limits, whether these be for the right to health or benefits concerning civil or social rights, must be considered part of a reasonableness grouping. National state or religious laws may allow for regimes which are differentiated among particular individuals in court proceedings "only in the case of a normative suit which is not obviously irrational or, worse, arbitrary".[115]

The principle of reasonableness stands out from the classical canons of equality and is elevated in Court reasoning to an "objective canon of rationality within the system", capable of toning down and tempering the "disparities introduced by the legislator (...) whatever the nature of subjective situations involved".[116]

This form of interpretation is repeated in 2008 ruling no. 306 where the Constitutional Court declares the obvious irrationality of imposing a condition on "the provision of a carer benefit – eligibility for which consists of (…) total inability to work as well as the inability to walk independently or to carry out everyday essential tasks, the condition being that the beneficiary must carry a document showing her/his legal right to remain (…) in Italy and which shows, among other things, that he or she has an income".[117] Practices such as this contradict the aims of social security and welfare, which characterize the provision of welfare benefits; the only condition which can rationally be imposed on their provision is "that the foreigner's document confirming her/his legal right to be on Italian soil does not show that her/his stay is episodic or short-term". The Constitutional Court also speaks of "intrinsic unreasonableness" in its January 2009 ruling no. 11 which declares unlawful article 80, paragraph 19 of the 2001 Finance Act in the section where it states that "incapacitated foreigners need to be in possession of a temporary resident's permit and to have proof of income in order to benefit from a disability pension".[118] Once again, disparity of treatment seems worthy of censure because making the recognition of a pension benefit conditional on a (temporary) residence permit for which proof of income is a pre-requisite is in direct contradiction with the *ratio* of support underlying the pension benefit scheme and what is considered an Italian citizen's due, "for whom the benefit of a disability pension presupposes that s/he has not crossed a given threshold income".[119]

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inspired such reference (the real need for restraint in spending or rather, more or less openly discriminatory purposes), is objectively capable of producing a discriminatory effect".

[115] Constitutional Court, ibid.

[116] The quotations are taken from M. Cuniberti, op. cit., p. 515.

[117] Constitutional Court ruling no. 306 of July 30, 2008. The appeal to the Constitutional Court concerned art. 80, c. 19th, of the Law of December 23, 2000, no. 388 and art. 9, c. 1st, of the Legislative Decree no. 286/98 as amended by art. 9, c. 1st of the Law of July 30, 2002, no. 189, later replaced by art. 1, c. 1, of the Legislative Decree of January 8, 2007, no. 3, covering art. 1 of the Law of February 11, 1980, no. 18.

[118] Constitutional Court ruling no. 11 of January 23, 2009.

[119] Constitutional Court decision, ibid. In this case the applicant, though residing in Italy with a valid (temporary) residence permit and although in possession of the requisite health and income conditions of Article. 12, para. 3 of Law no. 412/1991 and s.m.i., was found to be without a (temporary) residence card and the conditions needed to access a pension.

These patterns of thinking are aimed at identifying "the validating cornerstone of the legal edifice so as to keep checks on how it matches up not only to external parameters (constitutional provision) but also to an internal instance of plausibility or persuasiveness: the instance of reasonableness".[120] They have been widely used even in lower courts in an assortment of cases which run from recognition of nationality/naturalisation to discrimination in allocating units of public housing.

Regarding these two areas in particular, a vision of reasonableness seems to be gaining ground as the meta-normative parameter of conforming to the idea of "justice" or equity, where the balance of interests drawn up by the legislator may be amended and revised.

In the first case, for example, the Veneto Regional Administrative Court accepts an appeal by a Moroccan national who had been denied the granting of Italian nationality, emphasizing how "there is no base in reasonableness and experience for confirming, as the contested measure does, that in 2005 a person might not be completely reliable in terms of public order and civil life, just because, twelve years earlier, he had exhibited a behaviour which had since been decriminalised by the lawmakers, and which therefore was of limited social significance".[121]

The reasoning adopted by the Administration seems to run counter to the logic of the system[122] and the concept of reasonableness as a fair and rational compromise between conflicting judicial bodies which could be uncovered in the case in question. Compliance with an external justification which is extra-normative in character seems also to be at the forefront in the recent issue of constitutional legitimacy raised by the Lombardy Regional Administrative Court[123] in relation to article 40, paragraph 6, of the d.lgs. dated July 25, 1998, which confirms that, by possessing a temporary residence card or a temporary residence permit lasting at least two years, a foreigner has the pre-requisites allowing her or him access to a unit of public housing.[124] The Administrative Court, while not expressing any "a priori opposition to the laying down of limits in granting particular benefits to non-EU citizens, nevertheless stresses that the criterion allowing a two-year permit seems to be unreasonable because "it is tied to extrinsic circumstances dependent on the discretionary assessments of the Police authority which issues the said permits". The granting of two-year temporary residence permits is often for reasons related to

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120 F. Modugno, op. cit., p. 12.

121 Regional Administrative Court of Veneto, sect. III, ruling no. 3694, 26 November 2008.

122 Reasonableness is often invoked to reconcile situations that appear conflicting from a logical point of view. Recently, for example, the Regional Administrative Court of Lombardy declared a decision of the Regional Government of Lombardy unlawful in that it excludes from economic contributions granted to families with three or more children those foreigners who do not possess a (temporary) residence card or a long term EU permit on the assumption that "it seems totally unreasonable that to claim an economic benefit usually meant for the least well-off requires a minimum income which in connection with obtaining a residence card cannot be less than the annual social allowance (article 9 of Legislative Decree no. 286/98), thereby making the extent of support provided less incisive, or even completely useless".

123 Regional Administrative Court of Lombardia no. 188 of February 9, 2009.

124 These criteria have been taken from local and regional acts governing the delivery of grants for payment of residential rents.

the contingent labour market -as highlighted by the judge - without any connection to the requirement of staying in Italy over time and on a regular basis.

The adoption of this discriminatory element appears to be irrational and lends itself to unjust disparity of treatment, in violation of article 3 of the Constitution.[125]

In attributing importance to elements which turn out to be arbitrary with regard to the purpose of the social security system, or to be unjustified with regard to requirements linked to the guarantee of public order,[126] all the cases so far described contradict not only the internal logic of the system but also the need for social and material justice, which summarizes the logic of constitutional values and is reflected in the principle of reasonableness. This organising criterion "composes the needs of the actual case, proving to be a particularly effective tool"[127] to meet the needs of differentiation which have emerged in pluralistic society and which insist that the legal system be applied with reasonable equity.

The presence of this principle can lead towards "a mild ethnicisation", or a gradual transformation of the national juridical framework. The interpretive operations which use reasonable equity as a guiding criterion indeed demonstrate a high capacity to respond to issues identified with minorities, without undermining the fundamental principles of the system. In this sense, the compression of the concept of public order emerges as one of the main implements which the judiciary turns to in order to integrate foreign institutions into the state system. This hermeneutic form finds adequate support in the so called "decontextualised comparison", which is able to extract from a head-on comparison between laws the *ratio* underlying them and to identify the possible principles of connection between legal systems.

This "maieutic" operation, which is not risk-free, can dispel the prejudicial vision of foreign law and get down to the deep reasons which govern the regulation of individual matters. Within a civil law context, this *modus operandi* may turn out to be essential in the identification of similarities between institutions which, though nominally different, technically perform the same essential function. The functionalist approach, suitably yoked to an investigation of the individual aspects of the people involved, avoids solutions which may lead to unjust disparities in treatment between individuals and has the edge on the rediscovery of natural law as a unifying factor between legal expressions from different geographical and cultural origins.

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[125] The Regional Administrative Court highlights that "the often volatile nature of employment, especially for immigrant workers, means that they often lose a stable job and after a period of unemployment must accept temporary employment even after years of living in Italy" and thus, highlights the Court, "it could be possible (...) for a non-EU citizen, recently arrived in Italy, to acquire from the Quaestor a biennial permit, given a genuine offer of work, while the same decision might not be taken in the case of an immigrant who has lived within our territory for ten years".

[126] As in the case drafted in relation to the refusal of citizenship.

[127] M. Cariglia, op. cit., p. 195.

Recourse to law which find its legitimisation in the equity of the natural order may, in its logic and its aims,[128] become a privileged channel of communication for the identification of a core of "non-negotiable" principles which can be used to bring about the creolisation of the system[129] and at the same time block the road to "eccentric" solutions which are not adequately covered by the fundamental principles protected by the constitutional Charter.

In this light, the widespread presence of the reasonableness principle within the Italian juridical system facilitates the passage[130] towards equitable solutions allowing for the co-presence of needs and wants relative to minority identities and the need for self-preservation felt by the receiving society.

This constitutes a capacity for mediation, which will have to temper excessive individualisation of the system and abuse of extra-juridical materials in judicial decisions but which will not be allowed to ignore an investigation of the individual profiles of people under examination or an analysis of their actual relations with their original and their receiving communities. This investigation must consider the complexity of value characteristics and experiences adopted and undergone by people in the context of immigration, with the aim of leading the clash of norms and values away from an ideological context and into a more tangible one, one which is in many ways more objective, made up of concrete facts, people and interests.[131]

8. The need to respond to questions posed by intercultural democracy, the necessity of avoiding a distortion of the traditional undertones in juridical systems and the urgency of measuring current transformations so that adjustments may be made, if necessary, in their direction and in how they are undertaken, all of these lead with renewed interest to an examination of the comparison between juridical systems, seen as an investigative tool. Bringing foreign materials to bear and comparing them with the realities of individual rulings is a practice which has been gaining in vigour in recent years in

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[128] Natural law as discussed here is not based on transcendent elements, but is rather a self-evident set of rules that apply universally, as inherent to human reason. The future of European multiculturalism will be played out on the way in which these laws pan out, laws which Grotius called "*dictamen recte rationis*".

[129] The application of the concept of creolisation to cultural diversity and to the scale of globalization was introduced by the Swedish anthropologist Ulf Hannerz. On this point see: U. Hannerz, *La diversità culturale*, 2001, Il Mulino.

[130] The spread of the principle of reasonableness is a precursor to the explicit reference to natural law in judicial decisions.

[131] Thus, for example, the institution of polygamy in Muslim jurisdiction works as the legal transposition of a religious precept (or a different set of interpersonal relationships), just like monogamy in European countries. A truly secular state should avoid taking a position on this eminently ethical dispute and grant legal protection to both family models. The problem exists today with particular emphasis on family reunification after Directive 2003/86/EC, which prohibits the reunification of polygamous families and even minors with another spouse (no matter if the first or second wife). (This is) a ruling contrary to the basic principles of European legal culture on family law and art. 3 of the New York Convention on the Rights of the Child, whose only effect is to "not deter or combat polygamy, but to suppress any heavy interference with their development and family relationships which are already in place without this being desired by or being beneficial to any of the subjects of those reports". See the in-depth essay of P. Morozzo della Rocca, *Il diritto all'unità familiare in Europa, tra "allargamento" dei confini e "restringimento" dei diritti*, in *Diritto, immigrazione e cittadinanza*, 2004, I, p. 71.

both national and supranational courts, as unprecedented juridical issues loom large and as the need arises to "seek ulterior, new meanings to be given to texts adopted some time ago".[132]

In a European context, the phenomena of system integration favour this osmosis-like process which is heavily accelerated in the conflict of values typical of a multicultural society. Inserting a value element into a uniform regulatory context which was essentially conceived for the resolution of conflicts of interest, gives rise to widespread uncertainty which may be newly reflected in factors deriving from a comparative experience.

The use of this methodology is often to be found in the practices of the Court of Justice and the European Court of Human Rights. The former has developed the concept of "European constitutional heritage" and the latter the concept of "common ground". Reference to the laws of individual national states has nevertheless not thus far permitted the European courts to play a "forward-moving balance" role in the definition of controversies posed by multiculturalism. The reasons for this inability to guide and renew European law have to be sought, in part, in the ways in which foreign materials are used; this use often amounts to the mere conservation of the *status quo ante*. Resorting to references to sources which are not directly connected to the relevant legal system is actually an ancient phenomenon which underwent a remarkable expansion in the age of the great tribunals. Whereas at that time legal experts surveyed decisions (*decisiones*) handed down by European *auctoritas* and chose those which could support solutions appropriate to specific cases,[133] the model proposed by the Strasbourg and Luxembourg Courts is substantially different from the custom in vogue between the 16th and 17th centuries.

The phenomenon of circularity in laws originating in EU-wide systems and in the CEDU is based on a quantitative criterion; European judges often choose a solution which, under comparative scrutiny, is in the mainstream of European states. This mechanism can lead to a prioritisation of motivations which have a greater political consensus, to the detriment of the efficiency and efficacy of the proposed solution.[134]

This choice is rather short-sighted choice because the sensitive webs of problems suggested by the meeting of different cultures are not at all likely to be resolved by recourse to quantitative-accounting methods; they require the development of a guiding model, based on balanced solutions picked out

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[132] S. Bartole, *Il ricorso al diritto comparato*, op. cit., p. 231. Even in preparatory work on legal texts, reference to foreign materials is increasingly frequent.

[133] For more depth on this see: M. Fioravanti (ed.), *Lo stato moderno in Europa. Istituzioni e diritto*, Laterza, 2002; A. Cavanna, *Storia del diritto moderno in Europa. Le fonti e il pensiero giuridico*, Giuffrè, 1982. On the role of major Tribunals in the European process of sub specie interpretationis unification see the important study by G. Gorla, *Diritto comparato e diritto comune europeo*, Giuffrè, 1981.

[134] In this *humus*, debatable judgments were worked out, such as those issued by the ECHR in the field of religious symbols. With reference to the European Court of Human Rights and in the context of multicultural society, one school of thought emphasizes the need for a "tighter European control, reducing the extent to which the Member States of the Convention are taken into account, because this is about laying the foundations, forming an ample basis for 'normalized' coexistence in Europe between people of different cultures". On this point see: V. Cuccia *La manifestazione delle convinzioni religiose nella giurisprudenza della Corte europea dei diritti dell'uomo*, in *La comunità internazionale*, 2006, III, p. 576.

from among those which have been best established at national level or created *ad hoc* in order to resolve specific questions.

Comparative law should guide this procedure, which can amplify the High Courts' authority and contribute to the construction of an authentic intercultural democracy, based on the "right to not be equal" and on the "duty to respect all forms of diversity which do not imply the denial of other diversities".

The Italian judicial model seems to have been oriented towards this founding schema which draws nourishment from a vision of the possible existence of a "mild law", which could regulate a multicultural society via the creation of flexible laws, outline or "narrative" laws, as Jayme would have it, which "tend to be structured as rules of compatibility between cultures and values rather than as a rule of definitive prevalence and of the imposition of only one of the positions in play".[135]

[135] S. Rodotà, *Repertorio di fine secolo*, Laterza,1992, p. 161.

Paper n. 2

HEPATITIS B VACCINATION AND THE RISK OF DEMYELINATING DISEASE IN FRANCE

by

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HEPATITIS B VACCINATION AND THE RISK OF DEMYELINATING DISEASE IN FRANCE

by

Isabelle Chivoret♦

Abstract:

The difficult determinations of causation that arise in tort cases are particularly troublesome to the courts and lawyers when plaintiffs claim that the use of a defendant's product caused their injuries or disease. A perfect illustration of this issue is the concern that hepatitis B vaccine may cause or exacerbate a demyelinating disease in exceptional cases, in particular multiple sclerosis and Guillain-Barré syndrome. Indeed, scientific available data does not support such a suggestion, but French judgments specify circumstances under which the causal relationship between these vaccines and these diseases may be proven by presumptions of fact. In these cases, the opportunity to use presumptions for proving such a link does not seem to be justified.

Key words: Product liability, Pharmaceutical product, Hepatitis B vaccine, Demyelinating disease, Multiple sclerosis, Guillain-Barré syndrome, Causality, Causation, Imputability, Presumptions, Risk-benefit ratio.

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Introduction

All vaccines and drugs may cause side effects. It is the role of drug safety monitoring and epidemiological studies to identify and monitor these possible side effects, which must further be described in the various information documents that come along with any pharmaceutical product legally marketed in the European Union. Nonetheless, the evidence of an unquestionable causal link between an adverse effect and a substance is made difficult in the presence of scientific uncertainty. A perfect illustration of this issue is the concern that hepatitis B vaccine may cause or exacerbate a demyelinating disease in exceptional cases, in particular multiple sclerosis and Guillain-Barré syndrome[1].

[1] A demyelinating diseases is a nervous system disease. The primary demyelinating disease is multiple sclerosis (MS), "an inflammatory autoimmune disorder of the central nervous system with destruction of the myelin sheath surrounding neurons" (VIAL T, DESCOTES J. Autoimmune diseases and vaccinations. European Journal of Dermatology 2005;14;2:86-90). Guillain-Barré syndrome (GBS) is a type of demyelinating disease of the peripheral nervous system. It is "an acute inflammatory autoimmune demyelinating polyradiculoneuritis that results in progressive paralysis" (*ibid).* Rheumatoid arthritis is a chronic (long-standing) joint disease that damages the joints of the body.

Since hepatitis B vaccination began in 1982, different hepatitis B vaccines have been administrated to over a 1 billion people around the world[2]. In France, the legislation requires health professionals to be immunized against hepatitis B virus since 1991[3]. A mass immunization campaign against hepatitis B has been initiated by France's health minister Mr Douste-Blazy in 1994. One year later, the possibility that the vaccination may be linked to demyelinating diseases originated from cases reports describing the onset or recurrence of demyelination symptoms shortly after the vaccination. Therefore, the possibility of an association between the vaccination and such sides effects has received wide coverage in the French media. However, what do we know exactly about the risk to contract a demyelinating disease after the vaccination against hepatitis B?

The possibility of a link between the vaccination and demyelination events has been evaluated in several studies. Yet, so far, the weight of the available scientific evidence does not support the suggestion that the vaccination may cause or exacerbate demyelinating diseases[4]. Only the Hernán *et al.* study[5] which have investigated this issue some years ago admitted a link between the recombinant hepatitis B vaccine and an increased risk of multiple sclerosis. This study was published in the journal Neurology in September 2004 and has encouraged the World Health Organization (WHO) to take a stand on this controversial question. The Global Advisory Committee on Vaccine Safety (GACVS) of the WHO has thus carefully reviewed the scientific evidence on whether hepatitis B vaccine can cause demyelinating diseases and has decided that available scientific data does not demonstrate a causal relationship between hepatitis B vaccination and such diseases. Concerning especially the so mediated Hernán *et al.* study, the GACVS has decided that the evidence and argument submitted by the researchers were "insufficient to support the hypothesis of a link between hepatitis B vaccination and multiple sclerosis"

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2 KANE M. Global programme for control of hepatitis B infection. Vaccine 1995;13 Suppl 1:S47-S49.

3 Act n° 91-73 of 18 January 1991. Article L. 3111-4 of the French Public Health Code.

4 ASCHERIO A, ZHANG SM, HERNAN MA, OLEK MJ, COPLAN PM, BRODOVICZ K, WALKER AM. Hepatitis B vaccination and the risk of multiple sclerosis. New Eng J Med 2001;344:327-32. CONFAVREUX C, SUISSA S, SADDIER P, BOURDES V, VUKUSIC S, for the vaccines in multiple sclerosis study group. Vaccinations and the risk of relapse in multiple sclerosis. New Eng J Med 2001;344:319-26. DE STEFANO F, VERSTRAETEN T, JACKSON LA, OKORO CA, BENSON P, BLACK SB, SHINEFIELD HR, MULLOOLY JP, LIKOSKY W, CHEN RT. Vaccinations and Hepatitis B vaccine central nervous system demyelinating disease in adults. Arch Neurol 2003;60:504-9. SADOVNICK AD, SCHEIFELE DW. School-based hepatitis B vaccination programme ad adolescent multiple sclerosis Lancet 2000;355:549-50; STURKENBOOM M, ABENHAIM L, WOLFSON C, ROULLET E, HEINZLEF O, GOUT O. Vaccinations, demyelination and multiple sclerosis study (VDAMS): a population-based study in the UK. Pharmacoepidemiol Drug Safety 1999;8:S170-S171. TOUZE E, FOURRIER A, RUE-FENOUCHE C, RONDE-OUSTAU V, JEANTAUD I, BEGAUD B, ALPÉROVITCH A. Hepatitis B vaccination and first central nervous system demyelinating event: a case-control study. Neuroepidemiology 2002;21:180-6. WEIL JG, EINHAUPL KM. No increase in demyelinating diseases after hepatitis B vaccination. Nature Med 1999;5:964-5. ZIPP F, WEIL JG, EINHAUPL KM. No increase in demyelinating diseases after hepatitis B vaccination. Nature Med 1999;5:964-5.

5 HERNÁN MA, JICK SS, OLEK MJ, JICK H. Recombinant hepatitis B vaccine and the risk of multiple sclerosis: a prospective study. Neurology 2004;63:838-42.

and did "not justify discontinuation or modification of immunization programs with HBV"[6]. Given that the benefits of the vaccination have never been questioned, the risk-benefit *ratio* of the vaccination remains favorable. For this reason, national programmes of hepatitis B vaccination are still recommended by the WHO for all countries.

In spite of the lack of scientific data supporting a causal link between hepatitis B vaccination and the development or the exacerbation of demyelinating diseases, patients who developed such diseases after having received the vaccine claimed since the end of the 1990's that the latter has been the cause of their injury and asked for damages. To determinate whether these patients are entitled to receive compensation, judges have to decide whether the plaintiff has adequately proven that the injury was caused by the vaccine. In these circumstances, the dispute raises the question of the judicial treatment of scientific uncertainty in judgments involving pharmaceutical products. The specific question is: Can judges establish a causal relationship between a product (such a vaccine) and a damage (such a nervous system disease) despite the lack of scientific evidence of the causal link between the two? If so, in what circumstances?

Judges don't often have the opportunity to answer the question of this link. This relationship is indeed generally not disputable. For instance, people with hemophilia should not take aspirin because aspirin increases the risk of bleeding. Nonetheless, cases involving pharmaceutical products and scientific uncertainty usually present courts with a difficult causation issue and plaintiffs can be easily placed in the position of being unable to prove that the product has caused their injury. In the dispute of people who developed serious nervous system diseases shortly after receiving the hepatitis B vaccine, French administrative and judicial courts finally decided to establish in certain circumstances a causal link between vaccination and demyelinating diseases since the end of the 2000's (**I**). For reasons which will appear evident in the discussion that follows, the decisions of the courts of justice were viewed as a progress for followers of the compensation of "victims" of the vaccination[7]. However, these decisions were criticized in the medical world because it is not biologically plausible that the hepatitis B vaccine can cause or exacerbate demyelination. Besides, such decisions were not unanimously approved in the

6 World Health Organization Global Advisory Committee on Vaccine Safety: Response to the paper by MA Hernán and others in Neurology 14th September 2004 issue entitled "Recombinant Hepatitis B Vaccine and the Risk of Multiple Sclerosis".

7 See for instance GRYNBAUM L. Produits de santé défectueux: la Cour de cassation s'affranchit des doutes scientifiques. Gaz. Pal. 2009;328:47. LEGOUX A. Avis de l'avocat général. Gaz. Pal. 2009;225:9. MAURY F. Victimes du VHB (vaccin contre l'hépatite B): faut-il attendre une certitude scientifique pour les indemniser? Médecine & Droit, 2004:125. MAZEAUD D. La distension du lien de causalité a des limites. Dalloz 2004:1344. MISLAWSKI R. Vaccin contre l'hépatite B et scléroses en plaques; retour sur la causalité. Médecine & Droit 2010. RADÉ C. Vaccination anti-hépatite B et sclérose en plaques: première condamnation d'un laboratoire. RCA 2009;13. SARGOS P. Les effets indésirables du droit des produits défectueux en matière de dommages causés par des médicaments, et notamment des vaccins. JCP G 2009;41:308.

judicial world[8]. The establishment by judges of a causal link between hepatitis B vaccination and demyelinating diseases may indeed be criticized (**II**).

I - The establishment of a causal link between hepatitis B vaccination and demyelinating diseases

In cases related to the hepatitis B vaccination, facts are relatively easy to understand. The plaintiff who has contracted a demyelinating disease after being injected with an hepatitis B vaccine claims that the vaccine caused the disease and asks for compensation. In principle, the claimant has to prove that the damage is attributable to the product and courts must decide whether the claimant has adequately proven that the alleged injury has been caused by the product. In France, judges have answered the question of this causal link between the hepatitis B vaccine and demyelinating diseases in the legal framework of three kinds of liabilities: the liability of the French State for damages resulting from compulsory vaccinations, the employer's liability for damages resulting from work-related accidents, and the product liability[9]. Over the last 13 years[10], there has been an ambivalence towards the way post-vaccination events are viewed by courts. The causal issue was different according to the context of the vaccination. Nowadays, the case law seems stabilized and admits the establishment of a causal link between the hepatitis B vaccination and demyelinating diseases, despite the lack of scientific evidence data supporting such a relationship. The case law considers that this relationship may be presumed under certain circumstances. The cases related to compulsory vaccination and work-related accidents

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8 See notably BORGHETTI J-S. Vaccinations contre l'hépatite B et scléroses en plaques: en cas de doute scientifique persistant, prière de s'adresser à la juridiction la plus proche! RDC 2010;1:79. JOURDAIN P. Lien de causalité entre vaccination et maladie apparaissant ultérieurement: la jurisprudence s'affine. RTD civ. 2009:723. SERINET Y-M, MISLAWSKI R. Vaccination contre l'hépatite B: les conditions de la responsabilité du fait des produits défectueux. Dalloz 2004:898.

9 The resort to precautionary principle seems not convincing to admit the manufacturer's liability. According to this principle, which applies in the context of scientific uncertainty, "when an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically" (Wingspread Statement on the Precautionary Principle, 1998). Then the question should be: Should the precautionary principle justify precautionary measures, as the prohibition or the restriction of the hepatitis B vaccine, in the presence of the lack of scientific data supporting a causal link between hepatitis B vaccination and the development or the exacerbation of demyelinating diseases? It seems difficult to respond to this question with a positive answer, and thus to admit the manufacturer's liability because he did not take such measures. Indeed, the precautionary principle must apply to the proved benefits, not only to the presumed side effects, and for the moment the risk-benefit ratio of the vaccine remains favorable.

10 The first decisions concerning the hepatitis B vaccination have been rendered in 1997 and 1998: Court of First Instance of Nanterre, 4 April 1997: Nouv. Pharm. 2000;367:257. Court of First Instance of Nanterre, 5 June 1998: REVEL J. Les risques de la vaccination: rôle causal du produit ou prédisposition du patient? Dalloz somm. 1999:246. GALLOUX J-C. Obligation de sécurité du fabricant de vaccins. Dalloz somm. 2009:336. MONTEYNE P, ANDRÉ FE. Is there a causal link between hepatitis B vaccination and multiple sclerosis? See also GIRARD M. Questions et... réponses sur l'imputabilité médicamenteuse. Dalloz 2001:1251.

(**A**) and the cases related to products liability will be explained separately (**B**). Indeed, French judges apply special texts which take into account the compulsory character of the vaccination for certain employees.

A - The cases related to compulsory vaccinations and work-related accidents

The first judgments rendered in "the hepatitis B vaccination affair" have been delivered by both administrative and judicial courts in relation to compulsory vaccination and work-related accidents. In this legal framework, persons who have contracted demyelinating diseases following after the hepatitis B vaccination have different legal means to claim compensation for their injuries (**1**). Nevertheless, whatever the legal means chosen by claimants to ask for compensation, judges admit that the causal relationship between the vaccination and their diseases may be presumed under certain conditions (**2**).

1 - The law

A system of compensation was established for injury resulting from compulsory vaccination by the Act n° 64-643 of the first July 1964[11]. The Act introduced a no-fault and non-contractual liability of the French State. Such a liability is justified because the authority to enact rules relevant to the protection of the public health, like mandatory vaccination rules, derives from the State's general police powers. Vaccination against hepatitis B is imposed since 1991[12]. Nowadays, the Article L. 3111-4 of the French Public Health Code requires such an immunization for all persons exposed as a result of their professional activity in a public or private health care or medical prevention establishment to the risk of contamination, as well as all medical students[13]. The compensation procedure concerning compulsory vaccination is notably governing by the Article L. 3111-9 of the French Public Health Code. The article specifies that the compensation requires a damage directly imputable to the compulsory vaccination. Then, the imputability of the damage to the vaccination is explicitly required. Administrative judges are

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11 See concerning the accidents related to the compulsory vaccination: MODERNE F. La responsabilité administrative en cas d'accidents de vaccination. R. 1974;65; La responsabilité généralisée de l'État à raison des accidents causés par les vaccinations obligatoires. Dalloz chron. 1975:161; Un nouveau progrès législatif dans la réparation des conséquences dommageables des vaccinations obligatoires. R. 1986:583. The Act of 1964 was modified by the Act of 26 May 1975 and by the Act of 3 January 1985. See the decision of the Conseil d'État of 7 March 1958, which consecrated French State's presumed fault liability: Rec. CE 1958:153.

12 Act n° 91-73 of 18 January 1991. Article L. 3111-4 of the French Public Health Code.

13 See the Order of 6 February 1991 which establishes the conditions of immunization of persons covered by Article L.10 of the French Public Health Code, and the Order of 15 March 1991 which establishes a list of public or private health care or public health establishments in which exposed personnel must be vaccinated. See also the Act n° 2002-303 of 4 March 2002 which extends the protection regime to people who were vaccinated against hepatitis B before the enforcement of the law of the 18 January 1991.

competent for cases related to the French State liability for damages resulting from mandatory vaccination[14]. Pursuant to Article L. 3111-9 of the French Public Health Code, the application of the French State's no-fault liability regime, concerning compulsory vaccination, does not exclude the application of the work-related accidents or accident de service legislation[15].

A system of compensation was established for injury resulting from work-related accidents at the close of the nineteenth century[16]. Both administrative and judicial courts are competent to render judgments in the context of work-related accidents. If the employee work in the public sector, administrative judges are competent. If the employee work in the private sector, judicial judges are competent. Besides, it should be noted that in France the work-related accident is differently called when the employee work in the public sector. The term is accident de service. Furthermore, that is not only a terminological distinction because judges do not apply the same texts and thus the compensation proceedings concerning the work-related accident and the accident de service are different, especially as regards the link between the work and the accident, *i.e.* the recognition of the professional character of the accident.

On the one hand, judicial judges apply the Article L. 411-1 of the French Social Security Code. The Article defines the notion of work-related accident. A work-related accident is the accident, whatever is its cause, which arises out of or in the course of work and causes personal injury to any person employed by one or more employers or entrepreneurs. The case law establishes a rebuttable presumption of the link between the accident and the work, and thus of the professional character of the accident, when the accident occurred during working hours and at the place of work[17]. Such a presumption can be overturned if the accident was not sudden and if the employee was not subordinate to his employer[18]. Besides, the employer or the Caisse de sécurité sociale[19] can contest the professional

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14 Since recent French health system reforms (Act n° 2002-303 of 4 March 2002 and Act n° 2004-810 of 13 August 2004), claims shall be submitted to the office of National Indemnification for accidents of a medical nature, for nosocomial infections and for iatrogenic infections (ONIAM).

15 The Article considers that this liability regime should apply "without prejudice" to the application of another regimes. That is mean that, even though the liability of the French State is recognized, work-related accidents regulations or accidents de service regulations shall apply. See for a consecration of this solution: Second Civil Law Chamber of the Cour de cassation: 22 March 2005, n° 03-30551, Bull. civ. 2005;II;75:68: OLIVE P. Gaz. Pal. 2005;181:28; Conseil d'État, 9 mars 2007, n° 278665, 267635, and Conseil d'État, 10 April 2009, n° 296630, *op. cit.*

16 By instituting the employer's no-fault liability, the Act of 9 April 1898 has allowed victims of work-related accidents to obtain compensation under conditions more advantageous than these offered by tort rules. The Act was modified at several occasions. See Act of 29 October 1919, Act of 27 January 1993, Act of 30 October 1945 and Act of 30 October 1946. Since these two last Acts, the Sécurité Sociale compensate the employees victims.

17 See Social Law Chamber of the Cour de cassation, 28 March 1973, n° 72-10435, Bull. soc. 1973;194. The link is presumed because the accident provoked personal injury and arose suddenly at work.

18 See recently Social Law Chamber of the Cour de cassation, 23 May 2002, n° 00-14154, Bull. soc. 2002;V;178: PRÉTOT X. TPS 2002;268.

character of the accident. They can prove that the accident has no link with the work. The absence of any contestation during a limited-time leads to an implicit and definitive establishment of the causal relationship between the accident and the work (and thus, for instance, between a vaccination and the work which requires the vaccination). On the other hand, administrative judges apply the Act n° 84-53 of 26 January 1984 and the French Civil and Military Pensions Code. According to these texts, the relationship between the work and the accident de service has to be proven by the claimant. It does not exist in this legal framework such an automatic recognition of the link. This is a fundamental difference.

2 - Establishing of the law

The Cour de cassation has rendered several decisions relating to work-related accidents (Article L. 411-1 of the French Social Security Code) which are compensated if the presumption of the link link between the accident and the work is not overturned. On 11 May 2000[20], the court decided that the development of osseous disorders could not be considered as a work-related accident because the vaccination was not mandatory for the employee. Indeed, the employee decided to receive the vaccination (whatever if the vaccination was recommended by the occupational health physician). The employee was thus not under the authority of the employer. On 13 February 2003[21], the Cour de cassation decided that the incidence of a rheumatoid arthritis which occurred following a vaccination against hepatitis B could be considered, though, as a work-related accident, even though the vaccination was not imposed to the employee. Indeed, the employer asked the employee to be vaccinated. Then, the employee was under the authority of the employer. In the case under consideration, it is important to notice that the court also took into account the evidence of the link between the vaccination and the disease, but the proof of this link was not really relevant. The medical certificate of the employee's general practitioner attested indeed an unquestionable link between the disease and the vaccine, but was in complete contradiction with available scientific data. Moreover, the accident was not sudden.

An important decision rendered on 2 April 2003[22] by the Social Law Chamber of the Cour de cassation admitted that a multiple sclerosis could be considered as a work-related accident. The court delivered a ruling which clearly overturned the whole system of compensation for work-related accidents. In this

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19 In France, the employer have to take out insurance for its employees covering work-related accidents. The insurance (Caisse de sécurité sociale) covers compensation. For this reason, the Caisse de sécurité sociale can contest the professional character of the accident. See Articles 413-1 *et seq.* of the French Social Security Code.

20 Social Chamber of the Cour de cassation, 11 May 2000, n° 98-15632.

21 Social Chamber of the Cour de cassation, 13 February 2003, n° 01-20972.

22 Social Chamber of the Cour de cassation, 2 April 2003, n° 00-21768, Bull. civ. 2003;V;132: KOBINA-GABA H. Abandon du critère de souveraineté et confirmation du critère de la subordination. Dalloz jur. 2003:1724. VERKINDT P-Y. Accident du travail et vaccination. RDSS 2003:439.

new case, judges considered that the disease following a vaccination imposed by employer and carried out for work-related purposes can be considered as an work-related accident, whatever the cause of the disease or the date of the incidence of the disease. In the instant case, judges explicitly admitted that a work-related accident does not have to be sudden for being compensated and implicitly presumed the imputability of the disease to the vaccination[23]. On 25 May 2004[24], the Civil Law Chamber of the Cour de cassation rendered a decision concerning the following facts: an occupational health physician recommends the vaccination to an employee for whom the vaccination was not required for work-related purposes; the employee's general practitioner vaccinated the patient outside the place and the working time. In this case, the plaintiff contracted a multiple sclerosis after being injected by the hepatitis B vaccine and alleged that the incidence of the disease was a work-related accident. The court answered the question of the professional character of the accident, deciding that the vaccination was a compulsory medical act because it was asked by the occupational health physician[25]. Concerning a healthcare student for whom the vaccination was mandatory, the same solution was rendered by the Cour de cassation on 22 March 2005[26]. The court held that the causal link between the disease and the vaccination was adequately proved by a plaintiff's medical certificate. This decision was confirmed by a decision on 14 September 2006[27].

So the most that can be said is that judicial judges always discussed the justification or the professional character of the vaccination. Indeed, texts and the law case require such a link between the work and the accident. However, judges more rarely discussed the question of the causal link between the vaccination and the injury, even though they never affirmed the absence of any link between the disease an the vaccination. Indeed, this link is not explicitly required by texts and the law case. When judges analyze this link, it was very easily established by judges (proved by a plaintiff's medical certificate[28]). Finally, one element is really relevant to define a work-related accident in the framework of hepatitis B

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23 Even though such a presumption usually requires a time proximity between the vaccination and the first symptoms of the disease. See Chambres réunies. 7 April 1921: S. 1922;1:81. This is a constant case law. See for instance Social Chamber of the Cour de cassation: 8 June 1995, Bull. civ., 1995;V; 351 and 4 December 1997.

24 Second Civil Law Chamber of the Cour de cassation, 25 May 2004, n° 02-30981, Bull. civ. 2004;II;237: L'affection résultant d'une vaccination imposée par l'emploi constitue un accident du travail. TPS 2004;266. ROUGÉ-MAILLART C, JOUSSET N, GUILLAUME N, PENNEAU M. Complications neurologiques et vaccination contre l'hépatite B: l'impossible conciliation entre la preuve scientifique et la preuve judiciaire. Conséquences sur la pratique expertale. Médecine & Droit. 2005:89.

25 See contrarily: Social Chamber Law of the Cour of cassation, 11 May 2000, *op. cit.*

26 Second Civil Law Chamber of the Cour de cassation, 22 March 2005, n° 03-30551, *op. cit.* See *ibid* at 11.

27 Second Civil Law Chamber of the Cour de cassation, 14 September 2006, n° 04-30642: JCP 2006:1852: FANTONI-QUINTON S. RDSS. 2007:281.

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onseil d'État, 29 November 1967: RDP. 1968;680. See *contra* Conseil d'État, 20 March 1981, n° 19.121.

vaccination: the mandatory character of the vaccination, whatever the vaccination was required by employer or prescribed by the occupational health physician.

Administrative courts rendered numerous judgments in the legal framework of accidents de service[29]. In this framework, the relationship between the work and the accident de service has to be proven by the claimant. Originally, most of administrative courts were hostile to admit such a link[30]. Then, an employee submitted to a mandatory vaccination against hepatitis B could obtain compensation if the judge was judicial and not administrative. Such a solution was not easily comprehensive. The same reticence could be initially observed in compulsory vaccination cases involving the liability of the French State[31]. However, administrative courts finally admit the compensation of demyelinating diseases contracted after hepatitis B vaccination[32].

The Conseil d'État, the French Supreme Court in administrative matters, ruled for the first time in the dispute of hepatitis B vaccination on 9 March 2007[33]. The court admitted that the imputability of demyelinating diseases to the vaccination may not be inferred from the lack of conclusive scientific evidence and could be presumptively proved[34]. In one of this case, an employee, who was submitted to a compulsory vaccination, was vaccinated and developed a multiple sclerosis shortly after received the

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29 Act n° 84-53 of 26 January 1984 and the French Civil and Military Pensions Code.

30 Administrative Court of Appeal of Douai, 21 June 2005, n° 03DA01306: MICHEL J. Le juge, l'Engerix B, la sclérose en plaques et les données actuelles de la science. AJDA 2005:1945. See also Administrative Court of Appeal of Bordeaux, 6 December 2005, n° 03BX00793.

31 Administrative Court of Appeal of Nantes, 13 October 2005, n° 04NT01007. Administrative Court of Appeal of Douai, 17 October 2006, n° 05DA00803. Administrative Court of Appeal of Paris, 15 May 2006, n° 04PA01401. See *contra:* Administrative Court of Appeal, 16 May 2006, n° 02PA03495. This decision appears like an exception.

32 Administrative Court of Paris, 5 November 2002: BONNEAU J. Janus ou la double responsabilité (sclérose en plaques imputable à la vaccination contre l'hépatite B). Gaz. Pal. 2003:11. PAUVERT B. Responsabilité de l'Etat pour le développement d'une sclérose en plaques après une vaccination contre l'hépatite B. AJDA 2003:1502. The court recognized a certain and direct link between the vaccine and a demyelinating disease. See also Administrative Court of Appeal of Rennes, 18 February 2004.

33 Conseil d'État, 9 mars 2007, n° 267635, n° 278665, n° 283067, n° 285288: BRUN P, JOURDAIN P. Lien de causalité. *In* Responsabilité civile. Dalloz. 2007:2897. CARPI-PETIT S. Considérations sur la causalité entre la vaccination contre l'hépatite B et la sclérose en plaques JCP A 2007:2277. CRISTOL D. Responsabilité du fait d'une vaccination obligatoire contre l'hépatite B. RDSS 2007;543. DEFOORT B. Incertitude scientifique et causalité: la preuve par présomption. RFDA 2008:549. DIEU F. La responsabilité de l'État du fait des vaccinations obligatoires : la jurisprudence sur la vaccination contre le virus de l'hépatite B (à propos des décisions du Conseil d'État du 9 mars 2007, « Schwartz » et « Commune de Grenoble »). RDP 2008;4;1193. DIEU F. L'indemnisation des personnes atteintes de sclérose en plaques suite à leur vaccination contre le virus de l'hépatite B. Gaz. Pal. 2007;287:2. DAILLE-DUCLOS B. Responsabilité du fait des produits défectueux: la fin justifie-t-elle les moyens? JCP E 2009:2113. GROMB S, BENALI L, BÉRANGER B. Journal de médecine légale, Droit médical, Victimologie, Dommage corporel. 2008;2:101. HOCQUET-BERG S. Gaz. Pal. 2007;157;47-49; SPORTES C., RAVIT V. Décideurs Jurididiques et Financiers 2009;103-104;82-83. JEAN-PIERRE D. Sclérose en plaques et imputabilité au service liée à la vaccination obligatoire contre l'hépatite B: les conditions posées par le Conseil d'État. JCP A 2007;19:2108. LAUDE A. Reconnaissance de l'imputabilité au service de la sclérose en plaques due à la vaccination obligatoire contre l'hépatite B. JCP G 2007;II;10142. NEYRET L. L'imputabilité de la sclérose en plaques au vaccin contre l'hépatite B. Dalloz. 2007;2204. OLSON T. Conclusions du commissaire du gouvernement. Lien de causalité recoonu entre une maladie et le vaccin contre l'hépatite B. AJDA 2007:861.

34 Conseil d'État, 9 mars 2007, n° 267635 and n° 278665.

vaccine injections. This employee received a compensation from the French State on the ground of the Article L. 3111-9 of the French Public Health Code but asked for a compensation on the ground of the legislation concerning the accident de service. The Conseil d'État held that the imputability of the disease to the service could be presumed because the scientific available data does not indicate a link between the vaccination and the nervous system diseases, but does not exclude such a link, and thus considered that this imputability have to be based on a case-by-case analysis of three factual elements: first, the temporal relationship between the vaccination and the onset of the first symptoms of the disease, second, an absence of patient history, third, an absence of evidence of other causes of the disease[35]. In 2007, the solutions consecrated by the Conseil d'État were remarkable because, at the same time, the Cour de cassation refused to admit such a causal link between the vaccination and similar diseases in cases related to products liability. Indeed, compulsory vaccination and work-related accidents concern only a part of the people who developed demyelinating diseases after hepatitis B vaccination. For persons whose vaccination is not compulsory or when one or several requests have been rejected, the recourse to the common law is possible; it is the products liability.

B - The cases related to products liability

French product liability law can be divided into three main systems: contractual liability, tort liability, and defective product liability. The contractual liability does not concern lawsuits involving hepatitis B vaccine manufacturers because of the French prohibition for pharmaceutical products manufacturers to contract with users of these products[36]. However, in lawsuits involving these manufacturers, the Council Directive 85/374/EEC of 25 July 1985[37] and the tort liability have been applied (**1**). The most that can be said is that the establishment of the causal link between demyelination and vaccination was controversial (**2**).

1 - The law

"The producer shall be liable for damage caused by a defect in his product"[38]. The Product Liability Directive of 1985 introduced a strict liability of manufacturer for damages caused by a defect in the product. The Directive shall apply to pharmaceutical products, ignoring the specificity of these

35 In this case, the fact that the compensation was accorded before by the French State was relevant.
36 Article R. 5124-42 of the French Public health Code.
37 EEC Council Directive 85/374/EEC of 25 July 1985 on the Approximation of the Laws, Regulations, and Administrative Provisions of the Member States Concerning Liability for Defective Products. O.J. L 210/29. France enacted the Directive into national law ten years after the deadline for transposition, on 19 May 1998.
38 First Article of the Directive of 25 July 1985.

products[39]. The Directive requires the injured person to prove, the damage, the defect, and, the causal relationship between the damage and the defect[40]. Pursuant to the Article 6.1 of the Directive[41], "a product is considered to be defective "when it does not provide the safety which a person is entitled legitimately to expect". The Directive shall not apply to products put into circulation before the date on which the act implement the directive enter into force[42]. In France, the Directive was only implemented in France by Act n° 98-389 of 19 May 1998, entered in force on 21 May 1998[43]. This system applies to products put into circulation after the 21 May 1998 and is without the prejudice to other pre-existing contractual, non-contractual, or special liability systems. Nevertheless, the two hepatitis B vaccines commercialized in France[44] were put into circulation at the end of the 1990's. As a consequence, the Directive has never been directly applied in the context of hepatitis B vaccination. However, the Directive shall indirectly apply to such products. Indeed, the European Court of Justice (ECJ) required national courts, when applying national law, whether adopted prior to or after the Directive, to interpret that law in the light of the wording and purpose of the directive since the Marleasing case[45]. Then, Members State which have not implement the Directive in the three years from the date of the notification of the Directive, *i.e.* before the 30 July 1988[46], must apply their intern law in the light of the

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39 See concerning the application of the products liability Directive to health products: BLOCH L. Pour une autre présentation de la responsabilité du fait des produits de santé. RCA 2009;16. FOUASSIER E, VAN DEN BRINK H. Produits de santé défectueux: premières applications des articles 1386-1 et suivants du Code civil. Gaz. Pal. 2002;171:11. LAUDE A. La responsabilité des produits de santé. Dalloz 1999:189. LAUDE A. Aperçu de la jurisprudence nationale en matière de responsabilité du fait des médicaments défectueux. RDSS 2005:743. CLERC-RENAUD L. Quelle responsabilité en cas de dommages causés par des produits de santé? RLDC 2007:11. OUDOT P. L'application et le fondement de la loi du 19 mai 1998 instituant la responsabilité du fait des produits défectueux: les leçons du temps. Gaz. Pal. 2008;320:6. See also "La responsabilité du fait des produits de santé défectueux", RDSS 2008;6:1005.

40 Article 4 of the Directive of 25 July 1985. Article 1386-9 of the French Civil Code.

41 Article 1386-4 of the French Civil Code.

42 Article 17 of the Directive of 25 July 1985.

43 Act n° 98-389 of 19 May 1998 sur la responsabilité du fait des produits défectueux: JO of 21 May 1998, Articles 1386-1 *et seq.* 1386-18 of the French Civil Code. See notably concerning the adoption of the act: GHESTIN J. Le nouveau titre IV du Livre III du Code civil. "De la responsabilité du fait des produits défectueux". L'application en France de la directive sur la responsabilité du fait des produits défectueux après l'adoption en France de la directive sur la responsabilité du fait des produits défectueux après l'adoption de la loi n° 98-389 du 19 mai 1998. JCP 1998;I;148. JOURDAIN P. Commentaire de la loi n° 98-389 du 19 mai 1998 sur la responsabilité du fait des produits défectueux. RCA chron. 1998;16. LARROUMET C. La responsabilité du fait des produits défectueux après la loi du 19 mai 1998. Dalloz chron. 1998:311. VINEY G. L'introduction en droit français de la directive européenne du 25 juillet 1985 relative à la responsabilité du fait des produits défectueux. Dalloz chron. 1998:291. See concerning the condemnation of the French State: European Court of Justice (ECJ), 25 April 2002, Commission des Communautés européennes c/ France, aff. C-52/00.

44 GlaxoSmithKline (now GSK) and Aventis Pasteur-MSD (now Sanofi Pasteur-MSD, the vaccines division of Sanofi-Aventis Group) are the pharmaceutical companies involving in marketing hepatitis B vaccines in France. GSK involves in marketing Engerix B® and Sanofi-Pasteur MSD involves in marketing the GenHevac® B.

45 The ECJ has called in those circumstances national judges to interpret the national law in accordance with the provisions of EC legislation. See Case 106/89 Marleasing SA v La Comercial Internacional de Alimentacion SA [1990] ECR 1839: the ECJ reiterated that under Article 249 EC, it "lies on all elements of the state, including the courts, and required national courts, when applying national law, whether adopted prior to or after the Directive, to interpret that law in the light of the wording and purpose of the directive".

46 The Directive was notified to Members State the 30 July 1985. Then, Members State had three years for implement the Directive before the 30 July 1988.

wording and purpose of the directive when the products were put into circulation after this day and before the coming into force of the legislation implementing the Directive.

Applying the intern law to the light of the wording and purpose of the directive, French judges developed a strict liability regime (l'obligation de sécurité de résultat) on the ground of the Articles 1147 (contractual liability)[47], 1382, 1383[48] (fault liability), and 1384[49] of the French Civil Code (the liability for damages caused by things)[50]. This strict liability regime applies to manufacturers require the same conditions which are consecrated by the Product Liability Directive: the injured person must prove the damage, the defect, and the causal relationship between the damage and the defect but there is no mention of the causal relationship which could normally exists between the use of the product and the damage, neither in the Directive, nor in the strict safety liability regime. Nonetheless, in products liability cases involving hepatitis B vaccine, the question is not to know whether the product defect cause the damage, but to know whether the product itself cause the damage (the imputability of the damage to the product). In all the products liability cases involving hepatitis B vaccine, the main question at which judges must answer is to know whether the alleged damage is imputable to the hepatitis B vaccine.

2 - Establishing of the law

In the very first products liability cases involving hepatitis B vaccine, judges were not hostile to award compensation to plaintiffs who developed demyelinating diseases after an hepatitis B vaccination and who sued pharmaceutical manufacturers of vaccines[51]. The Court of appeal of Versailles notably

47 The regime were initially consecrated in contractual relationships.

48 Pursuant to Article 1382 of the French Civil Code: "any act whatever of man, which causes damage to another, obliges the one by whose fault it occurred, to compensate it." Pursuant to Article 1383 of the French Civil Code: "everyone is liable for the damage he causes not only by his intentional act, but also by his negligent conduct or by his imprudence." Three elements are required to prove the fault liability: a fault, a damage, and a causal link between the two.

49 Pursuant the Article 1384 of the French Civil Code: "a person is liable not only for the damages he causes by his own act, but also for that which is caused by the acts of persons for whom he is responsible, or by things which are in his custody."

50 All studied courts' decisions in the following applied in general these articles (separately or together), interpreting these rules in the light of the wording and purpose of the directive. Exceptionally, courts' decisions mentioned the Article L. 221-1 of the French Consumer Code. Pursuant to article, "products and services must, under normal conditions of use or under other circumstances that may reasonably be foreseen by the professional, offer the safety that can legitimately be expected and must not be a danger to public health."

51 Court of First Instance of Nanterre, 4 April 1997, *op. cit.* at 9: the court ruled in favor of patient who have claimed compensation and sued the vaccine manufacturer. Surprisingly, the court mentioned the Article 1384 of the French Civil Code. In appeal: Court of Appeal of Versailles, 12 September 2003: RADÉ C. Preuve du lien de causalité entre l'injection à une patiente du vaccin anti-hépatite B Genhevac B et un syndrome de Guillain-Barré. RCA 2004;344. See also First Instance Court of General Jurisdiction of Nanterre, 5 June 1998, *op. cit.* at 9: the court applied the national law (Article L. 221-1 of the French Consumer Code), interpreting that law in the light of the wording and purpose of the directive. In appeal: Court of Appeal of Versailles: 2 May 2001: BYK C. Responsabilité médicale. *In* Bioéthique. Législation, jurisprudence et avis des

accepted to presume the imputability of a multiple sclerosis to the vaccination because of the temporal relationship between the injection of the vaccine and the onset of the first symptoms of the disease, the absence of patient history and the absence of evidence of other causes of the disease[52]. Judges applied the Article 1353 of the French Civil Code, which allows them to use presumptions[53]. Nevertheless, on 23 September 2003[54], a decision of the Cour de cassation overturned that decision and held that patients had not indeed developed diseases as a consequence of the vaccination and had not to be compensated by pharmaceutical companies manufacturing the vaccine. The Cour de cassation considered that judges of the Court of Appeal had based their decision on an hypothetical causal relationship. However, the court did not close the door at any compensation to plaintiffs who suffered demyelinating diseases. According to some commentators of the decision, the three factual elements retained by judges were not definitely condemned[55]. The Cour de cassation only overturned the decision because of the contradictory elements on which judges had based their presumptions: judges mentioned that both medical expert's opinion and available scientific data do not indicate the existence of an association between the vaccination and the disease, but they admitted the link between the two because of the existence of the three aforementioned elements. They should probably mention that the scientific available data does not exclude such a link. For other commentators of the decision, the court decided that presumptions of fact could not be used for proving the imputability of the disease to the

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instances d'éthique. JCP G 2002;I;146. GROMB S, KIRMAN M-G. Vaccination contre l'hépatite B et sclérose en plaques. Médecine & Droit 2001;51:22. JOURDAIN P. Causalité juridique et incertitude scientifique. À propos du lien de causalité entre le vaccin contre l'hépatite B et l'apparition de la sclérose en plaques. RTD civ. 2001:891 and 896.

52 Court of Appeal of Versailles: 2 May 2001, *op. cit.*

53 Pursuant to Article 1349 of the French Civil Code, "presumptions are the consequences that a statute or the court draws from a known fact to an unknown fact". Pursuant to Article 1353 of the French Civil Code: "the presumptions which are not established by a statute are left to the insight and carefulness of the judges, who shall only admit serious, precise and concurrent presumptions, and in the cases only where statutes admit oral evidence, unless a transaction is attacked for reason of fraud or deception."

54 First Civil Law Chamber of the Cour de cassation, 23 September 2003, n° 01-13063 and n° 01-13064, Bull. civ. 2003;I;188: FAICT O. MISTRETTA P. Responsabilité du fait des produits défectueux: présumer n'est pas démontrer. JCP E 2003;I;1749. GOSSEMENT A. L'administration de la preuve en situation d'incertitude scientifique: la position attendue de la Cour de cassation dans l'affaire de l'hépatite B. LPA 2004;12:14. JONQUET N, MAILLOLS A-C, MAINGUY D, TERRIER E. Conditions de la responsabilité d'un fabricant de vaccin à raison d'une sclérose en plaques faisant suite à des injections d'un vaccin contre l'hépatite B. JCP G 2003;II;10179.JOURDAIN P. L'incertitude scientifique empêche de reconnaître un lien de causalité entre le vaccin contre l'hépatite B et l'apparition de la sclérose en plaques. RTD civ. 2004:101-103. LEVENEUR L. CCC 2003;12:19. MERCIER C, SICOT I. Le rappel à la rigueur de la Cour de cassation en matière de responsabilité du fait des produits défectueux. Médecine & Droit 2004:50-53. MAURY F, *supra* at 7. MÉMETEAU G. Vaccination préventive de l'hépatite B et sclérose en plaques: être médecin ou être juriste? LPA 2004;81:9. NEYRET L. Vaccination contre l'hépatite B: fin du débat judiciaire? Dalloz 2003;2579. SERINET Y-M, MISLAWSKI R. *Supra* at 8. MAZEAUD D. La distension du lien de causalité a des limites. Dalloz 2004;1344. STOFFEL-MUNCK P. Responsabilité civile. N° 2. La causalité. JCP G 2006;I;111. VINEY G. La responsabilité du fait des produits défectueux. *In* Responsabilité civile (Étude). JCP G 2004;I;101. The court applied the Articles 1147 and 1382 of the French Civil Code, interpreting these articles in the light of the wording and purpose of the directive.

55 NEYRET L. *Supra* at 56.

vaccine in presence of scientific uncertainty[56]. Since 2003, the link was never considered as established in the products liability context[57].

On 22 May 2008[58], the Cour de cassation rendered several controversial decisions, which were let us presume that the solution of the Conseil d'État will be probably consecrated later. The court held that the damage, the product defect and the causal link between the two could be establish by presumptions of fact, in the framework of products liability legislation, according to the Article 1353 of the French Civil Code. However, the decision did not mention that the imputability of the damage to the product could be proved by presumptions, so fundamental in the cases which concern us. Nevertheless, the recourse by judges to presumptions for proving the imputability of the damage to the product was effectively validated in two decisions of the Cour de cassation rendered in 2009.

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56 GOSSEMENT A. *Supra* at 56.

57 Court of Appeal of Versailles, 25 November 2005: HÉNIN C. La responsabilité du fait des médicaments: de quelques rappels nécessaires sur ses fondements et ses conditions. LPA 2006;100:6. First Civil Law Chamber of the Cour de cassation, 24 January 2006, n° 03-19534, Bull. civ. 2006;I;33: GRYNBAUM L. Conditions d'application du régime des produits défectueux. JCP G 2006;II;10082. LEVENEUR L. La sécurité à laquelle on peut légitimement s'attendre n'est pas absolue. CCC 2006;5;77. RADÉ C. Le "syndrome de Guillain-Barré". RCA 2006;3;91. ZARKA J-C. Responsabilité civile. Conditions d'application du régime des produits défectueux. JCP G 2006;I;10082:1055-64. NEYRET L. La défectuosité: nouvel enjeu du contentieux du vaccin contre l'hépatite B. Dalloz 2006:1273. SARCELET J-D. Responsabilité du fait des produits défectueux: le moment de la mise en circulation dans l'appréciation du caractère défectueux. LPA 2006;45:6. Court of Appeal of Montpellier, 4 April 2006. Court of Appeal of Paris, 2 June 2006: GIZARDIN B. Observations du ministère public. Gaz. Pal. 2006;229:32. ONAT A. Pharmacie. Gaz. Pal. 2006;343:58. RADÉ C. Laboratoires pharmaceutiques (vaccin anti-hépatite B). RCA 2006;10;306. Court of Appeal of Lyon, 22 November 2007, n° 06/02450: ONAT A. Responsabilité du producteur de vaccin: résistance ou dissonance à la Cour d'appel de Lyon? Gaz. Pal. 2008;159:52. Court of Appeal of Lyon, 12 February 2008, n° 06/01764.

58 First Civil Law Chamber of the Cour de cassation, 22 May 2008, n° 06-10967, Bull. civ. 2008;I;159, n° 06-14952, Bull. civ. 2008;I;147: BRUN P, Quézel-Ambrunaz C. Vaccination contre l'hépatite B et sclérose en plaques: ombres et lumières sur une jurisprudence instable. Revue Droit Civil 2008. BRUN P, JOURDAIN P. Préjudices causés par le vaccin contre l'hépatite B. *In* Responsabilité civile. Dalloz 2008:2894. BORGHETTI J-S. Retour sur le rapport de causalité entre la vaccination contre l'hépatite B et la survenance de la sclérose en plaques. RDC 2008:1186. DAILLE-DUCLOS B. Vaccin contre l'hépatite B et sclérose en plaques: appréciation du lien de causalité et du défaut du produit en cas d'incertitude sur l'origine du dommage. JCP E 2008:2137. GALLMEISTER I. Lien de causalité entre la sclérose en plaques et le vaccin contre l'hépatite B. Dalloz 2008:1544. GRYNBAUM L. La certitude du lien de causalité en matière de responsabilité est-elle un leurre dans le contexte d'incertitude de la médecine? Le lien de causalité en matière de psanté: un élément de la vérité judiciaire. Dalloz 2008:1928. GRYNBAUM L. Vaccins contre l'hépatite B et produits défectueux: les présomptions constituent un mode de preuve du lien de causalité et du défaut. JCP G 2008;II;10131. JOURDAIN P. Lien de causalité entre la vaccination contre l'hépatite B et la sclérose en plaques: la Cour de cassation assouplit sa jurisprudence. RTD civ. 2008:492. JULIEN J. De la responsabilité des fabricants de vaccin (ou du réveil de la causalité). Dr. de la famille 2008;7;17. PEIGNÉ J. Lien de causalité entre la sclérose en plaques et le vaccin contre l'hépatite B. RDSS 2008;578. PIERROUX E. Vaccination contre l'hépatite B et sclérose en plaques: vers l'admission judiciaire d'un lien de causalité. Gaz. Pal. 2008;176:19. RADÉ C. Vaccination anti-hépatite B et sclérose en plaques: le tournant? RCA 2008;8. ROUYÉRE A. Questions de méthode. RFDA 2008:1011. SINTEZ C. Responsabilité du fait des médicaments défectueux: trois arrêts attendus pour un revirement mesuré. LPA 2008;169:6. STOFFEL-MUNCK P. Certitude du lien de causalité. *In* Responsabilité civile. JCP G 2008;I:186.

On 22 January 2009[59], the court held that the Court of Appeal had correctly researched wether the factual elements of the case were sufficient for presume the causal link between the disease and the vaccination but decided that judges correctly excluded this link because there existed another causes of the disease[60]. On 9 July 2009, two decisions were rendered by the Cour de cassation[61]. In the first decision[62], the court overturned the decision rendered by the Court of Appeal because judges did not research, despite the lack of scientific evidence of the link between the disease and the vaccination, wether the factual elements of the case were sufficient for presume the causal link between the disease and the vaccination. In the second decision[63], the Cour de cassation approved the decision rendered by the Court of Appeal, considering that the link between the disease and the vaccine could be presumed, despite of scientific uncertainty, because of the temporal relationship between the vaccination and the onset of the first symptoms of the disease the absence of patient history and the absence of evidence of other causes of the disease. Then, the Cour de cassation adopted the reasoning of the Conseil d'État in decisions aforementioned of 9 March 2007. The judicial case law accepts thus to consider certain circumstances under which the link between a demyelinating disease and a vaccination against hepatitis B may be presumed[64].

Part II - Critiques of the establishment of a causal link between hepatitis B vaccination and demyelinating diseases

Any judgments involving pharmaceutical products involves science and any tort case involving science involves scientific uncertainty. Scientific uncertainty can concern both the etiology of a disease

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59 First Civil Law Chamber of the Cour de cassation, 22 January 2009, n° 07-16449, Bull. civ. 2009;I;11: DESHAYES O. Causalité. RDC 2009;3:1028. KOUCHNER C. Responsabilité en matière de recherche sur la personne. Gaz. Pal. 2009;143:33. SARGOS P. L'importance de la distinction entre l'origine et la causalité amplifiée. JCP G 2009;II;10031.

60 Such a genetic predisposition. See for an absence of consideration of such an element: Conseil d'État, 4e et 5e sous-sec., 24 July 2009, n° 308876: BORGHETTI J-S. *Supra* at 8.

61 Second Civil Law Chamber of the Cour de cassation, 9 July 2009, nO 08-14493, n° 08-11073, Bull. civil, 2009;I; 176: BORGHETTI J-S. *Supra* at 8. GALLMEISTER I. Vaccination contre l'hépatite B: responsabilité du laboratoire. Dalloz 2009:1968. BRUN P. Responsabilité civile. Dalloz 2010:49. GRYNBAUM L. *Supra* at 7. LEGOUX A. *Supra* at 7. RADÉ C. *Supra* at 7. SARGOS P. *Supra* at 7.

62 Second Civil Law Chamber of the Cour de cassation, 9 July 2009, nO 08-14493. The court applied the Article 1353 of the French Civil Code and the Article L. 411-1 of the French Social Security Code, interpreting these articles in the light of the wording and purpose of the directive.

63 Second Civil Law Chamber of the Cour de cassation, 9 July 2009, nO 08-11073. The court applied the Article 1147 of the French Civil Code because the strict safety obligation were originally contractual. Usually, the court applied the Article 1382, 1147 and 1384 of the French Civil Code.

64 See *contra* First Civil Law Chamber of the Cour de cassation, 24 September 2009, n° 08-16097: GALLMEISTER I. Dalloz 2009:2426. The link was not established in this case. See also Court of Appeal of Paris, 8 January 2010, n° 07/03209 and n° 07/19039.

(objective) and the conditions of the transmission of a disease (subjective)[65]. In cases involving products such as hepatitis B vaccines, decisions of French courts are rendered in a context of objective scientific uncertainty. Indeed, the scientific evidence data does not really know the etiology of demyelinating diseases. Then, the causes of these diseases, especially multiple sclerosis, are largely unknown[66]. So, the question was: can judges establish a causal relationship between a product and a damage despite the lack of scientific evidence of the causal link between the two? If so, in what circumstances? As shown, the vast majority of French courts recently held that the relationship of demyelination and vaccination could be proved on a case by case basis though international scientific researches are unable to answer generally the question. Indeed, both civil and administrative judges used presumptions for proving this causal relationship. Then, judges clearly affirmed that Law does not have to confirm Science. Nevertheless, the possibility that judges can establish such a link on a case by case basis meanwhile scientific uncertainty related to the general imputability which could exist between the diseases and the vaccination is not acceptable. The principle of the establishment of the link itself should be denounced (**A**). The criteria elaborated in the method of the demonstration of the link are also not convincing and thus the conditions of the establishment of the link should be disapproved (**B**).

A - Critiques of the principle of the establishment

The question of the causal link between a damage and a product is a crucial question in all cases involving health products. However, this is a double-barreled question. The first question is to know whether in a general way a particular damage can be caused by a product (abstract or general causality). The second question is to know whether a specific damage was caused by a product in a particular case (specific or individual causality). General causality concerns the ability of a product to cause a kind of damage. Specific causality concerns the material link between a product and a damage in a particular case[67]. The general causality is never explicitly requires by texts. Only the specific causality is required. Indeed, this is not the role of judges to establish a general and abstract link between a product and a damage. In the course of delivering reasons for judgment, judges must pay regard to the background in

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65 See concerning the distinction: GHILHEM J. La réception juridique de l'incertitude médicale. Médecine & Droit 2009:131.

66 See *ibid* at 4.

67 See concerning the distinction: BORGHETTI J-S. Vers un régime spécial de responsabilité du fait des produits de santé? RDC 2007:1157. BORGHETTI J-S. La responsabilité du fait des produits. Étude de droit comparé. Préf. VINEY G. Paris. LGDJ. 2004, n° 268 *et seq.* NEYRET L. *Supra* at 34. ROUYÈRE A. *Supra* at 56. SARGOS P. La certitude du lien de causalité en matière de responsabilité est-elle un leurre dans le contexte d'incertitude de la médecine? La causalité en matière de responsabilité ou le « droit Schtroumpf ». Dalloz 2008:1935. SERINET Y-M, MISLAWSKI R. *Supra* at 8.

question and appreciate whether a product could cause or not a damage on a case by case analyze[68]. Nevertheless, judges always implicitly answer the first question of the general causality before answering the question of the specific causality. Generally, this first question is not problematic, but in cases involving health products, especially pharmaceutical products, this question is often problematic because we don't know if the product is able to cause a kind of damage. Then, the question is: Can judges answer the question of a specific link between a product and a damage, in a particular case, while this link is abstractly impossible to prove? In the hepatitis B vaccination affair, judges finally decided to answer the question of the specific causality by using presumptions to establish the specific causal link between a demyelinating disease and a vaccination against hepatitis B. Then, judges did not explicitly answer the question of the general causality but they implicitly recognize this causality. Nevertheless, Law should confirm Science when scientific uncertainty concerns this general link. For this reason, the impossibility to prove the link between hepatitis B vaccination and demyelinating diseases contracted by claimants should not be consecrated (**2**). On the contrary, when Science confirm an abstract causality which can exist between a kind of adverse effect and the use of a product, judges should have the possibility to prove this link in certain circumstances (**1**).

1 - The possibility to prove the link in presence of scientific uncertainty

That is not the first time that French courts accept to presume the causal link between a product and a damage in presence of scientific uncertainty. Theses decisions have been held in the context of French contaminated blood affair and the hepatitis C affair. In these affairs, some persons who have received transfusion of blood or blood products became infected with the Human Immunodeficiency Virus (HIV) or the Hepatitis C Virus (HCV). These persons claimed for damages against blood transfusion centers, hospitals, clinics or French State but they were often unable to proved that the damage had caused their injury. Face at the victims' difficulty to prove this causal relationship between their contamination by the HIV or by the HCV and the transfusion of blood or blood products, judges have decided to consider that the causal link between the transfusion and the contamination could be considered as proved under certain conditions. As regards the Article 1353 of the French Civil Code and the adequate causation, judges presumed the link between transfusions and contaminations because of the absence of the contamination before the transfusion, the incidence of the contamination after the transfusion and the absence of other causes of the contamination[69]. Finally, lawmakers consecrated

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[68] Such a specific causality is explicitly required by the aforementioned Article L. 3111-9 of the French Public Health Code and implicitly by the work-related accidents legislation.

[69] First Civil Law Chamber of the Cour de cassation, 12 April 1995, n° 92-20747: Bull. civ. 1995;I;179, n° 92-11950 and n° 92-11975: Bull. civ. 1995;I;180: JOURDAIN P. La responsabilité civile des centres de transfusion sanguine et des

these presumptions of fact by the Act n° 91-1406 of 31 December 1991[70] and the Act n° 2002-303 of 4 March 2002[71]. In cases related to damages linked to HCV, to HIV, or to the hepatitis B vaccination, the elements which are able to presume a link between a damage and a product are similar. Recently, the Cour de cassation admit in another context the link between the incidence of a disease (Lyell syndrome) and the absorption of a drug (Zyloric®). On 5 April 2005[72], judges retained very similar elements, such as the proximity time between the cessation of the treatment and the cessation of the trouble and the absence of another causes of the disease for presuming the link between the syndrome and the alleged damage.

Some authors wondered about the consecration of presumptions of law in the hepatitis B vaccination context. Nevertheless, it is fundamental to notice that in the precedent frameworks, there is no scientific uncertainty (or a very marginal scientific uncertainty) concerning the possibility of being contaminated by these virus or by this syndrome after the administration of the product. The causality was supported by scientific available data. In such a context, the consecration of presumptions were comprehensive. Judges based their presumptions on an established fact, according to the Article 1349 of the french Civil Code. The Article defines the presumptions in fact. It precises that "presumptions are the consequences that a statute or the court draws from a known fact to an unknown fact"[73]. The consecration of such presumptions is though not easily acceptable, in the context of the hepatitis B vaccination, because the link between the product and the damage is not scientifically proved. The resort to presumptions of fact for proving a causal link between a disease and a vaccination seems artificial because presumptions of fact do not have for purpose to answer a general question. Besides, what is the known fact in the context of persons who contracted demyelinating diseases after being

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cliniques en cas de contamination de transfusés par le VIH: la Cour de cassation prend position. JCP G 1995;II;22467. Conseil d'État ass., 26 May 1995: MOREAU J. SIDA transfusionnel: responsabilité sans faute des centres de transfusion sanguine intégrés à l'hôpital. JCP G 1995;II;22468. LEROY J. Responsabilité des cliniques en matière de transfusion sanguine. RDSS 1995:766.

70 Article 119 of the Act n° 91-1406 of 31 December 1991. Article L. 3122-2, *al.* 1 of the French Public Health Code. The Act of 1991 established a compensation program for persons infected with HIV as a result of HIV-contaminated blood products.

71 Article 102, *al.* 1 of the Act n° 2002-303 of 4 March 2002, concerning the HCV.

72 First Civil Law Chamber of the Cour de cassation, 5 April 2005, n° 02-11947 and n° 02-12065, Bull. civ. 2005;I;173: BRUN P, JOURDAIN P. Responsabilité civile. Dalloz 2006:1929. CHABAS F. Responsabilité du fait des médicaments. Droit & Patrimoine 2005. HÉNIN C, MAILLOLS A-C. La responsabilité du fait des médicaments: à la recherche d'un équilibre entre rigueur et pragmatisme. LPA 2005;122:9. JOURDAIN P. Produit défectueux: ne pas confondre danger et défectuosité. RTD civ. 2005:607. JOURDAIN P. Défaut du produit de santé: mise en oeuvre des critères tirés de l'insuffisance d'information sur les risques et du bilan bénéfices/risques. RTD civ. 2006:325. GORNY A. La causalité à nouveau en péril. Dalloz 2005:2256. GRYNBAUM L. Lien de causalité entre l'absorption d'un médicament et le dommage subi par le patient et appréciation du caractère défectueux du produit. JCP G 2005;I;10085. LAUDE A. *Supra* at 37. RADÉ C. Laboratoire pharmaceutique (Syndrome de Lyell). RCA 2005;189. REBEYROL V. Les effets secondaires des médicaments et la responsabilité des laboratoires producteurs. LPA 2005;137:16. VINEY G. Responsabilité civile. JCP G 2005;I;149. See also First Civil Law Chamber of the Cour de cassation, 22 May 2008, n° 07-17200.

73 Article 1349 of the French Civil Code.

vaccinated? There is no such known fact in this context. Courts draw consequences from a negative fact (the risk is not excluded)[74].

This consideration concerns especially the products liability law. The liability of the manufacturer is not governed by a logic of compensation. The products liability regime established by the Directive does not establish presumption concerning the causal relationship between the product and the damage. Furthermore, it seems illogical to research a causal link between the product defect and the damage in the case in which the product cannot cause the damage. The imputability of the damage to the product should be appreciate before the causal link between the eventually product defect and the damage. Moreover, this imputability should be studied before the product defect. Then, the establishment of such presumption seems not conform the Directive. The same observation should be considered in the context of work-related accidents and compulsory vaccination, even though the link between the accidental consequences of a compulsory vaccination and the vaccination itself is not required by texts. When this link is established by judges, the proof of this relationship is not persuasive. The link between the alleged injury and the incidence of the vaccination is only based on a coincidental temporal association between the two. In presence of scientific uncertainty related to the causes of the demyelinating diseases, judges should not admit the possibility to prove by presumptions the causal link between such diseases and the vaccination.

2 - The impossibility to prove the link in presence of scientific uncertainty

Scientific uncertainty is related to the possibility of being infected by a demyelinating disease after an hepatitis B vaccination, and thus to the general causality which could exist between the damage and the product. When scientific uncertainty concerning such a causality, Law should confirm Science. Indeed, the resort to presumptions of fact in such a situation has not solid basis. Causation in law need to be direct and certain. The causal relationship between the product and the damage which cannot be established by scientists have to reflect scientific knowledge and the dispute which interests us should stop as soon as the link cannot be proved by science because this link is the first and the most obvious condition of any product liability. Such a relationship between the product and the damage have ever been consecrated in the framework of products liability. In an interesting decision which have been rendered by the First Civil Law Chamber of the Cour de cassation on 27 February 2007[75], the court

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74 See ROUYÈRE A. *Supra* at 56.

75 First Civil Law Chamber of the Cour de cassation, 27 February 2007, n° 06-10063: BORGHETTI J-S. Vers un régime spécial de responsabilité du fait des produits de santé? RDC 2007:1157. BRUN P, JOURDAIN P. Responsabilité civile. Dalloz 2007:2897. GOUTTENOIRE A, RADÉ C. Vaccin contre l'hépatite B et sclérose en plaques. RCA 2007;5;165.

refused to admit the link between a demyelination and a vaccination against hepatitis B. In consideration of scientific available data and medical expert's opinion, which do not indicate such a link, the court decided that this link could not be deduced from the hypothesis that the risk, not demonstrated, cannot be excluded. The court held that "health products liability requires the prove of the damage, the *imputability* of the damage to the *administration* of the product, the product defect, and the causal link between this product defect and the damage". The Cour de cassation reaffirmed that the plaintiff must prove the three classical required elements (the damage, the product defect, and the causal link) but required a new one: the imputability of the damage to the administration of the product. For the first time, this condition was explicitly required, concerning health products liability.

The proof of the imputability of the damage to the use of the product is a constant and obvious condition in all liability products regimes. Even if texts do not mention this condition, the imputability of the damage to the product is usually required by judges. For this reason, the solution consecrated by the court should be approved, especially in the health products liability. The court limited the solution to health products liability. Thus, the Cour de cassation attributed to health products a certain specificity in the legal framework of products liability[76]. The court mentioned the imputability of the damage to the *administration* of the product and required the proof of this condition concerning health products. It appears evident that the administration of a product only concerns specific products which have to be administrated to the patient or ingested by the organism of the patient. The court probably wanted to remind judges which ruled in the hepatitis B vaccination framework of the necessity to prove both the link between the damage and the product and the link between the damage and the defect product. For this reason, the court's decision should also be approved. Since 2007, such a decision was regrettably never held and courts faced potentially difficult issues concerning the method for establishing the proof of the link between demyelination and vaccination.

B - Critiques of the conditions of the establishment

The reasoning adopted by judges in the hepatitis B vaccination context can be divided in two main parts. Firstly, judges insist on the limits of the scientific truth and thus may consecrate the autonomy of the judicial truth (1). Secondly, judges use presumptions for establishing on a case by case basis a

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The decision applied the Articles 1147 and 1384 of the French Civil Code, interpreting these articles in the light of the wording and purpose of the directive.

76 See notably BORGHETTI J-S. Thesis. *Supra* at 65.

specific imputability between the product and the damage (2). Nevertheless, the two parts of judges' reasoning are not convincing.

1 - The non exclusion of the link by science

The vast majority of cases, administrative and judicial judges affirm the limits of the scientific truth and insist on these limits. Indeed, judges usually declare that scientific studies are not able to support a link between demyelinating diseases and hepatitis B vaccination but do not formally exclude such an association. Then, judges demonstrate that scientific available data is unable to answer the question. Above all, they demonstrate that science cannot formally exclude a causal link between the damage and the product. This element is very important. According to judges, the analysis of the eventual characterization of the link depends on the establishment of this requirement. Scientific non-exclusion of is a prerequisite which is required by the judicially research of such a link. This element shows a certain relationship of Law and Science. If scientific studies formally exclude the relationship of the damage and the product, judges will not be able to characterize the causal relationship. Law and Science become dependent. On the contrary, insofar as the link is not excluded, judges will be able to establish it. Law and science become independent. According to judges, Law does not have to confirm Science because Science does not exclude the general link which could exist between the damage and the product. The autonomy of Law at this level is clear. The main problem in the reasoning of judges is that the vast majority of scientific available data exclude this link: there is no association, no link, no relationship between vaccination and demyelination. Even if Science always involves a part of doubt, Science excludes the link.

2 - The use of presumptions

Judges consider explicitly or not that they may use presumptions of fact for proving a link between a product and a damage though this link is not proved by scientific available data. By using presumptions, judges adopt an inductive reasoning. Administrative and judicial judges generally considered that three elements are able to constitute serious presumptions of the imputability of the damage to the vaccine: the time proximity between the incidence of the disease and the vaccination, the absence of patient's history, the absence of other causes capable to explain the disease. Although these criteria are far too complicated to be analyzed fully in the present context, it seems worthwhile to pay attention to these elements.

On the other hand, two elements are related to the absence of the other causes of the disease: the absence of patient's history and the absence of other causes which are able to explain the disease. By utilizing these two criteria, judges use a method which consists to eliminate the possible other causes of the damage (causation by exclusion). In this method, it appears that the answer derives from a deductive model (probably) of reasoning. The plaintiff have to prove, first, that he had no history of the disease before the vaccination. Nevertheless, this element seems not relevant because the causes of the disease are largely unknown. We do not identify in particular what could be genetic predispositions for such diseases. However, this solution does not conform the french case law related to the incidence of genetic predispositions in the establishment of causation. Indeed, French courts accept to compensate victims who had genetic predisposition to the damage suffered[77]. The rule which applied is: you take the victim as you find it. Besides, the plaintiff must prove the absence of other causes which are able to explain the disease. This criterion also appears not relevant because the etiology of demyelinating diseases, especially multiple sclerosis, is largely unknown.

On the other hand, judges consecrate a chronological element. This is the element related to the time proximity between the first onset of the disease and the vaccination. In the framework of work-related accidents, the link between the vaccination and the work is implicitly established because of the time proximity between the incidence of the disease and the vaccination even if judges do not mention it. In several decisions, administrative and judicial courts consider explicitly that the first onset of the disease must occur during the few months (often less than two months) following the vaccination[78]. This element perplex us. Judges put in place another apparent scientific element which is absolutely not proved by science. Obviously, this element does not sufficiently prove the link between the disease and the vaccine[79]. Indeed the most likely explanation of the scientific available data concerning the causal relationship between the two is a coincidental association. As precedent ones, this element is not

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77 See for instance Second Civil Law of the Cour de cassation 15 December 1986, Bull. civ. 1986;II;193. 21 May 1990, Bull. civ. 1990;II;122. 28 October 1991, Bull. civ. 1991;II;259. 28 February 1996. 19 February 1997: RADÉ C. La consécration de la présomption d'imputabilité du dommage à l'accident et l'abandon du critère de l'implication du véhicule dans le dommage. See also MONTANIER J-C. L'incidence des prédispositions de la victime sur la causalité du dommage. Thesis. Préf. DEJEAN DE LA BÂTIE N. Grenoble II. 1981. HOCQUET-BERG S. Études offertes à Hubert Groutel Paris Litec 2006;8:173.

78 See notably Conseil d'État, 4é and 5é sous-sect., 24 July 2009, *op. cit.* The Court decided that in reason to the long time which separates the first symptoms of the disease and the vaccination, the causal relationship between the two is not established. See decisions in which the imputability of the disease to the vaccine was not established: Conseil d'État, 9 March 2007, n° 285288 (ten months before the vaccine injections and the first onset of the disease) and n° 283067 (ten years). See Second Civil Law of the Cour de cassation, 14 September 2006, n° 04-30642, *op. cit.*

79 See MAURY F. *Supra* at 7. ROUGÉ-MAILLART C, JOUSSET N, GUILLAUME N, PENNEAU M. *Supra* at 23.

conclusive. Finally, none of the three criteria retained by judges are appropriate for justifying presumptions of the imputability of a nervous system disease to an hepatitis B vaccine[80].

Conclusion

To conclude, the dispute of the persons who contracted demyelinating diseases after the hepatitis B vaccination shows the uneasy relationship between Science and Law. The analysis of the aforementioned decisions demonstrates that the legal truth does not always have to confirm the scientific truth. Indeed, French courts finally decide to establish in certain circumstances a causal link between hepatitis B vaccination and demyelinating diseases, while scientific available data does not support a relationship between the vaccination and demyelination events. Then, French courts allow plaintiffs to be compensated for their injury though all studies which analyze this issue demonstrate that administration of the hepatitis B vaccine and onset or relapse of demyelinating disease are not linked.

French judges finally recognize the causal relationship between demyelination events and hepatitis B vaccination on a case by case analysis, and specify circumstances under which this causal relationship may be proven by presumptions of fact. Rules which permit to establish such a link are different according to the context of the dispute (the liability of the French State for compulsory vaccination, the liability of the employer, the liability of the manufacturer), insofar as these rules contain certain criteria as the mandatory character of the vaccination which can make easier the proof of the link. Nonetheless, elements retained by judges for admit this link are similar (generally, the temporal relationship between the injection of the vaccine and the onset of the first symptoms of the disease, the absence of patient history and the absence of evidence of other causes of the disease).

In this complex legal framework, the use of presumptions of fact for proving such a link seems to be artificial. The Law should embrace Science when scientific available data does not support a link between a kind of injuries or diseases and the exposure to a product. Then, judges should not recognize the causal relationship between the use of the hepatitis B vaccine and the occurrence of a demyelinating disease. The institution of presumption of law can be imagined, but seems not to be justified in the hepatitis B vaccination affair. Such presumptions are indeed consecrated in the French law, but concern

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80 See concerning another vaccine: First Civil Law Chamber of the Cour de cassation, 25 June 2009, n° 08-12781, Bull. civ. 2009;I;141: SARGOS P. *Supra* at 7. GRYNBAUM L. *Supra* at 7. JOURDAIN P. *Supra* at 7. The First Civil Law of the Cour de cassation held that an unquestionable scientific evidence of the causal relationship between a vaccine and a damage cannot be required but can result from presumptions which are sufficiently serious, precise and concordant to justify a conviction, according to the Article 1353 of the French Civil Code.

hypothesis in which scientific uncertainty is almost non-existent. Finally, the analysis of the decisions rendered in the dispute of the hepatitis B vaccination affair should not lead to the consideration that doubt have to benefit claimants. Indeed, the courts' decisions which condemn a person, whoever it is, to compensate a damage are not justified when no element proves or allows seriously to presume that the damage was caused by a defendant's conduct.

Essays

Essais

Ensayos

Paper n. 3

FINANCIAL INVESTORS AS CONSUMERS AND THEIR PROTECTION:

RECENT ITALIAN LEGISLATION FROM A EUROPEAN PERSPECTIVE

by

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FINANCIAL INVESTORS AS CONSUMERS AND THEIR PROTECTION:

RECENT ITALIAN LEGISLATION FROM A EUROPEAN PERSPECTIVE

by

Cristina Amato and Chiara Perfumi♦

Abstract:

The present paper is firstly concerned with protections of investors in the Italian legislation and within a European context. Part I shall discuss in detail the definition of 'investors' as consumers in the European as well as in the Italian legislation. Part I shall therefore provide the reader with sufficient constructive elements in order to understand the present inconsistencies of definitions that instead deserve the utmost attention at both European and national levels. Secondly, in contrast with a legislative policy that seems to encourage recourse to private remedies, the argument supported in Part II of this paper questions the effectiveness of excessive private remedies if they are not buttressed by a consistent and rational framework. After dealing with the Italian offer of out-of-court settlement procedures (guarantee indemnification funds; no-fault funds) and collective redress procedures (collective injunctions; damages class actions; compulsory settlement), the argument put forward in Part II of this paper is that private remedies and access to justice lack clarity and are still excessively complex. An efficient protective system should first seriously enforce public remedies available (criminal sanctions and fines); secondly, it should simplify remedies and access to justice through the establishment of a hierarchy of remedies mandatory settlement attempts should come first, leading to an indemnity guarantee and excluding other ordinary suits. Only in case of failure an ordinary lawsuit may then be brought, either via individual actions or through class actions for damages, leading eventually to the awarding of economic damages. Last: access to indemnity funds should be permitted only in cases of defendant insolvency.

Key words: Financial Investors – Consumers – Italian Legislation – European Legislation – Indemnification Fund – Collective Injunction – Damages Class Action

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Summary

Part I - Financial Consumers and Applicable Provisions in Italy; 1. Introduction: The Peculiarity of Italian Financial Markets - 2. European Perspectives on "Customer Protection" and Financial Markets; 2. Protection of Financial Investors As "Consumers" in the Italian Legal System: The state of the Art; 2.1.Consumer and the Italian Financial Market; 2.2. Recent Regulations issued by Banking Authorities; 2.3. Special Consumer Protection legislation; 2.4. Transition.
Part II - The Law in Action: Providing Investors with Adequate Protection; 1. Remedies and Access to Justice: A European Perspective; 2. 2. Extra-judicial remedies for Investor Complaints and Access to Justice: An Italian Perspective; 2.1.1. Guarantee Indemnification Fund within The Settlement procedure and the Arbitration Chamber; 2.1.2. No-fault Indemnification Fund; 2.2.1. Collective Injunctions; 2.2.2. Class Actions for damages
Final remarks

Introduction: The Peculiarity of Italian Financial Markets

In the last decade, the Italian financial market has been gradually and profoundly transformed. After the scandals of Cirio, Parmalat[1] and the Argentinean Bonds, the market-oriented system has become exposed to a dangerous instability[2].

The major objective of the domestic regulation on financial markets has rested upon solidity and transparency of parties as a structural principle in a 'commercial-banking' perspective, whilst protection of savers (i.e. people who have invested saved monies in financial instruments of some sort) has until very recently been a 'secondary and indirect' purpose limited to the specific case of consumer law[3]. The distinction between 'saver/investor' and 'consumer', overtaken by Community policies, has been taken into consideration by national authorities on financial markets.

The implementation of EC Directives on consumer credit and distance contracts for financial services, on the one side, and the compelling need of protection of investors against abuses perpetrated by

[1] On this issue see : G. Ferrarini, P. Giudici, 'Scandali finanziari e ruolo dell'azione privata: il caso Parmalat', in F. Galgano and G. Visintini (eds.), *Mercato finanziario e tutela del risparmio. Trattato di diritto commerciale e di diritto pubblico dell'economia*, (CEDAM, Padova, 2006), v. XLIII, 197. G. Ferrarini and P. Giudici, *Financial Scandals and the Role of Private Enforcement: The Parmalat Case (May 2005)*, ECGI - Law Working Paper No. 40/2005. Available at SSRN: http://ssrn.com/abstract=730403 or doi:10.2139/ssrn.730403.

[2] G. D'Alfonso, 'Violazione degli obblighi informativi da parte degli intermediari finanziari: la tutela del risparmiatore tra rimedi restitutori e risarcitori', *La responsabilità Civile*, 12 (2008), 965.

[3] G. Alpa and P. Gaggero, 'Profili della tutela del risparmiatore', *Società*, 5 (1998), 520. See M. Bessone, 'Mercato finanziario, tutela del risparmio e pubblica vigilanza. Lo scenario internazionale ed il mercato italiano', in P. Perlingieri and E. Caterini (eds.), *Il diritto dei consumi*, (Rende: Edizioni scientifiche calabresi, 2005), II, 21.

financial intermediaries on the other have recently led to the introduction of different remedies aimed to provide them access to justice.

Scope of the present contribution is first to discuss in detail the definition of 'investors' as consumers in the European as well as in the Italian legislation. Part I shall therefore provide the reader with sufficient constructive elements in order to understand the present inconsistencies of definitions that instead deserve the utmost attention at both European and national levels.

Part I - The Financial Consumer and the Applicable Provisions in Italy.

1. European Perspectives on "Customer Protection" and Financial Markets.

EC financial-services law has developed in two different directions: by the enactment of rules on prudential and market supervision on the one hand, and by contract-related rules governing the provision of particular financial services on the other[4]. The European Treaties offer several possible legal bases for regulating the purchase of financial services products, relating to promotion of the internal market or to consumer protection. Arguably, 'the legal bases indicate a hierarchy of policy objectives which prioritises the internal market above consumer protection'[5].

The sectors involved in this evolution are normally limited to three main directories[6]: markets, instruments and financial intermediaries. However, there is a fourth one, that is, consumer-savers and their adequate protection.

The consumer purchasing financial services suffers from psychological and clear inferiority complexes in his/her contractual position, from the point of view of information and actual freedom of choice. This situation is even more evident as regards the four main pillars of the financial markets, which are banking, insurances, investments and thrift savings plans. Therefore, the way forward to protect savers and purchasers of financial products is to move towards the implementation of the transparency principle[7] and personal autonomy.

Protection of the consumer/saver/insured party means, at the same time, to enable a correct functioning of the market, as it avoids the dispersion of capital, profiting the community as a whole and

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[4] Green Paper on Financial Services Policy (2005-2010) (COM(2005) 177 final). See on the economic and policy context for a single market in financial services: M. Kenny,' The Protection of Non-Professional Sureties in Europe: the uncommon core of European Private Law?', in A. Colombi-Ciacchi (ed), *Protection of Non-Professional Sureties in Europe: Formal and Substantive Disparity*, (Nomos: Baden-Baden), p. 362.

G. Ferrarini, 'Contract standards and the Markets in Financial Instruments Directive (MiFID): An Assessment of the Lamfalussy Regulatory Architecture', *European Review of Contract Law*, (2005), 19.

[5] J. Long, 'Navigating the Maze: Reviewing the Information Disclosure Requirements in the Financial Services Acquis', *European Business Law Review*, (2008), 493.

[6] C. Iurilli,'Short selling, intermediazione finanziaria, asimmetrie informative ed esperienza dell'investitore', *La responsabilità Civile*, 10 (2006), 795.

[7] G. Chinè,'La tutela del risparmiatore nel diritto vivente', *Il Corriere del Merito*, 8-9 (2005), 873.

an adequate level of social justice. The contract must thus to be appreciated as the expression of individual freedom in the market to purchase according to a conscious and informed decision.

The integration of different interests related to the respect of competition rules, on one hand, and the making of fair contracts, on the other, lead to the signing of a contract freely and consciously entered into by the parties and the realisation of a free and efficient market[8].

This need for protection can, perhaps, be better expressed by constitutionally-oriented considerations (i.e. from a fundamental rights perspective) providing the judiciary 'with a powerful tool to adapt traditional contract law instruments to contemporary democratic and social values', making the contract an important vehicle for social justice policies[9].

For these reasons, the protection of financial services consumers must not disregard the subjective characterization of the investor according to his/her low professional, moderately professional or highly professional level of investing sophistication.

At the same time, the nature of this protection must be objective, considering that the financial market regulatory system does not only involve private law principles, but also, and especially, public law ones as well, which concern the safeguarding of the entire financial system[10].

The aim of protection, in fact, is the solidity, the reliability and the efficiency of the market, whereas investor protection is connected to the reliability of the system, which in turn is based on the principles of proper disclosure, transparency of contractual operations and good faith, all aimed at meeting the individual's needs in the market[11].

However, in order to appreciate the real scope of this regulatory policy and the degree of protection granted, a clear delimitation of the definition of investor must be given.

Only in some cases the investor is considered as a consumer, thus enjoying a higher level of protection. Most financial instruments are purchased by customers using professional intermediates.

The Directive on distance marketing of consumer financial services[12] refers to consumers[13], but it leaves to the Member States the possibility of extending the scope of the directive to non-profit organisations

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[8] See F. Camilletti, '*L'art. 2 del codice del consumo e dei diritti fondamentali e i diritti fondamentali del consumatore nei rapporti contrattuali*', *Contratti*, 10 (2007), 907 ; F. Scaglione,'Buona fede in contrahendo e ordine pubblico economico nel sistema del diritto privato del mercato', *Giurisprudenza italiana* (2008) 1.

[9] A. Colombi Ciacchi, 'The Constitutionalisation of European Contract Law', *European Review of Contract Law*, (2006), 180. See the European perspective on the phenomenon in C. Mak. *Fundamental Rights in European Contract Law*, (Kluwer Law International, 2008). Perplexities on the protection of weaker parties from risky financial transaction are considered by O. Cherednychenko, *Fundamental Rights, Contract Law and the Protection of the Weaker Party*, (Sellier: München, 2007), 272 ff.
See, for example, the surety protection models. This approximation is only desirable if it can offer a useful instrument at national level according to the specificity of the internal socio-economic context and legal culture. See A. Colombi Ciacchi, 'Formal and Substantive Disparity in European Suretyship Law: A Comparative Summary', in A. Colombi Ciacchi (ed), *Protection of Non-Professional Sureties in Europe: Formal and Substantive Disparity*, (Nomos: Baden-Baden), 395.

[10] C. Iurilli, 'Short selling', 795.

[11] C. Iurilli, 'Short selling', 795.

[12] Directive 2002/65/EC of the European Parliament and of the Council of 23 September 2002 concerning the distance marketing of consumer financial services and amending Council Directive 90/619/EEC and Directives 97/7/EC and 98/27/EC.

and people making use of financial services in order to become entrepreneurs, as such could find themselves unprepared to properly judge such investments, similar to that of an ordinary consumer[14]. However, the strict interpretation given by the ECJ[15] seems to bar any extensions of the concept of consumer even if national laws would allow that[16].

Nevertheless, in an effort to supersede the narrow subjective range of application of consumer law[17], some scholars try to set aside all different contractual relationships affected by asymmetries between the supplier and recipient, in the light of a more general policy of 'customer protection'[18].

The Markets in Financial Instruments Directive[19] (hereinafter, 'MiFID') seems to follow this trend. It is directed at protecting retail clients that are not necessarily consumers. Similarly, the Rome I Regulation[20] concerns situations where there are 'contracts concluded with parties regarded as being

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[13] Dir. 2002/65, art. 2d) : 'consumer means any natural person who, in distance contracts covered by this Directive, is acting for purposes which are outside his trade, business or profession'.

[14] Recital 29: 'This Directive is without prejudice to extension by Member States, in accordance with Community law, of the protection provided by this Directive to non-profit organisations and persons making use of financial services in order to become entrepreneurs'.

[15] The classic definition of 'consumer' as 'a natural person who, in the transaction covered by the relevant directive, is acting for purposes which can be regarded as outside his trade or profession' has been given a narrow interpretation by the ECJ, that has excluded, for instance, start-up contracts, assignments of consumer claims, and mixed contracts. This has been the case of the Directives on doorstep selling, consumer credit, unfair contract terms, timeshares, distance selling, and consumer sales and guarantees. Actually, certain authors have highlighted the fact that 'this concept has usually been taken over to contract law directives, without reflecting that the case law originated from the specifics of the jurisdiction rules under the Brussels Convention, where special jurisdiction is an exception to the general principle *actor sequitur forum rei*': H.-W. Micklitz and N. Reich, 'Cronica de una Muerte Anunciada: The Commission Proposal for a « Directive on Consumer Rights', *Common Market Law Review*, (2009), 482. Interpreting these rules, the ECJ has developed, in conformity with the information model, 'a European consumer image', according to which the 'reasonably well informed and reasonably observant and circumspect consumer' prevails: G. Straetmans, 'Some Thoughts on the Future European Consumer Acquis', in *European Business Law Review*, (2009), 429.

[16] *Cape snc v Ideal Service srl*, 21 November 2001, Joined Cases C 541-542/99. The Spanish government contended that 'the definition of consumer given by the Directive does not make it impossible for Member States, when transposing it, to treat a company as a consumer in their domestic law, but the decision clearly stated on the point affirming that: 'it must be observed that Article 2(b) of the Directive defines a consumer as 'any natural person' who fulfils the conditions laid down by that provision, whereas article 2(c) of the Directive, in defining the term 'supplier or seller', refers to both natural and legal persons. It is thus clear from the wording of Article 2 of the Directive that a person other than a natural person who concludes a contract with a seller or supplier cannot be regarded as a consumer within the meaning of that provision. 'Accordingly, the answer to the second and third questions must be that the term 'consumer', as defined in Article 2(b) of the Directive, must be interpreted as referring solely to natural persons'. See on this point : G. Straetmans, 'Some Thoughts on the Future European Consumer Acquis'*, European Business Law Review*, 2009, 442.

[17] The consumer acquis has been limited by the Commission to eight directives currently under review, but 'given that consumer protection as such embraces far more than the acquis, account will have to be taken of the case-law of the Court in particular, and of the broad definition in the B2C directive in future policy initiatives': L.W. Gormley, 'The Consumer Acquis and the Internal Market', *European Business Law Review*, ?? (2009), 420.

[18] V. Roppo, 'From Consumer Contracts to Asymmetric Contracts: a Trend in European Contract Law?', in *European Review of Contract Law*, (2009), 304. Therefore, as it has been argued, 'the extent to which consumers are to be "protected" is part of the larger debate on how interventionist States ought to be': H. Unberath and A. Johnston, 'The Double-headed Approach of the ECJ Concerning Consumer Protection', *Common Market Law Review*, ?? (2007), 1237.

[19] Directive 2004/39/EC of the European Parliament and of the Council of 21 April 2004 on markets in financial instruments amending Council Directives 85/611/EEC and 93/6/EEC and Directive 2000/12/EC of the European Parliament and of the Council and repealing Council Directive 93/22/EEC.

[20] Regulation (EC) No 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I).

weaker, those parties should be protected by conflict of- law rules that are more favourable to their interests than the general rules' (Recital 23) [21].

Consumer protection rules are thus conceived here as special rules for specific cases based both normatively and conceptually on the more general rules of private law[22]. Besides, since the DCFR does not contain a specific chapter relating to contracts involving the supply of financial services[23], the inclusion of the already existing PEL FSC in the DCFR, as supported by many authors, 'would make an important contribution to the creation of a coherent structure of rules on service contracts in general, and financial-service contracts in particular'[24].

The EU institutions, instead, through the Proposal for a Directive on Consumer Rights seem to go in the opposite direction[25], that would split the retail market into two separate markets as it contains, on the one hand, rules that are only applicable to consumers, narrowly defined (art. 2(1)) but, on the other hand, a quite broad substantive scope aimed at regulating a wide spectrum of subject (art. 3)[26].

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[21] Recital 23 reads: 'As regards contracts concluded with parties regarded as being weaker, those parties should be protected by conflict of- law rules that are more favourable to their interests than the general rules'. Then, Recital 24 contains a more specific reference to consumer contracts. Financial services such as investment services and activities and ancillary services provided by a professional to a consumer (Art. 6) are specifically concerned by the proper functioning of the internal market as it creates a need for certainty related to the law applicable and the free movement of judgments (Recital 29). Therefore, for conflicts-of-law rules in Member States, art. 6 provides for designation of the same national law irrespective of the country of the court in which an action is brought.

[22] See M. Hesselink, 'The Consumer Rights Directive and the CFR : two world apart ?, *European Review of Contract Law,* (2009), 299.

[23] As concern the aspects at stake, it has to be underlined that in the Draft on the Common Frame of Reference (hereinafter: 'DCFR') the definition of consumer is extended to mixed contracts, whilst its subjective range of application is maintained: even though Small and Medium Enterprises (hereinafter: 'SME') are often in very similar positions than consumers there is a sharp contrast between the way consumers and small businesses are treated. See M. Hesselink, 'Common Frame of Reference & Social Justice', *European Review of Contract Law*, (2008), 264.

In any case, from the reactions to the Green Paper it results that several stakeholders asked for clarification regarding the relationship between the future horizontal instrument and other EU legislation or ongoing legislative procedures, other directives (*i.e.* Directive on Distance Marketing of Financial Services) and the Draft of a Common Frame of Reference (DCFR).

A consumer organisation argued that all consumer directives should be included and this should comprise also the Financial Services Directive: see DG Health and Consumer Protection, 'Preparatory Work for the Impact Assessment on the Review of the Consumer Acquis', p. 34. Available at: ec.europa.eu/consumers/rights/detailed_analysis_en.pdf.

In the same line, several businesses, preferred the horizontal instrument as a common denominator to all the Consumer *Acquis*, including a limited scope to only few items, (like, for example, the notion of consumer) they suggested anyway that it must include in that case also financial services: DG Health and Consumer Protection, 'Preparatory Work', 43.

Finally, some others note that , in particular, the financial sector may be worried by the possibility that the introduction of a horizontal instrument would supersede specific financial services legislation (vertical instruments such as MiFID and the UCITS Directive, which regulate the activities of asset managers and fund managers and distributors), imposing additional burdens and possibly interfering with the basic principles of operation and management of funds activities (e.g. the UCITS Directive and MiFID already regulate the provision of information requirements): DG Health and Consumer Protection, 'Preparatory Work', p. 44.

[24] O. Cherednychenko and E.C. Jansen, 'Principles of European Law on Financial Service Contracts?', *European Review of Private Law*, (2008), 443: "Given that financial-service contracts are not 'regulated specifically' in the DCFR, the provision of Article II – 1:108(1) under (a) does not apply. This implies that the rule of Article II – 1:108(1) under (b) applies and that only the 'rules applicable to contracts generally' apply to that part of the mixed contract that involves the supply of a financial service. The further corollary of this is that, in the context of either the Principles of European Law (PEL) or the DCFR, genuine financial-service contracts are only governed by general contract law provisions".

[25] Proposal for a Directive on Consumer Rights of 8 October 2008, COM (2008) 614 Final.

[26] See M. Hesselink, 'The Consumer Rights Directive', 295.

In any event, according to Art. 3(2) of the Proposal, financial services should be exempted, with the exception to certain off-premises contracts[27].

2. Protection of Financial Investors As 'Consumers' in the Italian Legal System: The state of the Art.

2.1. The 'Investor' in the Italian Financial Market.

The client of a banking/financial institution must face a veritable 'legislative forest' of provisions: therefore the actual notion of 'investor' must be defined according to Italian law in order to verify, therefore, the law applicable.

Traditionally, the investor's contractual position is governed both by general consumer law and special legislation provided by the *Testo Unico Bancario*[28] (Consolidated Act on Banking, hereinafter: 'T.U.B.') and by the *Testo Unico della Finanza*[29] (Consolidated Act on Finance, hereinafter: 'T.U.F.'), as well as related regulations issued by the Banca d'Italia (Bank of Italy) and by the Italian public financial authority for regulating the Italian securities market (CONSOB)[30] aimed at their implementation.

The 'T.U.B.' is exclusively devoted to the banking sector. Part of this legislation is addressed to all bank clients according to a 'neutral' notion aiming to include professional, as well as corporate, bodies having a contractual relationship with the bank, whilst rules on consumer credit concern only 'consumers' pursuant to the definition provided by the Consumer Code[31], as we shall see here below.

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[27] The provisions of the Directive on consumer rights cover contracts relating to financial services "only insofar as this is necessary to fill the regulatory gaps" (par. 11). Anyway, according to the Draft Report in the Proposal for a Directive of the European parliament and of the Council on Consumer Rights prepared by the Committee on the Internal Market and Consumer Protection (2008/0196(COD)) the current reading of art. 3 should be modified. The reporter, Andreas Schwab, proposes a different version of art. 4, par. 1° concerning the scope of "targeted full harmonisation" measures. Therefore, this article should not apply to contracts falling within the scope of Directive 2002/65/EC. These contracts are moreover excluded from the application of consumer information and withdrawal right rules for distance and off-premises contracts (art. 4b, par. 2a).

[28] Legislative Decree no. 385 of 1 September 1993, Consolidated Law on Banking.

[29] Legislative Decree no. 58 of 24 February 1998, Consolidated Law on Financial Intermediation, implemented by Consob Regulation no. 11971 of 14 May 1999.

[30] Banca d'Italia and Consob equally sharepowers of control and supervision over financial markets. Their roles are defined according to the purpose pursued, that is the fairness of behaviours (Banca d'Italia) and the supervision of market stability (Consob): B. Cavallo, 'Dissesti finanziari e sistema istituzionale: il ruolo delle attività di controllo', in F. Galgano and G. Visintini (eds.), *Mercato finanziario e tutela del risparmio. Trattato di diritto commerciale e di diritto pubblico dell'economia*, (CEDAM : Padova, 2006), v. XLIII, p. 15.

[31] See Articles 121-126. Article 121 of the 'T.U.B.' repeats at the first paragraph the definition of consumer as 'natural person who is acting for purposes which can be regarded as outside his trade or profession'. At the same time, the fourth paragraph enumerates those cases excluded from its range of application. (Letter a), for example, refers to 'financing instruments that have an aggregate value inferior or superior to limits imposed by a CICR resolution producing effects since the 30th day from its publication on the *Gazzetta Ufficiale*'. Consequently, if the person that received the financing is a 'natural person who is acting for purposes which can be regarded as outside his trade or profession', but the financial operation has a greater value, the contract can no longer be regulated by consumer rules).
See G. Carriero, *Autonomia Privata e disciplina del mercato. Il credito al consumo,* 2nd edn, (Giappichelli: Torino, 2007), p. 66; R. Lener, *Forma contrattuale e tutela del contraente « non qualificato » nel mercato finanziario,* (Giuffré : Milano, 1996), pp. 53-55.

The 'T.U.F.' aims to provide protection for a general category of 'investors' related to financial intermediaries[32], against unreliable financial investments going beyond ordinary risk standards proper to these types of transactions, respecting the duties of care and fairness, and, more generally, contributing to the efficient functioning of financial markets[33].

The implementation of these Acts is hence granted by secondary legislation enacted by the *Banca d'Italia* (Bank of Italy) and *Commissione Nazionale per le Società e la Borsa*[34] (CONSOB). Both authorities have equivalent powers of control and supervision over financial markets. Their role is defined according to the purpose pursued, that is, the fairness of given behaviour (Banca d'Italia) and the supervision of market stability (Consob).

Finally, the Consumer Code (d.lgs. n. 206/2005, enacted in October 23, 2005) grants the consumer special protection in consumer credit contracts[35] and financial services[36], where consumer is meant to be a "natural person who is acting for purposes which can be regarded as outside his trade or profession"[37].

The implementation of the definition of consumer in Italian legislation relating to the financial markets is emblematic of the truly passive nature of the reception of mass (standardised) contracts in our legal system[38]. Consumer legislation actually exists only in the areas where EC law imposes such protective rules (i.e. consumer credit and distance marketing of consumer financial services); where, instead, the European legislature did not intervene, different criteria have been used (i.e., estate intermediation, securities' public offers, banking transparency).

Together with rules directly regulating contracts, professionals especially qualified for the provision of financial services are bound by a set of rules of conduct aimed at governing and orienting their professional activity.

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[32] Art. 5.1b. See V. Roppo,'Sui contratti del mercato finanziario, prima e dopo la MiFID', *Rivista di diritto privato*, 3 (2008), 485.

[33] Art. 21. There is a sharp contrast, in Italy, between some authors and the case law on the definition of these obligations and the applicable remedy (contract liability or nullity). See: Trib. Genova (Genoa), 18 April 2005; Trib. Genova, 15 March 2005; Trib. Mantova (Mantua), 1 December 2004; Trib. Venezia (Venice), 22 November 2004; Trib. Firenze (Florence), 19 April 2005; Trib. Roma, 25 May 2005; Cass, Sez. Un., 19 December 2007, n. 26725, *Contratti*, 3 (2008), 221.
A. Di Majo,'Prodotti finanziari e tutela del risparmiatore', *Corriere giuridico*, (2005), 1285; V. Roppo, 'La tutela del risparmiatore fra nullità e risoluzione (a proposito di Cirio bond & tango bond)', *Danno e Responsabilità*, 6 (2005), 604; V. Roppo,'La tutela del risparmiatore fra nulità, risoluzione e risarcimento (ovvero l'ambaradan dei rimedi contrattuali)', *Contratto e impresa*, 3 (2005), 896 ; R. Calvo, 'Il risparmiatore disinformato tra poteri forti e tutele deboli', *Rivista trimestrale di diritto e procedura civile*, 4 (2008), 1431; F. Galgano, 'Il contratto di intermediazioni finanziaria davanti alle sezioni unite della cassazione', *Contratto e impresa*, 1 (2008), 1; P. Morandi,'Prestazione dei servizi di investimento: forma dei contratti e regole di condotta degli intermediari finanziari', *Obbligazioni e contratti*, 11 (2008), 919.

[34] The *Commissione Nazionale per le Società e la Borsa* (CONSOB) is the public authority responsible for regulating the Italian securities market.

[35] Articles 40-43.

[36] The Directive 2002/65/CE concerning the distance marketing of consumer financial services has been directly inserted as a new Section of the Consumer Code (article 67*bis* to 67 *vicies bis*): Art. 7, l. n. 229 of 29 July 2009. A new Section IV bis of Chapter I of Title III of Part III has therefore been introduced. The beneficiary (art. 67*ter*1.d) of this protective legislation is thus the "consumer", defined in art. 3 a.

[37] Art. 3a.

[38] R. Lener, *Forma contrattuale e tutela del contraente «non qualificato»*, p. 49.

Thus, in this regard, an important role is played by financial operator self-regulation through the enactment of codes of conduct[39], alternative dispute resolution procedures and, quite often, by certain initiatives undertaken at the professional industry-wide level, in agreement with user/client associations.

2.2. Recent Regulations issued by Banking Authorities.

In this context, on the 18th of March 2009 Banca d'Italia published a document opened to public consultation containing (what should be) the new regulation on transparency in banking and financial services, now contained in the final version of 29th July 2009[40].

This new regulation aims to establish a sort of balance between efficiency needs and solidity of the banking and financial systems, on the one hand, and the protection of clients on the other. Major objectives are, therefore, the protection of clients and the promotion of competition, attempting to mitigate the risks to which the market is normally exposed.

In order to fulfil these objectives and to provide emphasis to the issues at stake, Banca d'Italia provides a series of graduated measures in relation to the nature of the services provided and the characteristics of the clientele to which they are targeted.

On the basis of the principle of proportionality, duties differ according to the features of services provided and their recipients. They are thus classified as follows, taking into consideration the varying intensity of the degree of protection:

- 'consumer', namely the natural person who is acting for purposes which can be regarded as outside his trade or profession;
- 'retail clients', understood as consumers, non-profit entities and businesses having total revenues lower than Euro 5 million and fewer than 10 employees[41];
- 'client', that is every natural person or legal person that has a contractual relationship, or that is willing to enter into such, with an intermediary.

Some provisions apply exclusively to contracts entered into with consumers or 'retail clients'. The status of 'consumer' or 'retail clients' must be verified by intermediaries before the conclusion of the contract. They can eventually change the characterisation of such status in the contract, once signed, only if the parties request such and so long as applicable conditions have been duly met[42].

It should be highlighted that in the document under consideration, the word 'consumer' appears to have a clear predominance over the other categories of clients.

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[39] G. Carriero, 'Codici deontologici e tutela del risparmiatore', *Il Foro italiano*, 10 (2005), 196.

[40] On the meaning of « transparency » in banking, see G. Alpa and P. Gaggero, 'Trasparenza bancaria e contratti del consumatore', p. 73 ss.

[41] This category was created previously by Consob Regulation n. 16190 of 29 October 2007, intended as 'non professional clients'.

[42] See the final version of 29 July 2009, p. 3.

Moreover, previous regulatory measures implemented in 2003 did not refer to any 'weaker party', as had been done before in the Instructions on Banking Supervision[43] and the 'consumer' was only referred to 'as natural person who is acting for purposes which can be regarded as outside his trade or profession' only in few cases.

That was the case, for example, of rules mentioning the duty to advise the consumer on his/her rights introduced under the Consumer Credit Directive[44] and of the duty imposed on the bank to deliver an informational prospectus to the consumer before the purchase of complex financial products.

As a result, while previous measures did not consider the nature of the recipient, being thus neutral, the new legislation appears more calibrated to their specific needs in the financial market[45].

Moreover, for those 'clients' that do not fall within the two preceding categories, general contract law must be applied.

Following the approach of the Civil Code model, different provisions cover standard contracts, on the one hand, and individually negotiated contracts, on the other.

The reinforced procedural protections require duties of transparency that correspond to general duties applicable to all recipients of financial services, except for those duties that expressly and solely refer to 'consumers' or 'retail clients'.

Finally, the new Section V is entirely devoted to distant means of communication, in order to define the scope of application of rules on pre-contractual information disclosure and as regards communications that are not required concerning offers executed through distant means of communications.

In this regard, different provisions are afforded for cases in which intermediaries deal with consumers and those in which they deal with professionals.

2.3. Special Consumer Protection Legislation.

The "client-consumer" that purchases a consumer credit contract is protected by special legislation currently located in the Consumer Code (Arts. 40-43) and the 'T.U.B.' (Articles 121-126), all of which makes the identification of the consumer quite confusing[46].

In fact, the TUB contains general rules protecting the 'client', and, some specific provisions on the 'consumer' applicable on the basis of the consumer's definition[47].

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[43] See G. Carriero,'Trasparenza delle condizioni contrattuali', *Diritto delle banche e dei mercati finanziari*, 2003, p. 4.

[44] Penultimate alinea, par. 2, Sezione II.

[45] P. Carrière and M. Bascelli,'Trasparenza delle operazioni e dei servizi finanziari: le nuove regole della banca d'Italia', *Contratti,* 6 (2009), 611.

[46] See R. Clarizia,'La nozione di consumatore nel codice del consumo e con riguardo ai contratti di credito al consumo', *Diritto dell'Internet*, (2006), 354 ; G. Carriero, *Autonomia Privata e disciplina del mercato*, p. 47.

[47] The lack of coherence in the same text is therefore frustrating: R. Lener, *Forma contrattuale e tutela del contraente 'non qualificato'*, p. 52.

Article 121 of the 'T.U.B.' repeats at the first paragraph the definition proposed by the Consumer Code according to which consumer is identified as a "natural person who is acting for purposes which can be regarded as outside his trade or profession".

The definition stresses two main aspects: a consumer can only be a physical person; and moreover, the purpose of the activity concerned must be non-professional, that is, the scope of the activity must be the satisfaction of some personal or family need.

Having regard to the first condition, Italian experts have increasingly proposed the extension of consumer protection to legal persons, in particular to corporate entities, paying particular attention to those having a not-for-profit purpose[48], such as associations, committees and consortia carrying out both external and internal activities[49]. This way, it would be possible to provide a more coherent definition of the "weaker" contractual party[50].

Nevertheless, this interpretation has been rejected both by the Constitutional Court[51] and the Supreme Court, the Corte di Cassazione[52], who have invoked the need for coherence towards European policy.

Having regard to the second aspect, related to the proper notion of 'consumer', the nature of the purpose is ascertained through a subjective test (often ignored by Italian courts of first instance) aimed at confirming how consumers act, taking into account form, circumstances of time and place, and

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[48] P. Bonofiglio, 'L'ambito soggettivo di applicazione dell'art. 1469*bis* c.c.', (comment on C.cost., 22 November 2002, n. 469, *Nuova Giurisprudenza Civile Commentata*, (2003), 182...

[49] E. Battelli, 'Consumatore: nozione, clausole abusive e foro del consumatore', *Il Corriere del merito*, (2006), 6; R. Bin, 'Clausole vessatorie: svolta storica (ma si attuano così le direttiva comunitarie?)', *Contratto e impresa/Europa*, (1997), 436 ; G. Carriero, 'Autonomia privata e disciplina del mercato', p. 67. R. Lener, *Forma contrattuale e tutela del contraente « non qualificato » nel mercato finanziario*, Milan 1996, p. 49.

[50] The target of consumer policy is thus to balance the asymmetry between the conflicting interests, giving consideration to the specific position of the weaker party. In determining the scope of protection, consideration should be given to the fact that the overall balance of the contract is acquired through the power of disposal apt to the professional market operators. In view of this, consumer protection could certainly be extended to incorporated entities should they act outside the range of the by-laws. This position has been adopted by the Italian Courts of first instance: in different circumstances they have forced the statutory rule denouncing discrimination: GdP Aquila, (ord.) 3 November 1997, *Giustizia civile*, (1998), I, 2314, case comment L. Gatt, 'L'ambito soggettivo di applicazione della normativa sulle clausole vessatorie'; Trib. Bologna, 3 October 2000, *Corriere giuridico*, (2001), 525 comment by R. Conti, 'Lo status di consumatore alla ricerca di un foro esclusivo e di una stabile identificazione: il Tribunale qualifica il condominio come un ente di gestione sfornito di personalità giuridica estendendone la tutela consumeristica'. See C. Amato, *Per un diritto europeo de consumatori,* (Giuffré: Milan, 2003), p. 20.

[51] C.cost, (ord.) 30 June 1999, n. 282, *Foro Italiano,* (1999), I, 3118, comment by A. Palmieri, 'L'ibrida definizione di consumatore e i beneficiari (talvolta pretermessi) degli strumenti di riequilibrio contrattuale'; C.cost., (ord.) 22 November 2002, n. 469, *Foro Italiano*, (2003), I, 332, case comment by A. Palmieri, 'Consumatori, clausole abusive e imperativo di azionabilità della legge: il diritto privato europeo conquista la Corte Costituzionale'; A. Plaia, 'Nozione di consumatore, dinamismo concorrenziale e integrazione comunitaria del parametro di costituzionalità: le persone giuridiche proprio per l'attività abitualmente svolta hanno cognizione idonea per contrattare su un piano di parità'; *Nuova Giurisprudenza Civile Commentata*, (2003), 178 case comment by P. Bonofiglio.
Recently: C.cost. (ord.) 16 July 2004, n. 235, *Foro Italiano*, (2005), I, 992, case comment by A. Palmieri, 'Alla (vana?) ricerca del consumatore ideale?'.

[52] Cass. 14 April 2000, n. 4843, in *Foro Italiano*, (2000), I, 3196; Cass. 25 July 2001, n. 10127, in *Giurisprudenza italiana*, (2002), 543 case comment by Fiorio, 'Professionista e consumatore, un discrimine formalista?'; in *Contratti*, (2002), 338 'La nozione di consumatore secondo la Cassazione'; *Giustizia civile*, (2002), I, 688, case comment by F. Di Marzio, 'Ancora sulla nozione di 'consumatore' nei contratti'; *Vita notarile*, (2001), 1330.
For this reason, even though this aspect is not expressly taken into account in the issue at stake, it is important to raise the problem, since it seems that the main obstacle has to be overcome through the European legislation.

payment conditions: the ambiguous definition is apparently directed to persons that '...act for extraneous purposes', thus allowing for different interpretations of the disposition[53].

Thus, the fourth paragraph of article 121 subsequently enumerates cases excluded from the range of application, making its scope more restricted than the one proper to consumer law.

Letter a), for example, refers to 'financing instruments that have a global value inferior or superior to limits imposed by a CICR resolution producing effects from the 30th day of its publication in the *Gazzetta Ufficiale*' (Italian Official Journal).

Consequently, if the person that received the financing is a 'natural person who is acting for purposes which can be regarded as outside his trade or profession', but the financial operation has a greater value, the contract may no longer be regulated by consumer rules.

In a different way then consumer credit legislation, actually remained in the TUB, Directive 2002/65/CE concerning distance marketing of consumer financial services has been reflected in a new Section of the Consumer Code (Article 67*bis* to 67 *vicies bis*)[54].

Hence, the importance of this statutory provision does not depend on the specific protection rules (restating the same regulatory terms introduced in 2005), but rather on the systematic effects on the coordination between rules,[55] as such set of rules is only applicable to the client that actually meets the objective and subjective standards of a consumer.

Moreover, the definition of 'financial service' is directly provided by the Consumer Code in articles concerning distance marketing of consumer financial services, under Article 67*ter*(b), but it does not exactly correspond to that given under Art. 33(3), related to unfair terms in consumer contracts. The latter, in fact, cross-referenced general principles expressed in points h) and m) of the second paragraph concerning permanent contracts for financial services. In this case, the professional has both a right of withdrawal and a *jus variandi* within a reasonable period of time, thus reducing the degree of protection granted to consumers[56].

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[53] Therefore, there is a creeping distinction between the consumer and the physical person who is acting for purposes that can be regarded as outside one's trade or profession, but whose purchase cannot be objectively qualified as a consumer contract according to the law.
See, for a consumer credit issue: Trib. Bologna, 18 January 2006, *Diritto dell'internet*, (2006), 354.
Consumer conduct may be defined as 'contractual' according to the concrete use of the contract. On the contrary, the purpose of the contract can be understood as having a positive or negative value. In the first case it is defined as the "consumeristic" purpose, whilst in the second as a 'non professional' one: E. Gabrielli, 'Il consumatore e il professionista', in E. Gabrielli and E. Minervini (eds.) *I contratti dei consumatori,* 2 vols (UTET, Turin, 2006), 13.

[54] Art. 7, l. n. 229 of 29 July 2009. Thus a new Section IV bis of Chapter I of Title III of Part III has been introduced.
See F. Bravo,'Nozione di «servizi finanziari » di cui al d.lgs. n. 190 del 2005 sulla «Commercializzazione a distanza di servizi finanziari ai consumatori» e collocabilità della disciplina nel codice del consumo', *Rivista Trimestrale di Diritto e Procedura Civile*, 2 (2007), 585.

[55] F. Bravo,'Commercializzazione a distanza di servizi finanziari ai consumatori', *Contratti*, 4 (2008), 373.

[56] F. Bravo,'Commercializzazione a distanza di servizi finanziari ai consumatori', 373.

2.4. Transition

It thus seems that in the Italian system we find a growing need for protection of weaker parties, also as regards financial contracts, even if traditionally they were regulated up until a few years ago only under market principles.

Different remedies have thus been introduced in order to provide adequate investor protection.

On the one hand, in fact, case law shows a certain tendency to act against non-transparent behaviour by economic actors/operators and, on the other, of the legislator (or delegated authorities) to establish a set of rules allowing consumers to attack the "stronghold" of banking interests.

In the same vein, several legislative provisions, such as the so-called '*decreto Bersani-bis*' (second Bersani decree), introduced important changes concerning loans by giving a new basis to the relationship between the client and the bank, by granting the former new advantages in 2008[57]. Class actions have thus been allowed under Article 32-*bis* of the 'T.U.F.', applying Articles 139 and 140 of the Consumer Code to consumer associations[58].

Finally, recent legislative and regulatory provisions[59] have introduced an indemnity guarantee fund as well as a no-fault fund, thus creating an alternative compensatory system aimed at compensating damages suffered by a general category defined as 'non professional' savers/investors[60].

Part II - The Law in Action: Providing Investors with Adequate Protection

1. Remedies and Access to Justice: A European Perspective

Institutional investors are the most significant focus of reform efforts on the securities markets. In the Italian as well as European contexts, the most debated issues mainly concern investment firm conduct and related liabilities, on one hand, and, on the other, great concern is devoted to controversial related issues of remedies and access to justice.

Recent legislation has faced both issues in the effort to regulate the financial market. Part II of this paper shall therefore address the complex statutory provisions dealing with protection of investors, highlighting the main contents and goals achieved by the European and Italian legislative frameworks. In dealing with the subject at stake a warning is necessary: there are several and scattered provisions in the European as well as in Italian legal systems that still do not form a coherent statutory framework able to offer efficient and simple purchaser protection in the securities market.

[57] It was successively confirmed by a Parliamentary Act, Law n. 126/2008.

[58] M.C. Paglietti, V. Zeno-Zencovich, 'Verso un 'diritto processuale dei consumatori'?', *La Nuova giurisprudenza civile commentata*, 6 (2009), 251.

[59] L. n. 266, 23 December 2005, Articles 343-345.

[60] L. n. 262, 28 December 2005, n. 262 *Disposizioni per la tutela del risparmio e la disciplina dei mercati finanziari*, as implemented by D.lgs. n. 179/2007 and by Consob Regulation n. 16190/2007.

In addition to consumer contracts, commercial and financial contracts have been deeply influenced by European legislation. Although the statutory framework remains fragmented and inconsistent in several parts – the implementation into the Italian legal system being of no help - it has renewed and refreshed the old-fashioned Italian Civil Code in the commercial and financial areas, providing it with an independent regulation which had previously been called for by several known scholars. In particular, and as regards the commercial area only, the new European legislation has dealt with consumer credit contracts, banking, sale of goods – movable and immovable property, and distance selling; in the financial investments' activities there have been several incursions of the European legislator at different stages: the pivotal principles and rules have been provided in Directive 2004/39/EC (MiIFD) regarding markets in financial instruments, as completed by Dir. 2006/73[61]. Another pivotal piece of legislation is Directive 2004/109/EC of the European Parliament and of the Council of 15 December 2004, concerning the harmonization of transparency requirements in relation to issuer disclosure for those whose securities are listed for trading on a regulated stock market (amending Directive 2001/34/EC). Finally, the legislative framework is completed by Dir. 2003/71 regarding the type of prospectus to be published when securities are offered to the public or admitted to market trading and by Dir. 2002/65 on distance marketing of consumer financial services.

As this paper addresses investor protection, investment products and investment firm conduct shall be dealt with, whilst commercial issues will be excluded[62]. In this legal area the general principles adopted at a European level may be summarised in a first set of guidelines: fair dealing and transparency (see Art. 14 MiFID[63]), disclosure (see art. 19 MiFID[64] , Dir. 2004/109[65], Dir. 2003/71[66]; Dir 2002/65 on

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[61] Directive 2006/73/EC of 10 August 2006 implementing Directive 2004/39/EC of the European Parliament and of the Council as regards organisational requirements and operating conditions for investment firms and defined terms for the purposes of that Directive. See also Commission Regulation (EC) No 1287/2006 of 10 August 2006 implementing Directive 2004/39/EC of the European Parliament and of the Council as regards record-keeping obligations for investment firms, transactional reporting, market transparency, admission of financial instruments to trading, and defined terms for the purposes of that Directive.

[62] A complete review of the commercial area legislation is provided by V. Buonocore, 'Problemi di diritto commerciale europeo', *Giurisprudenza commerciale*, I (2008), 3 ff., footnotes 31-37.

[63] Directive 2004/39/EC (MiIFD) of the European Parliament and of the Council of 21 April 2004, regarding markets in financial instruments, amending Council Directives 85/611/EEC and 93/6/EEC (implemented into the Italian system through D.lgs. 17 September 2007, n. 164).

Article 14 - Trading process and finalisation of transactions in an MTF: '1. Member States shall require that investment firms or market operators operating an MTF, in addition to meeting the requirements laid down in Article 13, establish transparent and non-discretionary rules and procedures for fair and orderly trading and establish objective criteria for the efficient execution of orders. 2. Member States shall require that investment firms or market operators operating an MTF establish transparent rules regarding the criteria for determining the financial instruments that can be traded under its systems.'

[64] *Article 19 - Conduct of business obligations when providing investment services to clients* **: '**1. Member States shall require that, when providing investment services and/or, where appropriate, ancillary services to clients, an investment firm act honestly, fairly and professionally in accordance with the best interests of its clients and comply, in particular, with the principles set out in paragraphs 2 to 8 […]'.

distance marketing of consumer financial services[67]), adequacy (see Art. 13 MiFID[68]) and appropriateness (Dir. 2003/71, Art. 7, par. 2 lett. b)[69]). All the above-stated principles have been implemented in the Italian system by way of the 'T.U.B.', (Title VI in particular) and the 'T.U.F' (Part II in particular: see par. 2 for more).

A second set of guidelines coming from the European legislation consists both of the preference for collective redress procedures compared to individual claims, and of the adoption of extra-judicial (outside of court) instruments of dispute resolution. As regards collective redress procedures, Art. 52, par. 2[70], MIFID (introduced into Part II, Title II, capo IV-*bis* 'T.U.F.') suggests that Member States maintain a list of 'bodies' who shall have recognised standing on behalf of consumers in order to ensure that the national provisions for the implementation of the MiFID Directive shall be applied. As in Dir. 93/13 (regulating unfair terms in consumer contracts) the *rationale* behind this provision is rooted in the pragmatic understanding that, for several reasons, investors (as well as consumers) are not strong enough to bring forward suits. This may be true because often the action would involve small claims, or because investors are not sufficiently aware of their rights, nor of the available redress procedures. On the contrary independent public entities (as in the case of England & Wales), or consumers associations (as in the case of Italy) are meant to represent investors' collective interests as a 'class', different in their nature from individual interests. Special attention to consumers' collective interests has been provided by European legislators through Dir. 98/27, now superseded by Dir. 2009/22, where the importance of protecting collective interests as opposed to individual interests is stresses. Whereas " collective

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65 Directive 2004/109/EC of the European Parliament and of the Council of 15 December 2004 on the harmonization of transparency requirements in relation to disclosure about issuers whose securities are admitted to trading on a regulated market (amending Directive 2001/34/EC), implemented into the Italian system by D.lgs. 6 November 2007, n. 195.

66 The entire Directive is devoted to appropriate information to the public, as clearly stated in:
Article 1- Purpose and scope '1. The purpose of this Directive is to harmonise requirements for the drawing up, approval and distribution of the prospectus to be published when securities are offered to the public or admitted to trading on a regulated market situated or operating within a Member State.'
This directive has been recently – although not significantly - amended by Dir. 2008/11.

67 The need to inform investors in distance selling of financial products is clearly stated in recital (21): ' The use of means of distance communications should not lead to an unwarranted restriction on the information provided to the client. In the interests of transparency this Directive lays down the requirements needed to ensure that an appropriate level of information is provided to the consumer both before and after conclusion of the contract. The consumer should receive, before conclusion of the contract, the prior information needed so as to properly appraise the financial service offered to him and hence make a well-informed choice. The supplier should specify how long his offer applies as it stands.'
The directive has been recently– although not significantly - amended by Dir. 2007/64.

68 *Article 13 - Organisational requirements:* 1. The home Member State shall require that investment firms comply with the organisational requirements set out in paragraphs 2 to 8 […].

69 *Article 7 - Minimum information : […]* 2. In particular, for the elaboration of the various models of prospectuses, account shall be taken of the following: […] (b) the various types and characteristics of offers and admissions
to trading on a regulated market of non-equity securities. The information required in a prospectus shall be appropriate from the point of view of the investors concerned for non-equity securities having a denomination per unit of at least EUR 50 000.

70 *Article 52 - Right of appeal:* […] 2. Member States shall provide that one or more of the following bodies, as determined by national law, may, in the interests of consumers and in accordance with national law, take action before the courts or competent administrative bodies to ensure that the national provisions for the implementation of this Directive are applied: (a) public bodies or their representatives; (b) consumer organisations having a legitimate interest in protecting consumers; (c) professional organisations having a legitimate interest in acting to protect their members.'

interests mean interests which do not include the accumulation of interests of individuals who have been harmed by an infringement…" (see Recital 3, Dir. 2009/22). This Directive applies to consumers' collective interests included in previous Directives listed in Annex I. Among them Dir. 2002/65 concerning distance marketing of consumer financial services appears, and this implicitly means that: *i.* investors are included in the consumer-wide class; and *ii.* collective redress should be encouraged and/or improved under national legislation. As we shall see further on (see par. 2.2.2.), a new form of collective redress remedy has recently been introduced into the Italian system under the form of a 'class action'.

As regards out-of-court settlements Art. 53 Dir. 2004/39/EC (MiIFD) suggests that Member States encourage 'the setting-up of efficient and effective complaints and redress procedures for the out-of-court settlement of consumer disputes concerning the provision of investment and ancillary services provided by investment firms, using existing bodies where appropriate'. As we shall see further on (see par. 2), extra-judicial (out of court) mechanisms have in fact been successfully introduced into the Italian legal system.

2. Extra-Judicial Remedies for Investor Complaints and Access to Justice: An Italian Perspective

The main impact on the Italian system of the abovementioned European legislation concerning financial markets consists of the following: a) rendering investment firm behaviour more transparent and therefore more trustworthy; b) improving the relationship between public institutions and citizens (see Art. 5 'T.U.F.', according to which: "to improve the fiduciary relationship between investors and institutions" is one of the main goals of financial brokers' discipline).

In particular, the general principles introduced by the EU legislation have been spread-out over layered levels into the 'T.U.B.' and "T.U.F.", and at present, transparency, fair dealing and duties of disclosure represent an essential part of the Italian (commercial and) financial legal system.

The most significant provisions are represented by Art. 21 'T.U.F'., which expressly requires fair dealing of investments firms (lett.a)), and which expressly adopts the 'know your customer rule' (lett. b), while lett. d) of the above-mentioned provision requires adequate organisational arrangements. It is also important to cite the regulations enacted by the Italian financial regulatory Authority (CONSOB): not only is the 'know your customer rule' described in more detail, but also the principle of adequacy is detailed and transformed into the 'suitability rule' (see Arts. 39 and 40 of regulation n. 16190/07)[71]. As for the liability arising from investment firm breaches of the adequacy/suitability rule, most Italian

[71] On the 'suitability rule' and 'know your customer rule', see R. Bruno, 'L'esperienza dell'investitore e l'informazione "adeguata" e " necessaria"', *Giur. comm.,* 2 (2008) 389; M. Guernelli, 'L'intermediazione finanziaria tra tutela del mercato, legislazione consumeristica e orientamenti giurisprudenziali', *Giur.comm*., 2 (2009) 360.

investment contracts transfer this risk to clients, by introducing contractual terms stating that the client has been exhaustively informed about the risks and consequences of the transaction, thus assuming that the client is fully aware of his/her commitments. Apart from this unlawful contractual practice, which should probably be considered as an unfair infringement of consumer rights under Dir. 1993/13, neither the 'T.U.F.' nor the regulatory instruments enacted by CONSOB have clearly stated the remedies available to investors should the investment firm breach any of its above-listed duties. This statutory silence explains why Italian lower Courts have recognised different remedies in case of individual lawsuits[72]: reliance damages deriving from pre-contractual liability, expectation damages deriving from breach of the financial contract, invalidity of the financial contract absent the required written form or due to the violation of mandatory rules.

In order to avoid the practical uselessness of remedies taken from the general law of contract, and also in compliance with the guidelines suggested at the European level (see par. 1 above), two different remedies have recently been introduced by Law 2005/262 for the protection of savings/investments: a) the 'guarantee indemnification fund'; and b) the no-fault indemnification fund.

a) Guarantee Indemnification Fund Within The Settlement Procedure and the Arbitration Chamber

This procedure was introduced by Art. 27 L. 2005/262, as implemented by D.lgs. 2007/179 (arts. 2-5) and subsequent regulations enacted by the Italian Financial Regulatory Authority' (CONSOB)[73]. In case of breach of disclosure duties required by Art. 21 'T.U.F.' on financial brokers, investors may ask for a settlement or an arbitration redress procedure held by CONSOB. Should the financial broker be found

[72] See on this issue: A. Tucci, 'La violazione delle regole di condotta degli intermediari fra "nullità virtuale", culpa in contrahendo e inadempimento contrattuale, *Banca, borsa, titoli di credito*, 5 (2007), 621; A. E. Fabiano, 'La negoziazione di bond e le conseguenze della violazione degli obblighi di informazione dell'intermediario tra responsabilità per inadempimento e nullità del contratto, *Banca, borsa, titoli di credito*, 3 (2007) 324; E. Lucchini Guastalla, 'Violazione degli obblighi di condotta e responsabilità degli intermediari finanziari', *Responsabilità civile e previdenza*, 4 (2008), 741. See also C. Amato,'Financial Contracts And 'Junk Titles' Purchases: A Matter of (In)Correct Information', Cambridge University Press, 308 ff. The chaos of different civil remedies has been recently solved by the Italian Supreme Court (*Corte di Cassazione*) by applying different principles and rules. According to the highest Italian Court, disclosure duties belong to the so-called 'rules of fair dealing'. Consequently, the proper remedies to be applied to breaches of those rules cannot be premised upon the validity/invalidity of the contract itself; rather, they must be based upon the content of the agreement, as it relates to the defendant's behaviour. This leads to the conclusion that broker liability depends, as to its nature and discipline, on the content of the informational disclosure, as well the context regarding the very moment such was delivered to the investor. In sum, financial broker liability can be either pre-contractual, if it concerns conduct and a set of disclosure delivered *before* signing the purchase of specific titles; or, to the contrary, it may be contractual, if it concerns the financial providers' conduct *in the course of the performance* of the purchase contract, resulting in a breach of contract. In both cases, the client-investor shall be awarded either reliance damages, in the former instance, or expectation damages, in the latter. See Cass. 29/09/2005, n. 19024, in *Danno e resp*., 2006, p. 25, comment by V. Roppo, G. Afferni, 'Dai contratti finanziari al contratto in genere: punti fermi della Cassazione sulla nullità virtuale e responsabilità precontrattuale', *Danno e resp*., 1 (2006), 30 ss.; Cass. Sez. Un., 19.12. 2007, nn. 26724 and 26725, *Danno e resp*., 4 (2008), 525; Cass. 17/02/2009, n. 3773, *Danno e resp*., 5 (2009) 503.

[73] See regulation n. 16763, 29 December 2008.

to be in breach of his/her duty, he/she will be compelled by the settlement or arbitration board to pay the economic loss suffered by the claimant. It is clearly an indemnity - that is set in compliance with CONSOB Regulations – as opposed to and different from full compensatory damages. The arbitration agreement inserted into financial contracts is binding only for brokers, not for investors, but – as we shall deal later - the settlement proceeding has now become mandatory. Standing is recognised for consumer associations pursuant to Art. 140 of the Consumer Code (see further, par. 2.2.).

This remedy is alternative to ordinary claims. Should the claimant be unsatisfied with the arbitration board's damage award, he/she may file claim in the ordinary courts that will – if the case so requires - award all damages suffered by investors in addition to the damages already recognised. This redress procedure still maintains the function of deterrence, and at the same time it provides a quick (although not cheaper) arbitration procedure.

b) No-fault Indemnification Fund

The second remedy originally introduced under the Budget Law of 23/12/2006, n. 266, and now implemented by L. 2007/179 (Arts. 8-9) consists of a *no-fault* indemnification fund, based on the absolute liability deriving from financial investment's brokerage activities (as regulated by Part II of the 'T.U.F.'). What is relevant for investors in order to obtain damages is that they provide evidence of the breach of brokers' duties and demonstrate the remoteness of the economic loss suffered by claimant. The indemnity is awarded only if a judicial decision or arbitration award has been delivered, and all sums investors already received from an ordinary judgment must be deducted. The fund is exclusively created by collecting half of the total amount deriving from criminal fines eventually paid by financial brokers, and it is managed by CONSOB. The latter has a right of recourse (taking action) against the defendant.

Subsequent to the recent financial scandals[74] in Italy, the goal of this remedy is to provide compensation to investors in cases of financial fraud. Notwithstanding CONSOB's right of recourse, the deterrent function of the remedy is thus almost completely ignored.

The main differences between the indemnification through settlement and/or arbitration procedure and the no-fault fund may be summarised thus:

- in case of a no-fault indemnity there must be a judicial or arbitration decision assessing any liability deriving from the breach of obligations stated in Part II of the 'T.U.F.'; and

[74] Regarding Cirio, Argentine and Parmalat bonds scandals, see C. Amato, 'Financial Contracts And 'Junk Bonds' Purchases in the Italian Legal System: A Matter of (In)Correct Disclosure', footnotes 31-36, proceeding of Durham Conference 'Conceptualising Unconscionability in Europe', forthcoming (Cambridge University Press).

- the indemnity therefore awarded shall be imposed, deducting any sums already awarded the claimant, whether he/she applied for an ordinary judgment or for arbitration redress procedures leading to the indemnity guarantee.

3. Collective Redresses

a) *Collective Injunctions*

As regards access to justice, individual claims will certainly be dealt with by judges or arbitrators. However, this solution has two significant disadvantages: *i.* it is subject to uncertainty as regards the applicable remedies (nullity/avoidability of contracts, breach of contract, pre-contractual liability: see text par. 2 and footnote 72 hereabove); and *ii.* overly high costs must be borne by individuals, especially where the financial loss suffered is not significant.

In this perspective, collective injunctions, as well as class actions, do represent efficient alternative remedies to ordinary individual claims. As already stated in par. 1, collective injunctions are highly recommended by the European legislature. After numerous attempts, the recently issued Directive on injunctions (Dir. 2009/22) has drawn a line between individual claims and collective injunctions. First, there is a difference in the protected interests: collective interests 'do not include the accumulation of interests of individuals who have been harmed by an infringement' (see recital 3 Dir. 2009/22). To the contrary, they consist of a *different* interest damaged by unlawful practices carried out by professionals infringing Community law. Secondly, the Directive at stake allows claimants (that is, associations, excluding individual claimants) to seek an order for the following, *i.* requiring the cessation or prohibiting defendants from any infringement; *ii.* requiring measures such as the publication of the decision, in full or in part, in such form as deemed adequate and/or the publication of a corrective statement with a view to eliminating the continuing effects of the infringement advertising the prohibitory/mandatory injunctions on national and/or local newspapers; and *iii.* that the losing defendant may payment to the public purse or to any beneficiary designated in or under national legislation, in the event of failure to comply with the decision within the deadline specified by the courts or administrative authorities, such to be a set amount for each day's delay or any other amount provided for under applicable national legislation, with a view to ensuring compliance with the decisions (see Art. 2 Dir 2009/22).

This provision (Art. 2 Dir. 2009/22) involves unlawful practices infringing Community law as outlined in the Directives listed in Annex I; such include the Directive on distance marketing of financial services, but any other violations of financial services legislation is not mentioned. Italian financial

legislation, to the contrary, grants standing to consumer associations representing collective consumer interests against *any* violations of investment services activities: Art. 32-*bis* 'T.U.F.'[75], in fact, refers back to Arts. 139 and 140 of the Italian Consumer Code, and both provisions regulate collective injunctions issued as redress for damages. Moreover, according to Art. 7 D.lgs. 2007/179, consumer associations may utilise an extra-judicial mechanism connected to indemnity arbitration procedures. These inconsistencies between Italian (financial) legislation and European general provisions on consumer protection still create great confusion, and thus leads to ineffective investor protection.

b) *Class Actions for Damages*

After a difficult gestational period, class actions have finally been introduced into the Italian consumer protection system[76] pursuant to Art. 140-*bis* of the Consumer Code. The new procedure became effective on 1 January 2010, although it may only be enforced against infringements of consumer law enacted after 15 August 2009. As we will state hereafter, it is a remedy that is certainly inspired by American-style class actions, although it has been extensively adapted to Italian procedural systems, and is definitely unknown in the European framework.

As a preliminary matter, it should be highlighted that Art. 140-*bis* Consumer Code sufficiently defines the range of application of the collective redress procedure: the subjective range is restricted to 'consumers and users of public services', whilst the objective range of application is limited only to specific situations. In other terms, it is not a *general* procedural instrument. In particular, it had been argued whether investors might be included under the definition of 'consumer', and thus under the range of subjective application of class actions. While previous drafts of the law dealing with class actions did contain a clear reference to investors, in the present version of Art. 140-*bis,* all references to investors have been removed.

It is true that investors have separate regulatory options under the 'T.U.F.'. In the above-mentioned Art. 32-*bis* the 'T.U.F.' refers to 'collective injunctions' (orders), rather to 'class actions for damages'. By the same token, consumer credit statutory regulations are dealt with under Arts. 121 ss. of the T.U.B., thus remaining outside the coverage range of class actions under the Consumer Code. Although the literal meaning - as well as the overall framework of the statutory provisions - do not leave any further objection to the argument excluding investors from class actions, this argument is nonetheless still not convincing.

[75] Provisions added by D.lgs. 2007/164 (implementing the MiFID Directive).
[76] The class action as described in the text was designed by Law 2009/99.

First, as the drafts of the law highlight, the recent financial scandals and the recent emergence of a new generation of organised financial trading systems do lead one to believe that investors and "savers" need to be protected through the same legal instruments available to *any* consumer.

Secondly, as often recalled in this paper, the discipline concerning the distance marketing of consumer financial services has recently been introduced into the Consumer Code. This means that financial services are implicitly included within the range of application of Art. 140-*bis* only if they are provided using distance selling methods. Clearly, it would be notably inconsistent to exclude from the purview of Art. 140-*bis* and from class actions financial contracts entered into through procedures other than through distance selling. In other words, the literal exclusion of investors from class action procedures is probably due to a rather clumsy introduction of a brand new procedural instrument whose range of coverage is not yet completely clear to the legislature itself, rather than resulting from a conscious choice made by the Italian legislature.

At any rate, Italian class actions – whether they will eventually be available to investors or not – do differ from those following the American model (as provided for under Rule 23 of the *Federal Rules of Civil Procedure*) at least in three major ways:
1. Italian class action suits may be brought not only by individuals, but also by associations (i.e. consumers' associations);
2. the participation in a class action is only possible through an 'opt in' system, while in the USA the opposite 'opt out' system has been chosen; and
3. no punitive damages may be awarded.

Class actions for damages also differ from collective injunctions in three key ways:
1. class actions represent the collective redress of *individual* although homogeneous interests, while collective injunctions are meant as suits brought in order to protect *collective* interests;
2. consequently, class actions may not only be brought by individuals, but also by representative associations: an option not permitted in the case of collective injunctions, where standing is only given to associations; and
3. the remedies obtained through class actions aim to award damages, whilst injunctions aim at prohibiting – in different ways – infringements of the law.

Final remarks

Protection of investors is far from being satisfactory: at a European, as well as national, level there are still non-standardised substantive and procedural rules governing the provision of financial services in the marketplace and investment firms' behaviour. Evidence of this statement of principle can be found in the narrow definition of consumer that does not fit into the definition of 'investor' or in the stratified legislation that – in both the European, as well as in the Italian legal systems - evidences inconsistencies and fragmented provisions.

As a consequence of the unsatisfactory statutory regulations, private remedies and access to justice lack clarity and are still excessively complex. They overlap and co-exist without offering practical and simplified solutions to investors. A weak party – provided that this definition is fully accepted – is also weak in seeking justice and redress. Too many remedies function too close together (leading to confusion and overlap) and/or too many redress suits are too similar in their procedural goals, thus potentially confusing investors, rather than protecting them.

A recent Italian Law (4 March 2010, n. 28) decided to require a compulsory settlement attempt before commencing individual or collective suits. In particular, the settlement proceeding provided for by Law 2007/179 (as implemented by Consob Regulation n. 16763, of 29 December 2008), with reference to financial contracts entered into among non-professional investors and brokers has now become mandatory[77]. This means that the indemnity guarantee (see par. 2.1.1.) can be more easily awarded through settlement proceedings managed by CONSOB and triggered by an individual, and not necessarily by a consumer association. Moreover, according to the abovementioned recent Law 2010/28 (Art. 12) the settlement agreement has immediate executory effects *vis-à-vis* defendants. This procedure may finally render overall consumer protection more effective, provided the following occur:

- Public remedies are seriously enforced. Although the Italian 'T.U.F.' (as well as the European MiFID Directive) contain special provisions addressing criminal sanctions and fines, national implementation of these provisions is still poor and does not achieve the goal of deterrence.
- Investors' protection is reviewed at the European level, first by including this definition in consumer protection legislation; and secondly by simplifying remedies and access to justice through the establishment of a hierarchy of remedies. The first remedy should consist of mandatory settlement attempt, leading to an indemnity guarantee and excluding other ordinary

[77]See P. Stella, *L'*enforcement *nei mercati finanziari* (Giuffré, Milan, 2008), p. 449 ff., where the A. regrets that important provisions like those provided for in the Law 2007/179 are not sufficiently supported by the overall enforcement system. And in fact, the importance of the enforcement of rules is the object of the abovementioned book, facing in a comparative and satisfactory manner the issue of enforcing investors' protective rules.

suits[78]. Should settlement not be reached, an ordinary lawsuit may then be brought, either via individual actions or through class actions for damages, leading eventually to the awarding of economic damages. Access to indemnity funds should be permitted for individuals or for investor associations only in cases of defendant insolvency.

[78] Although warning is given by S. Mulreed, in 'Private Securities Litigation Reform Failure: How Scienter Has Prevented The Private Securities Litigation Reform Act of 1995 from Achieving Its Goals', *San Diego L. Rev.*, 42 (2005) 779, 791-792. The Author argues that poor financial regulation may trigger 'strike suits', that is, opportunistic plaintiffs' behavior bringing frivolous lawsuits which place a corporation in a situation where it would rather prefer excessive settlements than proceeding with the full litigation process (trial, etc.).

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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

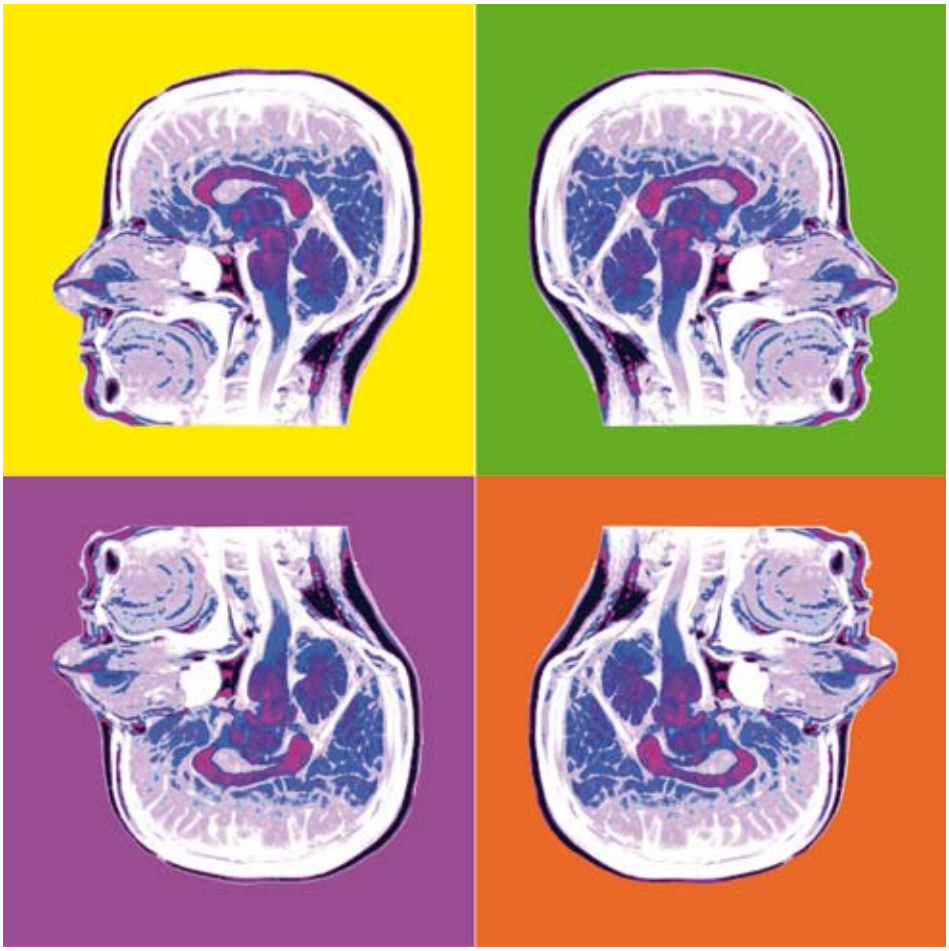
Federazione Regionale Ordine
Medici e Chirurghi della Sardegna

LIDER·LAB

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

Fondazione Banco di Sardegna

Banco di Sardegna

fondazione cariplo

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

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Prof. **Paolo Livrea**
Full Professor of Neurology Università di Bari - Presidente OMCeO Bari Italy

Prof. **Maurizio Muscaritoli**
Former President SINPE Università La Sapienza Roma Italy

Prof. **Herman Nys**
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

con il patrocinio

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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

Official languages: Italian – English *(Simultaneous Translation)*

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