

## Why a new Law Journal?

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There are a few features which make life sciences a peculiar and particularly challenging matter to be ruled by the law.

The law focusing on life sciences, first of all, means to deal with a number of multidimensional and ever-changing objects which constantly shed new light on new issues. Scientific discoveries always offer fresh knowledge and new queries, and their technological applications bring out original questions on unexplored potentials and risks. The viability of the foetus, for instance, is today very different from the 1973 meaning (in *Roe v. Wade*). Synthetic biology is evolving so rapidly that no widely accepted legal definitions exist as yet. Research on behavioural neurosciences is continually offering new intuitions and new disputes on decision making mechanisms. Cognitive enhancing is again moving the border between what can be considered healthy or ill. When (and if) the political consensus needed to rule on these issues is reached and a law is enacted, it can happen that the very matter at stake is not just the same as it was at the time the procedure began. Delays, gaps, inaccuracies in statutes may result, and when an individual case has come to an end the entire picture may have been radically changed. As remembered by the European Court of Human Rights in *S.H. and others v. Austria*, «this area, in which the law appears to be continuously evolving and which is subject to a particularly dynamic development in science and law, needs to be kept under review by the Contracting States».

The leverage for this endless change of science, secondly, is uncertainty. Uncertainty – quoting from the Sense About Science project – is «normal currency» in scientific research, which goes on because we do not know everything, and be-

cause part of what we know today is intended to be disconfirmed or out-dated tomorrow. If uncertainty is fuel for science, though, it is a threat for the law dealing with it. Legal rhetoric, still taught since the first class in Law Schools particularly in civil law countries, speaks about the basic principle of legal certainty as an instrument for equality before the law, a principle put at the very core of a number of legal systems. A certain margin of confidence in the predictability of future results is a must in legal systems trying to deliver justice or at least security in human relationships. How to combine, then, two rationales (scientific uncertainty, on the one hand, and legal certainty, on the other hand) that are so radically contradictory to each other to provide an authentic oxymoron?

Another pair of typical and traditional features usually attributed to legal phenomenon deals with the clarity, generality and impartiality of the law and of statutes in particular: *la loi est universelle, la loi vaut pour tous*. Here again, a third problem arises when law meets life sciences. In medicine as well as in neurosciences or biology, just defining the very object of the study is not easy. At which step of the developing process beginning with fertilization are we to acknowledge the beginning of pregnancy or the protection of foetus' life? US States, for instance, are presenting a very dynamic and diverse scenario on abortion, which becomes more and more complex every day. And what about stem cells and their legal status? Clarity, even after *Brüstle v. Greenpeace*, is far from being reached, and new references for preliminary rulings to the European Court of Justice are expected. The same variety may be found in the end of life area. Apart from the difficult distinction between vegetative and minimal conscious states, for instance, just a nuance may be at the basis of a competence-incompetence diagnosis, or of an evaluation of

the vulnerable status of the author of a living will. Even after the *ad hoc* Committee of the Harvard Medical School, the very definition of death and its legal treatment might be open to future developments (see the recent *Muñoz case*). And some concrete cases are so complex and linked to specific and difficult-to-generalise situations that even a single detail can suggest the adoption of an exclusive and distinct legal discipline, running sometimes on the edge of (or even beyond) the legal system. A case in point is the Daniel James decision in the UK, or the Vincent Humbert case in France or the Enzo Forzatti one in Italy, in all of which the difference between *praeter* and *contra legem* is not easy to be marked. The usual balancing test technique in the life sciences arena is coloured with thousands of shades.

Beside the mobility, the uncertainty and the variety which attune and shape the intersection between life sciences and the law, a fourth feature makes the picture even more complicated. Every side related to this area typically engages anthropological conceptions and the deepest moral values of each person. Thinking about the legal discipline of life sciences does not touch only legal notions such as autonomy, equity, reasonableness. It involves symbolic and morally crucial definitions of what is, or should be, a human being; and what is not, not yet or no more, a person. It implies drawing lines among conflicting fundamental liberties and duties, among individual rights and state and federal powers, always concerning hard cases where no consensus on the sound solution may be found. Working on the law of life sciences leads to deal with the meaning of such delicate and divisive concepts as those of dignity, conscience, personal identity, reductionism or determinism, going as far as calling into question the survival of free will. No surprise then that in plural and divided societies like ours, find-

ing agreements on these issues is particularly demanding.

The role of law, nevertheless, cannot be neglected. Patients, health professionals, researchers, all of us are already touched by life sciences' results and will be more and more affected by the applications of converging technologies. A number of recent cases (like *Novartis AG v. Union of India and Others* with the Supreme Court of India rejecting the evergreening strategy on Gleevec; or the *Fentanyl case* where the European Commission fined Johnson & Johnson and Novartis for a pay-for-delay agreement; or the *Avastin-Lucentis case* in which the Italian antitrust authority fined Novartis and Roche for colluding to keep doctors from prescribing a relatively inexpensive eye treatment in favour of a more expensive drug) witnesses that mere economic and profit interests may sometimes try to prevail on the genuine determination of contributing to the welfare and the health of the people. Where fundamental rights may be threatened, especially by powers driven by strong economic interests, law has to enter the field. *Mutatis mutandis*, Article 16 of the 1789 *Déclaration des droits de l'homme et du citoyen* is applicable: «Toute société dans laquelle la garantie des droits n'est pas assurée ni la séparation des pouvoirs déterminée, n'a point de Constitution».

If the law has definitively a role to play in life sciences, it has to take into account all the specific features indicated above. More than that. It has to strengthen its mission, in terms of promotion of fundamental rights and limitation of powers, starting from the specific characters of life sciences. The challenge at the core of this new journal is to study, to discuss and perhaps to suggest a law capable to deliver fairness and justice in an ever-changing scenario, to promote non discrimination and equality while facing uncertainty, to support consistency and rationality in a field

dominated by a case-by-case approach, to find consensus on very divisive issues. The challenge is to give a contribution to the discourse on a bi-law necessarily open to other non-legal disciplines, enriched by the comparative approach, rooted in and committed to be sensitive to a transnational reality and oriented to the promotion of shared constitutional principles, with a concern for pluralism and promotion of fundamental rights at the centre of its action. Indeed, life sciences force the law to recall and to put at the top of its priorities its authentic and original goal: the respect and the elevation of the human being.

In order to facilitate the broadest accessibility and dissemination of ideas and to boost the widest involvement and participation of researchers, the BioLaw Journal is platinum open access and free of charge and welcomes contributions in English, French, Spanish and Italian.

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