

Commentary

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The need for scientists and judges to work together: regarding a new European network

Amedeo Santosuosso*^{1,3} and Carlo Alberto Redi^{2,3}

Address: ¹Judge, Court of Milan, Via Freguglia 1, 20121 MILANO Italy, ²Director, Laboratorio di Biologia dello Sviluppo – Università degli Studi di Pavia, Piazza Botta 9, 27100 PAVIA, Italy and ³Promoting Group of the European Network for Life Sciences, Health and the Courts (ENLSC)

Email: Amedeo Santosuosso* - amedeo.santosuosso@fastwebnet.it; Carlo Alberto Redi - redi@unipv.it

* Corresponding author

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Abstract

Is it always true to say that science is, by definition, universal whilst laws and the courts which apply them are a classic state and national expression? Yes and no. In recent years a new scenario has opened all over the world. Courts intervene more and more in disputes on matters related to scientific procedures in the biological field. In doing so the courts' decisions are affected by scientific issues and ways of reasoning and, on the other hand, affect the scientific field and its way of reasoning. While the *old* matter of bioethics was still alive and while judges were improving their skill in dealing with hard matters, like refusal of medical treatments, abortion, euthanasia et cetera, a new challenge appeared on the horizon, the challenge of biological sciences, and especially of the most troubled field of human genetics. A completely new awareness is developing among judges that they belong to an international judiciary community, as informal as it is real. Such a community is, even at an embryonic stage, sufficiently universal to be able to come together with the international scientific community. The authors maintain we are in urgent need for new interaction between judges and scientists and of new international means in the light of such cooperation. Judges and jurists need to become better acquainted with scientific questions and learn to exchange ideas with scientists. They also need to set themselves against the latter's conceptual systems and be willing to put their own up for discussion. A European Network for Life Sciences, Health and the Courts is taking its first steps, and judges and scientists are working side by side to tackle the new challenges. The provisional headquarters are located at the University of Pavia (I), *Laboratorio di Biologia dello Sviluppo* and *Collegio Ghislieri* (e-mail: enlsc@unipv.it). ENLSC activity is inspired by the following idea: to be against science is as much antiscientific as to be acritically pro-science.

Introduction

Is it always true to say that science is, by definition, universal whilst laws and the courts which apply them are a classic state and national expression? Yes and no.

In this commentary we point out the new scenario that in recent years has opened all over the world. Courts intervene more and more in disputes on matters related to sci-

entific procedures in the biological field. In doing so the courts' decisions are affected by scientific issues and ways of reasoning and, on the other hand, affect the scientific field and its way of reasoning. Nowadays science affects law more and more and vice versa.

We maintain we are in urgent need for new interaction between judges and scientists and of new international

means in the light of such cooperation. A European Network for Life Sciences, Health and the Courts is taking its first steps, and judges and scientists are working side by side to tackle the new challenges.

Discussion

An unconscious coincidence

Although the intervention of the law in the field of medicine and life sciences is not a novelty, in recent years legal intervention in *old* bioethical and *new* science related matters has increased dramatically. Court decisions have become widespread in most countries. Parliamentary acts have regulated many aspects of women's and men's choices regarding their own bodies. Codes of conduct have been enacted in many fields: we may remember, in the field of experimentation on human beings, the Good Clinical Practice or the new issues of the Declaration of Helsinki or the documents by the World Health Organisation. They all lay down greatly important regulations, although not in a strictly legal sense. Finally, a new wave of solemn declarations has sprung up from international institutions. The *European Convention on Human Rights and Biomedicine* (Oviedo, 1997) is one of these, but not the only one. Let's remember the *UNESCO Genome Declaration* (1997) and the *Charter of Fundamental Rights of the European Union* passed by the European Council of Nice, 7th–10th December 2000. Significantly the Charter only puts issues such as personal integrity, informed consent or cloning in its first articles.

The general picture gives us the view of a great, varied and widely divided process of recognition and enforcement of the rights and liberties of women and men in the field of medicine, genetics and life sciences. The most important new rights and freedom in bioethics have been recognized in an ever-changing and troubled environment, characterized by the existence at a world level of a number of centres, institutions, independent authorities, professional societies and so on, with the judiciary and judge-made law playing a major role.

For example, if we think of the history of the right of patient's self-determination, that is the matrix of all liberties rooted in our own bodies, we can see that it was first enforced in judicial cases and decisions in many countries. Laws have usually been enacted later and have often put limits on judicial standards.

Furthermore, in the earlier cases from European countries or from the US, judges were clearly not aware of each other. And even in recent years, we cannot be sure if they have been aware of each other's decisions. However, in many rulings the fundamental concept of self-determination is held with surprising similarity of concepts and adopted legal criteria.

On the other hand in some situations a real problem of lack of scientific knowledge among judges came to the fore. Consider, for instance, the case of experimentation on human beings. In this field there is a sort of *continuum* between rules that regulate relations between subjects (a typical characteristic of those of law) and strictly technical rules which concern scientific requisites and methods of carrying out research. This poses great problems of definition and concept.

The Italian Constitutional Court fell into a scientific pitfall handling the well-known *Di Bella* affair. In the late Nineties the Italian Dr Di Bella cured many cancer patients according to a therapy made up by himself. The Ministry of Health, the Society of Oncologists and the Italian National Health Service did not consider such a therapy as scientific based. Patients applied to the Italian National Health Service for the reimbursement of the expenses for the *Di Bella* therapy. Hence the question was whether the National Health Service was right not having considered such a therapy as scientifically based and having refused to bear its costs. The Italian Minister of Health, set up a scientific committee (chair: Prof. Umberto Veronesi) that prepared a clinical trial on the *Di Bella Therapy*. Although the criterion of access for patients was not as strict, some patients were excluded from the trial. The Constitutional court said that in doing so the patients' right to health had been violated and, consequently, the law was against the Constitution.

The key point is the following: the implicit assumption of the court was that the right to health can't tolerate the rationale of clinical trial, that is, in other words, the necessity to select people to be admitted to the trial according to the scientific hypothesis on which the experimentation is based. In doing so the court showed a clear lack of knowledge of how a clinical trial works and of its scientific assumptions (without selection of the patients it is simply impossible to speak about a scientific experimentation). The point is more clear if we consider that, before the experiment, nobody knows if the risk for health of individuals is greater for those enrolled in the trial or for those excluded. It is simply a matter of fact, and the response depends on the results and the effects of the experiment. In this light, we should ask how do we consider the right to health violated. We could consider it violated according to the *chances* given by the participation in the experiment (even if chances in a trial are both negative and positive) or according to the results of the trial, however we can know them just at the end of the trial.

Up to a certain point judge-made laws on medicine and bioethics have followed national paths, developing rules of judgement linked to specific real-life scenarios. Ignorance of foreign languages has led English speaking jurists

to disregard the work and experiences of jurists from France, Germany and other countries, even when handling the same issues or dealing with concepts and criteria which were not dissimilar. The ignorance of mainland European jurists has led to exactly the same situation.

These cultural and national barriers have not, however, prevented the formation of a sort of *communis opinio* (a shared set of legal standards) between judges from widely differing legal systems. It is extraordinary that this has happened in a way which appears to be largely "unconscious". Judges have identified the rule of the case reasoning by principles: a phenomenon in which a number of themes and ideas become a kind of collective discourse on both sides of the Common/Civil Law divide or in countries belonging to totally different traditions such as Japan. The question of the spread of the patient's right to self-determination regarding medical treatment and the diffusion of the legal standard of informed consent is the most important of all.

The present day's challenge

While the *old* (may we say so?) matter of bioethics was still alive and while judges were improving their skill in dealing with hard matters, like refusal of medical treatments, abortion, euthanasia et cetera, a new challenge appeared on the horizon. We are thinking of the challenge of biological sciences, and especially of the most troubled field of human genetics.

Let's recall some particular cases.

a. Now that our DNA has been decoded and genetic information becomes more available, more and more new privacy issues are at stake. One of the biggest genetic privacy problems is employment discrimination. Cases of people fired after employers learned they were at risk from hereditary disorders or of people not offered a job because of their genetic condition having been reviewed. Insurance coverage is another area of concern. Insurance companies may increase premiums or deny coverage for those known to have certain genetic predispositions. Some insurance companies require genetic testing as a condition of coverage. And unfortunately, these examples of genetic discrimination are not isolated incidents [1].

b. In the area of reproductive science, the availability of more information during pregnancy will have major repercussions. Suppose a woman considering pregnancy is tested to determine whether she carries genetic traits that could harm her child. The test is negative and the woman becomes pregnant, but the child is born severely deformed. The laboratory made a mistake. The woman sues the laboratory, claiming she based her decision to have a child on the results of the negligent testing. Is the

laboratory liable? Is the answer different if the test, even when properly done, correctly identifies harmful traits only 30 percent of the time? What do we do with claims for "wrongful life?" We will no doubt see more of these claims as our ability to predict genetic disorders continues to improve. Unfortunately, there are few standards for this kind of testing. We need guidance sooner rather than later, because we are already facing questions that only a few years ago seemed unimaginable – and we are grappling for the answers.

c. In other situations the matter was about the property of sperm of a deceased man and the inheritance rights: is the sperm an "asset" of the estate and is it, therefore, covered by the property settlement? Or is it the object of a "unique form of 'property'" that arose from the man's "fundamental right to procreate with whom he chooses"? And, if yes, can it only be distributed as the deceased man had intended? [1]

d. the case of genetic population studies. Many genetic population studies are carried out in many parts of the world and in Europe as well. The most famous case can be found in Iceland. The central point of the Iceland case is that of a law which gives a private licence to the total heritage of medical and genetic data of the entire Icelandic people, past (from when the data first became available), present and future. The problem is whether a resource of this kind, non-repeatable and non-renewable, can be considered a resource of the state, of its representative institutions, of the nation or of the individual citizens. Who, of all these, has the power to dispose of this resource? The elective assemblies, moreover deciding by majority, do certainly not have unlimited powers. No theory of political representation includes the possibility of granting, for profit making purposes, goods of such a personal nature of the entire population [2].

e. the case of shared genetic data. The situation is clearly outlined in the European Union Recommendation 1997(5). Point 58 of the *Memorandum* to the Recommendation deals with the problem in a very original way:

"The collection and processing of genetic data involves the storage of data concerning third parties. These *third parties* may be constituted by members of the data subject's genetic line or collateral relatives or members of his/her social family. The drafters agreed to *accord an intermediate status* to members of the data subject's genetic line so as to distinguish them from third parties in the strict sense of the term and to *grant them a hybrid legal protection*."

However, we have to stress that nobody, not even the European Recommendation, defines the concept of *inter-*

mediate status and of **hybrid legal protection**. As a consequence both criteria, according to which such a hybrid should be defined, and the way of managing the conflicts among *third parties* having an *intermediate status* are completely unclear.

In conclusion, in all the situations under points a.-e., and others like these, the problem is as follows: how should legal and scientific categories interact with each other? What is the meaning of such an interaction in which judges and scientists are parties? How could they have a proper dialogue? What is the institution or the site in which such a dialogue should properly take place?

The peculiarity of the new challenge, the scientific challenge

Some aspects of the new challenge are common or similar to those of the *old* bioethical field. Both in bioethical cases and in science-law cases, judges have to face and to manage with disciplines and fields which are different from the law: morals, philosophy or life sciences.

Other aspects are quite different and new. There are great problems of definition and concept along the complex crest of relations between legal and scientific rule making. Traditional legal concepts are seriously challenged. We are thinking of the concept of individual, person, responsibility/liability, political representation or, simply, of judicial proceeding, when judges have to get scientific knowledge in the biotechnology's super-heated political and economic environment.

Let's go back to the genetic data that are shared among the members of the same genetic line. The concept of individual is seriously questioned: if everybody shares a part of its genetic dowry with the members of the same genetic line or collateral relatives may we continue saying that everybody has his own genetic dowry? Of course if we affirmed that the simple fact of sharing data gives each "shareholder" the right of disposal of data of the other "shareholders", we would end up denying any genetic privacy. However we have to give a response to the members of a genetic line who need to know more about the genetic data of other members for health reasons.

That's the reason why the Italian Privacy Authority (1999) authorized a hospital to disclose the father's data (against his will) to his daughter who had to decide whether to have children or not [3]. In other situations there is a tension between a physician's duty of confidentiality to the patient and a duty of disclosure to others who may have a medical need to know genetic information about the patient. In 1996, one New Jersey court took its turn at providing answers in a case involving a woman who had colon cancer that spread through her body. When she

looked at the medical records of her late father, she discovered he had died from the same hereditary condition. She sued her father's physician for failing to warn her of her predisposition to the condition. The New Jersey court [*Safer v. Estate of Pack* (1996 N.J.Sup.Ct., App. Div.)] found that physicians do have a duty to warn individuals known to be at risk of avoidable harm from a genetic condition [1].

Judges have not found the response to such or similar problems in existing (written or unwritten) laws. But they had to give their decision. Hence they have identified the *rule of the case* reasoning *by principles*. Recourse to principles in order to identify the rule of the concrete case has odd effects. If the principle invoked is of a very high and general level, such as that of personal integrity or personal liberty, the judge carries out an operation the result of which may also be taken up in other legal systems, provided there are three conditions: the case to be decided poses the same problem, there are no specific rules regulating it and, finally, the legal system recognises the same general principle. This type of decision, given the lack of local sources of law, has a rate of comparability clearly higher than those on subjects regulated by specific rules. Therefore, a judge, directly or not, makes sometimes recourse to a rule of judgement used in a previous case by a judge from another legal system.

Many sources of law are supranational and therefore apply in different countries. Consequently, judge-made law, fruit of the recourse to general principles and of the search for the rule of the case starting from stratified and heterogeneous supranational rules, appears, in part, to be positioned directly beyond the state dimension. A judge-made law constructed in this way seems, therefore, to separate itself not only from the written law of that state but also of the context of the territory and the legal system in which the judges are working, a context which, even in the most open and premonitory theorizations, has not been questioned.

Faced with all this, the Common Law model may be evoked above all to mark the distance between the ways in which the law on life sciences questions are created and evolve and the traditional concepts of Civil Law. But the reference to the Common Law, if taken literally, is conceptually and historically misleading. The Common Law systems are rooted more in history and experience than in general and abstract rationality. As Oliver Wender Holmes stated in his historic work "The Common Law:

The life of the law has not been logic: it has been experience. The felt necessities of the time, the prevalent moral and political theories, intuition of public policy, avowed or unconscious, even the prejudice which judges share

with their fellow-men, have had a good deal more to do than the syllogism in determining the rules by which men should be governed [4].

The essential characteristics of Common Laws are a historical continuity within which the judicial creation of rules is positioned and has a distinct local rooting. On the contrary, the judge-made law we are dealing with here does not often have any precedent to refer to, nor even a solid historical bed on which to base itself. It has not a local dimension, so much so that sometimes judges make recourse to precedent from other countries. As a consequence, each national judge-made law can be understood only as a part of a wider (in some respects, universal) judicial attitude towards the rights of citizens and people on their own bodies and lives.

In short, if the conceptual order which we are suggesting is closer to Common Law than to Civil Law, it needs to be clear that we are speaking of a universal Common Law whose roots and ways of working still have to be understood and constructed. It may be more correct to speak of a universal judge-made law, which is a more neutral and descriptive expression of a reality which is calling us to a great work of rigour and imagination. The judge-made law we are dealing with is, therefore, first a transnational law.

A new (coincidental) horizon for law and science

Many signs tell us that a set of first level rights is being created on a world level. They regard the person and his/her own body and life. On the one hand, they concern the individual for the mere fact of existing in his/her corporeal and biological dimension. On the other, they lay down conditions for access to the society (*pactum societatis*).

In this process transnational judge-made law has a prime, albeit not exclusive, role which faces, at a constitutional level, conflicts which were hitherto unheard of or were dealt with in a different manner, especially as moral problems. One of the many examples is that of the Italian Constitutional Court when it spoke of the freedom to dispose of one's own body as a postulate freedom of the person. Or the statement (in the international debate) whereby a process of "constitutionalising death" is underway, or even, of recognising the "due process of dying", in a language of public freedom.

On the other hand a completely new awareness is developing among judges that they belong to an international judiciary community, as informal as it is real. The judges have different powers according to the regulations of individual states. However, when they have to tackle the question of scientific applications in the biological field they discover that state legislation does not provide adequate

solutions and that it is often necessary to make recourse to law sources which transcend their respective legislatures. The community operates, above all, through the exchange of judicial standards, knowledge and experiences, direct and informal contacts as well as those of international meetings in which judges and scientists debate side by side starting with the problems and not from the differences in national laws [5].

Such a community is, even at an embryonic stage, **sufficiently universal to be able to come together with the international scientific community**. And this is a real novelty. In this sense we could say that it is not true anymore that science is, by definition, universal whilst laws and the courts are a typical state and national expression. In this perspective the interaction between the world of law and the world of science is, and will be ever more so, essential for developing our work. Of course, universality of science and universality of law are different under some respects. We tolerate a certain amount of relative difference in the world of law, because of differences in societal values and differences in viewpoints even on the basis of shared values.

Conclusions

what should we do?

We've seen that in most cases judges have held important and innovative principles, but often without being aware of what other judges, in other countries, had decided in similar cases. This means that our first duty is to increase the consciousness of judges as to how common their problems are and how often their rulings are similar to each other's. In other words, judges should be more aware they are playing a role of great importance in the enforcement of new rights and freedom regarding the human and they should be aware of the great responsibility they are entrusted with. Judges should be more aware both of the universal context in which their decisions are embedded and of their contribution to that kind of *communis opinio totius orbis* (a universal shared set of legal standards) which has already begun to form on the basis of questions posed by life sciences.

Judges and jurists need to become better acquainted with scientific questions and learn to exchange ideas with scientists. They also need to set themselves against the latter's conceptual systems and be willing to put their own up for discussion. These results may be achieved through the creation of occasions and places for international meetings involving judges and jurists, interested in issues of law-science, and scientists.

In this perspective a *European Network for Life Sciences, Health and the Courts* (ENLSC) is taking its first steps. It has, although operating in Europe, a worldwide perspec-

tive and regards as a task of priority the co-operation with similar organizations all over the world. It continues the activity of study and judicial education which had relevant occasions in the International Meeting *Bioethical Matters and the Courts: Do Judges Make Law?* (Milan 2001) [6], the participation of European judges and scientists in the *1st and 2nd International Working Conversation* (Kona 2001 and Ottawa 2002: see the web site <http://www.einshac.org/>), the International Conference *Juridical and Psychosocial Implications of Human Genetics* (Rome 2002), the *I Residential Course for Judges on Present Biological Problems and Judicial Implications* (Pavia 2002) [7] and the International conference *Bioethics and Judges* (Lausanne 2003).

A promoting group of such a European Network is currently operating. The next meeting (with the participation of judges and scientists from European countries and invited colleagues from US, Australia, Canada and Africa) is planned for June 3rd – 4th, 2003 in Pavia (to receive the ENLSC letter or to get in touch with the Promoting Group e-mail: enlsc@unipv.it). The provisional headquarters are located at the University of Pavia (I), *Laboratorio di Biologia dello Sviluppo* and *Collegio Ghislieri*, which have given their initial support.

ENLSC foresees that in the next few decades the issues related to science and the law will reasonably increase, both in frequency and importance. It consequently aims, on one hand, to offer European judges and Courts occasions of contacts and the most relevant and critical information in the field of life sciences and health and, on the other hand, to offer scientists the opportunity to understand and debate the legal and social framework in which they operate. Furthermore, ENLSC aims to promote both among judges and scientists a better knowledge of how science affects the law, and vice versa, and to increase the awareness about reasoning and assumptions in the fields of science and the law.

The main activities of the European Network are as follows:

- in cooperation with institutions dedicated to judicial education, with universities and research centres, to organise courses and seminars in order to respond to the growing learning needs of the European judges in science-law matters;
- To facilitate access of the Courts to the scientific information that is necessary to deal with the cases that they will be confronted with increasingly.
- To create opportunities in which the worlds of the life sciences and the law (both universities and judges) can work together. In doing so they can tackle the extremely

difficult problems arising from the interaction between the categories of the law and those of science.

In short, ENLSC activity is inspired by the following idea: to be against science is as much antiscientific as to be acritically pro-science.

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