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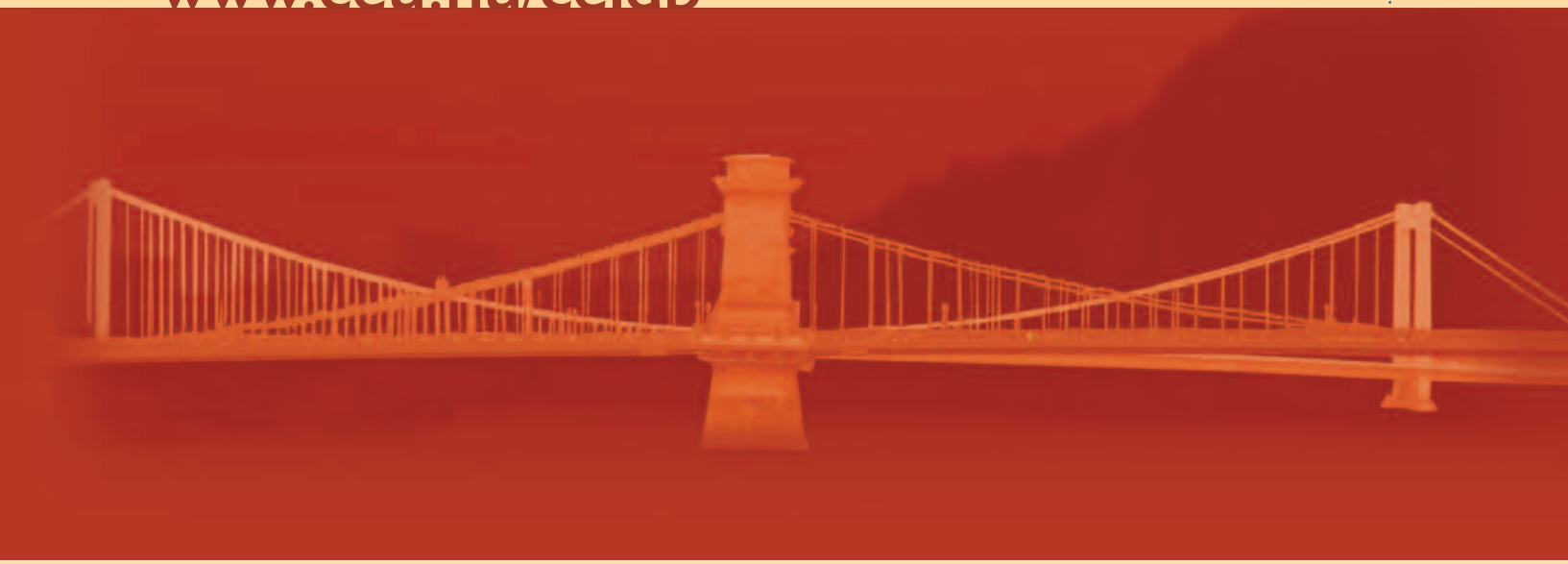

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CELAB

Center For Ethics And Law In Biomedicine

2008–2009

ANNUAL REPORT

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1. FOREWORD

The academic year of 2008–2009 was a very intensive period for the Center for Ethics and Law in Biomedicine (CELAB). We participated, simultaneously, in five European Commission funded research projects (GeneBanC, NANOPLAT, Privileged, RemediE and the TissEu), and contributed to three more EU projects as consultants. In addition to working on these European programs, CELAB also completed a UNESCO financed project on the implementation of the three bioethics declarations in five countries of the wider Central European region (Croatia, Czech Republic, Hungary, Italy, and Serbia). We also continued our bioethical research collaboration within the francophone network of RUIB *(Réseau Universitaire International de Bioéthique)* established in 2007. Over the course of the last academic year, CELAB organized and hosted two international workshops, as well as arranged a series of film screenings on various bioethics issues for CEU students. As an indication of the intensity of our work at CELAB, the results of our research have been published in nine languages: Croatian, Czech, English, French, Italian, Hungarian, Portuguese, Serbian and Slovenian.

Among the EU sponsored research projects, perhaps one of the biggest achievements was to complete and publish a comparative survey of the available legal regulations of biobanks in eleven European Union member states (Cyprus, Czech Republic, Estonia, Greece, Hungary, Italy, Latvia, Lithuania, Malta, Poland and Romania). Research within the GeneBanC project required the application of interdisciplinary methods: collection of data through desk research, compiling and administering detailed questionnaires, conducting fieldwork and interviewing relevant experts in the region.

We worked out two sets of questionnaires and evaluated the responses we received from thirteen countries. Besides analyzing the results of the questionnaires, we also made field visits to biobanks in Budapest and Pécs (Hungary), Brno (Czech Republic), Szczecin (Poland) and Cluj (Romania). Petra Bárd and myself presented two papers at the Final Conference in Leuven, both of which are soon to be published in Belgium. The main outcome of this project is a series of detailed country reports published in a booklet form.

In addition to the fields in which we had conducted research before, we have developed expertise in some new research areas, such as the social-ethical aspects of nanotechnology and the intellectual property aspects of regenerative medicine.

Participation in the NANOPLAT project prompted us to accumulate knowledge on the recent advances in nanotechnology, even outside of our traditional research interest in the ethics and law of life sciences. This short but very intense project focused on the deliberative processes in shaping the contours of policies in the field of nanotechnologies. In the framework of this research, Enikő Demény and Pétek Kakuk conducted a series of interviews and participated in several national and internation-

"...the imagining of potential futures is intrinsic to all those practices we term science: sciences are not phenomenologies but phenome-technologies. They try to conjure up in reality, by technological means, what they have already conjured up in thoughts."

Nikolas Rose (2007) *The Politics of Life Itself*, p.79

al conferences. They studied deliberative processes that are usually regarded as a democratic supplement, but in practice they might also lead to an undemocratic bypassing of the regular representatives of the common voice. This is especially true in the case of new technologies.

In 2008 we started to work on another new topic within the framework of the RemediE project, which lies at the intersection of ethics and biotechnology. The emergence of biotechnology and the extension of the scope of patent rights have by now become a public concern. From genes through genetically modified plants and animals to human cells, each stage of accretion of patentability in this arena has been contested. Much of this opposition arises from cultural concerns about the moral appropriateness of property rights being applied to living, especially to human-derived cells. Because of these ethical controversies, this EU funded research project gives us an opportunity to understand the process in which biotechnological research becomes increasingly commercialized and lucrative new markets for technological advances are created.

Patents provide strong stimuli for research, but they also have diverse, and often adverse, impacts on available therapies. With CELAB research fellows Márton Varjú and György Kovács, we worked on the collection and evaluation of various patent regimes in biomedical research and therapy with special emphasis on regenerative medicine. This project, however, is also especially relevant in tackling fundamental changes to the field of life sciences. The emergence and global dominance of transnational research-based corporations is characteristic of the biotechnological industry and forms a special market the ethical and legal principles of which are not yet crystallized.

The workshop CELAB organized in the framework of the TissEu Project was a successful event as the international experts invited analyzed a new and often misinterpreted perspective on biobanking: the questions of tissue anonymization.

During the last academic year, we also participated as consultants in several other EU projects, namely *From GMP to GBP* (From GMP to GBP: Fostering Good Bioethical Practices (GBP) in the European Biotech Industry), *NMD–Chip* (Development of Targeted DNA Chips for High Throughput Diagnosis for Neuromuscular Disorders) and *BBMRI* (Biobanking and Biomedical Resources Infrastructure).

In addition to our European Commission funded research projects, we continued our bioethical research collaboration within the francophone network of RUIB. This network, which has been expanded since its establishment, currently works on several thematic issues of bioethics and biomedical law and in each interdisciplinary workshop panel the participants seek to explore and understand

the cultural differences behind the formulation of various bio-legal norms. In the first workshop, the concepts of identity and anonymity were explored in the context of new reproductive technologies, often applying the perspectives of sociology and cultural anthropology. In the second panel meeting, we focused on adolescents' right to take an active part in health care decisions in various legal cultures. The first book presenting the findings of this research network was edited by Brigitte Feuillet-Liger and published by Bruylant in Brussels with the title *Procréation médicalement assistée et anonymat*.

During 2008–2009, two more books were published: one in English at the Berghahn Press, Oxford and the other in French at the L'École des hautes études des sciences sociales. The book on the *European Kinship in the Age of Biotechnology* was edited by Carles Salazar and Jeanette Edwards. The book written in French with the title *Défis contemporains de la parenté* (in English, *Contemporary Challenges to Parenthood*) was edited by Enric Porqueres i Gené. Both of these publications were late fruits of our previous legal-anthropological European research project "Public Understanding of Genetics" (PUG) in which Enikő Demény and myself had participated.

With the participation of bioethicists, decision-makers and lawyers, we organized a workshop on the implementation of the bioethics instruments of UNESCO. In the framework of this project CELAB published the three related UNESCO Declarations in five regional languages (Croatian, Czech, Hungarian, Italian, and Serbian). These are to be used in ethics teaching in Hungary and other countries of Central Europe.

During the past academic year, the activities of CELAB received strong media attention. Our detailed report on the media appearances of various CELAB fellows can be seen at our website. Here I would like to mention only two events: on February 11, 2008 the Hungarian weekly economic journal HVG published an on-line article about the Center, and on August 5, 2008 a special radio program was dedicated to our work at Radio Kossuth where several CELAB fellows were interviewed.

As it is impossible to list all of our activities during the 2008–2009 academic year, I would like to invite the reader to take a look at our website at www.celab.hu and to obtain some more information from this Report.

With this Report I would like to express my gratitude to the Central European University, to our colleagues at Gender Studies, Legal Studies and Political Science Departments, our associated research fellows, to the Academic Cooperation and Research Support Office and to everyone who helped to realize our dreams to establish and run an interdisciplinary research center in the field of bioethics and law within biomedicine.

Judit Sándor
Director of the Center for Ethics and Law in Biomedicine
Central European University

2. ACTIVITIES

2.1. RESEARCH

2.1.1. GeneBanC: Genetic Bio- and Data-Banking: Confidentiality and the Protection of Data

Partners:

University of Oslo, Norway
University of Leeds, United Kingdom
Catholic University of Leuven, Belgium
CEU, CELAB, Hungary
University of Vienna, Austria
Website: http://www.genebanc.eu

In the GeneBanC project, a Specific Targeted Research Project (STREP) funded by the European Commission in the Sixth Framework Programme, our aim was to investigate the existing regulatory framework of biobanks across the European Union: to focus on the collection and analysis of legislation and regulation regarding the establishment, management and functioning of classical, population and forensic biobanks across Europe. An important objective was to look at the similarities and differences in such legislation and regulations, in order to formulate recommendations towards a harmonization of European legal practices and laws.

The European jurisdiction was divided up into two parts: our team focuses on Cyprus, the Czech Republic, Estonia, Greece, Hungary, Italy, Latvia, Lithuania, Malta, Poland, Romania, the Slovak Republic and Slovenia, whereas the Leuven team will address the laws of the remaining fourteen Member States. The general starting point of the project is that there is no harmony in the law that regulates biobanks across Europe. The relevant law differs in each of the Member States. In addition, on the international and European levels, as well as in most Member States, there is no specific biobank law. Hence, even at the national level, there is a large amount of diverse legislation that is only partly relevant. On top of that, even in our days certain issues are still unregulated in a number of countries. Consequently, it is very difficult for practitioners to know which rules need to be followed and there are a lot of interests that are not properly protected, like the privacy of research subjects, the right to informed consent, etc.

Since in the majority of the Member States there is no specific law with a matching title, it is often a problem for biologists, doctors or even ethicists to identify the appropriate documents. Even if the laws are identified, the relevant parts have to be found for translation. In order to enhance data collection, CELAB has prepared, together with the Leuven team, two questionnaires: one for classical and population biobanks, and another for forensic biobanks. We identified the contact persons and sent out the questionnaires. Whenever necessary, researchers visited biobanks and made interviews.

The two main preliminary methods for the mapping of the relevant pieces of domestic legislation were conducting interviews with national experts and sending them a questionnaire in those cases when spatial distances did not allow a face-to-face discussion.

Several questions arose as to whether the initial division of biobanks into classical, population and forensic reflects a legal necessity, or corresponds to the difference in the nature of the legislation. Finally we decided that the threefold division of biobanks is

less satisfactory from a legal point of view, as there are no real legal differences between the regulations of classical and population biobanks. Therefore we have drafted two kinds of questionnaires: a general one for population and classical biobanks and another one for forensic biobanks.

Whenever we conducted interviews, we simultaneously organized study trips to both classical and forensic biobanks interviewing the professors, doctors, police officers, forensic experts and technicians about the problems they faced in their every day duty – be it data protection or privacy concerns, some other ethical or even technical issues.

The work we conducted was truly interdisciplinary. It was most often biologists, doctors or ethicists who sent back the replies to our questionnaires, or whom we had the opportunity to make an interview with. We cross-checked the information collected in each jurisdiction by approaching scholars with the same questionnaire. Unfortunately, we received different, even contradictory answers to the same questions in the same jurisdictions. This discrepancy can probably be explained by the fact that there are no biobank laws in the region, and the background ethical codes and legal norms are interpreted in different ways by different scholars and practitioners. Existing everyday practices of operating biobanks also show great diversities even within the same Member State.

At the end of the project we summarized the regulatory framework of each national jurisdiction in country reports. We sought to adhere to the black letter law, but to achieve a fuller picture it was necessary complement this part by a description of the existing regulatory practices in the various biobanks and forensic databanks.

CELAB Participants in the project: *Judit Sándor* (principal investigator), *Petra Bárd* (researcher) and *Enikő Demény* (researcher).

2.1.2. PRIVILEGED: Privacy in Law, Ethics and Genetic Data

privileged
privacy in law, ethics and genetic data

Main Partners:

University of Sheffield, United Kingdom
Biomedical Law Center, University of Coimbra, Portugal
University of Vilnius, Lithuania
CELAB, Central European University, Budapest, Hungary
Webpage: http://www.privileged.group.shef.ac.uk/

The full title of the PRIVILEGED Project is "Determining the Ethical and Legal Interests in Privacy and Data Protection for Research Involving the Use of Genetic Databases and Biobanks." The aim of the project is to make recommendations for research practice and public policy, including regulatory options at the national and European level and to promote the optimal relationship between research using genetic data and bio-banks and ethical interests in privacy. Ethical interests in privacy are being explicated through surveys, descriptions and comparisons of the alternative conceptions of privacy currently operating throughout Europe, Israel, Japan and Taiwan, paying particular attention to the relative interests accorded an individual as a member of a group.

The strategic objectives of the project were: (1) to identify, analyze and compare different ethical, cultural, and social concepts of privacy as engaged by research using genetic data and bio-banks; describing areas of common understanding and recognizing significant points of difference within both the conceptions themselves and their relationship with research; (2) to describe and compare Member State regulation of research using genetic data and bio-banks, with particular reference to data protection, and to evaluate the relationship between regulation (including associated strategies of compliance) and the ethical needs of privacy; (3) to establish in what ways and to what

extent data protection regulations may be either consistent or inconsistent with, or insufficient for, the protection of identified ethical interests in privacy; and (4) to make recommendations for research practice and policy at national and European level for the promotion of a harmonious relationship between research using genetic data and biobanks and data protection and privacy interests as articulated at both the national and European levels.

The Project started in 2007 and lasts for 36 months. It is one of the largest research networks in which CELAB participates, includes 49 Research Partners in various European countries and in Israel, Taiwan and Japan.

Workshops in 2008–2009 were held in Bawtry (England), Coimbra (Portugal) and Vilnius (Lithuania).

CELAB Participant in this project: Prof. *Judit Sándor*.

2.1.3. NANOPLAT: Development of a Platform for Deliberate Processes on Nanotechnology in the European Consumer Market

Partners:
National Institute for Consumer Research, SIFO, Oslo, Norway
CRIC, University of Manchester, Manchester, United Kingdom
Institut für Ökologische Wirtshaftsforschung–IÖW, Berlin, Germany
TUSIAD, Sabanci University Competitiveness ForumCF, Istanbul, Turkey
University of Bergen, UoB, Bergen, Norway
Strategic Design Scenarios, SDS, Brussels, Belgium
CELAB, Central European University, Budapest, Hungary
Webpage: www.nanoplat.org

The objectives of this project were to evaluate selected deliberative processes in Europe, at both EU and national levels, and to develop a deliberate and science-based platform for a stakeholder dialogue in Europe and beyond in the field of nanotechnology.

The theoretical aspects of the work were discussed and clarified in the Manchester workshop, on September 2008. Consortium members agreed that the Nanoplat project will focus on mundane and ordinary products already existing on the market, as well as on technologies "already developed and soon to be marketed" – as opposed to the more farfetched visions of possible futures. This approach should ground the project in everyday reality, but it also brings in some urgency, since these are the products which are already in the public domain. Paradoxically, such products might have been neglected in the present research on ethical, legal and social aspects of nanoscience and nanotechnology because so much attention has been paid to high-profile innovation and the imagined social, economic and environmental benefits and consequences. That is why in this project we decided to choose as illustrative empirical probes mundane everyday products such as cosmetics and sunscreens, household cleaners and sports equipments.

The strength of such a framework is that whilst empirically grounded, it nevertheless draws in a wide range of stakeholders identified directly as participating in these processes (as producers, consumers, or other groups with interests and concerns aligned to these processes). Further, it allows us to identify groups whose voices so far have been excluded or marginalized. A third asset is the ability to connect separated perspectives conceptually; identifying positions of stakeholders on governance and responsibility, on polity and policy; mapping contradictions and tensions in detail, as well as recognizing policy recommendations for negotiating such tensions.

After finalizing the theoretical framework, the members started the empirical part of the project. First, they reviewed a number of selected deliberative processes both at national and European level and then conducted semi-structured interviews on the topic of nanotechnology and deliberative process with selected stakeholders (policy representatives, retailers, producers, NGOs and users of nanotechnology). The conclusions of the empirical work were presented in the second Nanoplat workshop held in Istanbul, on March 24–27, 2009. The last phase of the project was dedicated to the development and design of an

online deliberative platform on nanotechnology. After a series of online testing exercises, the platform was presented to the invited stakeholders in Brussels, on June 24–25, 2009.

Apart from their involvement in the Nanoplat project, CELAB researchers have participated in a number of nanotechnology-related dissemination and policy activities in Hungary. After their first presentation about this issue at the *Environmental Ethics* conference in Szeged in September 2008, they presented a paper on the *Nanotechnology* 2008 conference in Veszprém, Hungary. The title of the presentation was: "The social, ethical and legal aspects of nanotechnology." The conclusion that CELAB Researchers have drawn from the conference is that much has to be done in order to raise the awareness among scientists about the importance of the ethical, legal and social implication of their research and more importantly, of the applications of their research.

CELAB was also represented at a seminar titled *Nanotechnology: Risk Assessment and Legislation Initiatives in the European Union*, organized by the Hungarian Food Safety Office. The organizers realized the importance of integrating different perspectives in addressing the challenging aspects of nano-food and organized this seminar as a starting point of the dialogue among different partners.

Another important event was *The Responsible Development of Nanotechnology: Governance Challenges – High Level Workshop,* organized by the Budapest University of Technology and Economics, in Budapest, on April 17, 2009. In this workshop CELAB Researchers gave a presentation on "Situated challenges and opportunities for nanotechnology in Hungary". They presented for colleagues from UK, Ukraine, Russia, Poland and Hungary their results from the Nanoplat project and contributed to the debate about the state of art, the challenges and opportunities of nanotechnology in the Central and Eastern European region.

CELAB participants in the project are *Judit Sándor* (principal investigator), *Péter Kakuk* (researcher) and *Enikő Demény* (researcher).

2.1.4. REMEDiE: Regenerative Medicine in Europe: Emerging Needs and Challenges in a Global Context

Partners:
SATSU, University of York, United Kingdom
University of the Basque Country, Spain
University of Hanover, Germany
Life Science Governance Institute, Austria
CELAB, Central European University, Budapest, Hungary
University of East Anglia, United Kingdom
Webpage: http://www.york.ac.uk/res/remedie/

The globalization of regenerative medicine is gathering pace, yet has not been examined with respect to its medium and long-term implications for European regulators, the corporate and clinical sectors or patients located within different member states. It is a field characterized by complex dynamics across a range of scientific, clinical and industrial sectors, highly unstable, yet developing rapidly. Regenerative Medicine (RM) is also important to Europe, given the emerging competition from Asia/Pacific and North America regions that are making health biotech development a priority and investing in what they perceive to be an industry of the future. April 24th 2007 saw the EU Parliament adopt the 'Advanced Therapies Regulation' to harmonize guidelines that will, if approved by the Council, create a centralized process for approving new tissue and cell engineering therapies. This is an important basis for stabilizing the RM market and research in Europe: this project examines

the current and emerging socio-economic, political and bioethical issues to be addressed in Europe as work in the RM field accelerates.

This three-year collaborative project examines the socio-economic, political and bioethical implications for Europe of near-term and future global developments in the field of regenerative medicine. It will adopt an interdisciplinary approach which brings together social science and humanities researchers to understand the emerging needs, expectations and challenges that Europe faces. It is conceptually and methodologically innovative, empirically robust and policy relevant.

The main objective of this project is to bring together the range of fields associated with novel interdisciplinary research that locates these specific issues in a wider global context to determine their increasing inter-linkage and divergences with respect to socio-economic, political and bioethical domains. This will also involve basic research with respect to the systematic collection of evidence across them.

The project is future-oriented with respect to exploring the emerging global market for RM and the hype, expectations, risks and prospective regulatory demands it will generate that the EU will need to address. For example, monitoring the acceptability of using imported bodily material in stem cell research and therapy will become increasingly important particularly in guarding against an international black market developing in oocytes, embryos, tissues and cell lines: in this regard, the EU parliament has singled out the oocyte trade as in need of particular attention, given the potential for exploitative trade circuits.

Economically, regenerative medicine is likely to have a significant impact on the future development of the world healthcare industry. At the present time, the world health care market is estimated to be in the vicinity of USD 8,000 billion, with the global pharmaceutical market accounting for a tenth of this figure. The worldwide market for regenerative medicine is conservatively estimated to be USD 500 billion by 2010, while the European market is expected to reach USD 15 billion. Of the areas of research that comprise regenerative medicine, tissue engineering is the closest to successful commercial development. Although initially led by the US, the last ten years has seen a decided shift towards other areas of the globe. Within

Europe, a total of 436 companies are currently engaged in research in the field, 40 percent of these being based in the UK or Germany. Other sizeable international interests include Australia, Japan, Israel, and increasingly, India, China, South Korea and Singapore, all of whom have committed long-term federal or national investment into regenerative medicine. As it moves towards a fully-fledged health market, research and development in regenerative medicine is becoming an increasingly globalized affair, involving global dynamics of intellectual property rights; human rights and gender issues; scientific labor; clinical trials and tissue sourcing.

The combination of multiple globalization pressures and the self-directed policies of individual member states in Europe produces distinct approaches to governance at the state, regional and international levels of government. Globalization in the field of regenerative medicine is therefore likely to be as much about the heterogeneity of policy as it is about 'convergence'.

In the RemediE Project the CELAB team is responsible for the Work Package No 6. on "EU and Global Bioethics: Intellectual Property and Cultural Difference." Our main task within this project is to explore the relevance of bioethical soft laws in different intellectual property regimes. Special attention will be paid to the status of the human body in the field of regenerative medicine, benefit-sharing and morality clauses, especially in cases of transnational research.

In the framework of this project, in 2008–2009 we attended and presented papers at two workshops in York, one conference in London and one in Vienna.

Furthermore, we have developed an international database of the legal sources of regenerative medicine.

CELAB participants in this project are *Judit Sándor* (principal investigator), *Enikő Demény*, *György Kovács*, and *Márton Varju* (researchers).

2.1.5. Tiss.EU: Evaluation of Legislation and Related Guidelines on the Procurement, Storage and Transfer of Human Tissues and Cells in the European Union – An Evidence-Based Impact Analysis

Partners:
Department for Ethics and History of Medicine, University of Göttingen, Germany – Coordinator
Medical Law and Bioethics Group, Institute for German and European Private and Commercial Law, University of Hanover, Germany
Center for the Study of Global Ethics, University of Birmingham, United Kingdom
Stockholm Bioethics Center, Stockholm University, Sweden
Fondazione Lanza, Padova, Italy
Forensic & Legal Medicine, School of Medicine and Medical Science, National University of Ireland, Dublin
Center de Recherche Droit, Sciences et Techniques, Université Paris 1, France
Institute of Bio-Law „Legal Pathways", Aerdenhout, Netherlands
Department of Medical History and Ethics, Vilnius University, Lithuania
CELAB, Central European University, Budapest, Hungary
Webpage: http://www.tisseu.uni-hannover.de/

The acronym Tiss.EU stands for "Evaluation of Legislation and Related Guidelines on the Procurement, Storage and Transfer of Human Tissues and Cells in the European Union – an Evidence-Based Impact Analysis." The project, funded by the European Commission as part of the 7th Framework Programme, runs from March 2008 to early 2011 and addresses questions of ethical and legal regulation in relation to research using human tissue. Tiss.EU is made up of four parts, the ethical and legal aspects of which are going to be looked at by the project partners: first, procurement, storage and transfer of tissue and cells for research; second, rights and entitlements to tissue and cells; third, anonymization and pseudonymization to protect privacy rights; and finally, research using biobanks.

Within the Tiss.Eu Project, the CELAB team focuses on anonymization and pseudonymization for privacy protection in the following countries: Bulgaria, Czech Republic, Hungary, Slovakia and Romania. CELAB organized a conference in the spring of 2009 and reported on the impact of EU legislation and documents in this country group. As a culmination of the project, recommendations are to be drafted for possible ethical and legal guidelines in the interests of European-wide convergence and harmonization.

Anonymization and Pseudonymization as Means of Privacy Protection – An International Workshop

CELAB organized and hosted the Second International Workshop of the Tiss.EU Project in Budapest on April 6–8, 2009 with the title *Anonymization and Pseudonymization as Means of Privacy Protection*. The workshop made a major contribution to one of the four Focal Themes of the Tiss.EU project (Focal Theme C) by addressing questions of anonymization and pseudonymization in privacy protection in relatively unexplored jurisdictions of Central and Eastern Europe, such as the Czech Republic, Hungary, Slovakia and Romania. Due to the interdisciplinary nature of the workshop's subject, invited speakers represented a wide range of disciplines, such as law, medicine, philosophy and information technology.

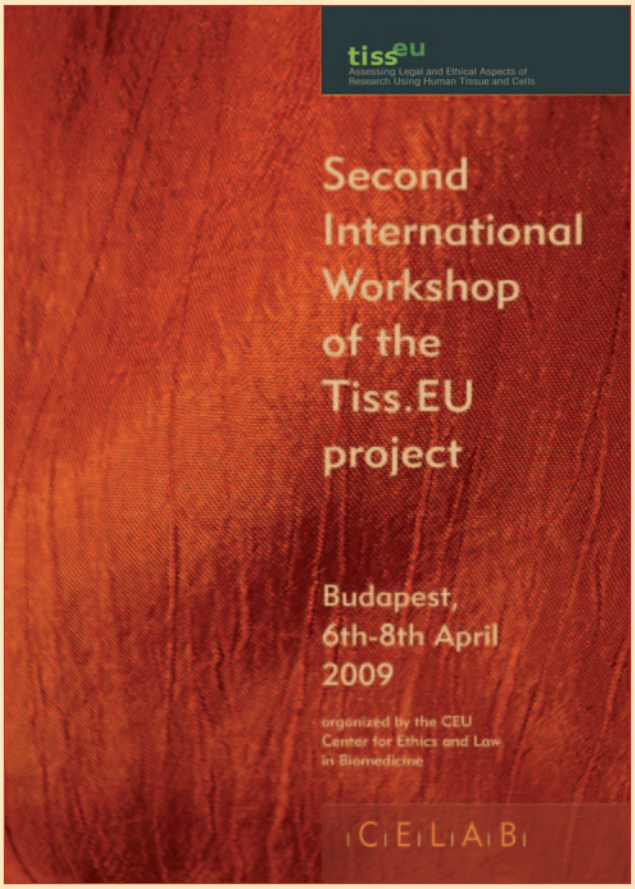
The structure of the workshop followed a two-track approach: on the one hand speakers presented their countries' regulatory framework and existing practices concerning anonymization, and on the other, scholars addressed various related theoretical concerns and problems. Emphasis was placed on the geographical scope of the workshop: not only experts summarizing the related legal rules in their own countries, but whenever possible, also scholars addressing some theoretical issues were invited from Central Eastern European jurisdictions.

The substantive part of the workshop started with general presentations framing the issue of anonymiza-

tion and pseudonymization. This first session was chaired by *György Kosztolányi*, Hungarian professor, clinical geneticist and member of the Hungarian Academy of Sciences. The first speaker was *Christian Lenk*, who as representative of the coordinating institution, the University Medical Center of Göttingen, greeted the audience and emphasized in his introductory remarks the special importance of personal and genetic data in ethics and law. He raised the crucial issue of common standards of anonymization in medical research and that of privacy of and control over medical data.

Judit Sándor, Director of CELAB representing the host institution of the workshop, gave a thorough mapping of anonymity issues. She emphasized the various and divergent functions and the lack of a uniform definition of anonymization through the example of international instruments and the Hungarian pieces of legislation. She gave a balanced analysis of the pros and cons of anonymization. Genetic data is never collected alone; in some jurisdictions dozens of pages long questionnaires need to be filled out by the patients or donors who often have to disclose special or sensitive information. On the one hand, these data are a treasure for researchers, while on the other, they pave the way towards potential genetic or other type of discrimination. Should we attempt to overcome the negative sides of deleting the link between the individual and his or her data, alternative means of privacy protection have to be found. Judit Sándor concluded by saying that anonymization is just one method, but in itself it will not be a cure to the threats of discrimination.

The keynote speech was delivered by *Bernice S. Elger*, professor at the University of Geneva, Switzerland, author of numerous papers, and books on biobanks and the narrower topic of the ethical, legal and practical problems of anonymization and pseudonymization. Professor Elger first framed the debate around anonymization, i.e. she talked about the clashing interests, the importance of biobanking and privacy protection. Her starting point was that while human DNA sampling and data collection, as well as the sharing and exchange of information are important for genetic research, clinical care and future treatments, the corresponding ethical and legal framework is still poorly defined. Most institutions have no written policies or agreements regarding this activity, and even if there was a willingness on the side of hospitals, clinics and research institutes to adjust their practice to some general norms, researchers or drafters of internal guidelines are in an extremely difficult position due to the large



number of international, national and professional guidelines that contain different, sometimes even contradicting recommendations relevant for biobanks. The extremely rich presentation was followed by a discussion, where important and controversial questions were raised

The second session was chaired by CELAB Researcher *Enikő Demény*. The first speaker in this session was *Ants Nomper*, senior lecturer at the University of Tartu in Estonia, who presented his thoughts on autonomy through the example of Estonian population databases. Estonia is of particular interest to researchers in the field of bioethics, and especially to those interested in biobanking. As Ants Nomper pointed out, Estonia gave the world not only Skype, but also some controversial innovations in the field of

bioethics. The first target jurisdiction to be addressed was Slovakia. *Jan Koller* from the Central Tissue Bank, University Hospital Bratislava, addressed traceability requirements and privacy protection in Slovakian tissue and cell establishments. *Professor Daniel Kuba* from the Slovak Centre for Organ Transplantation and professor at the Slovak Medical University Bratislava

explained the organization and structure of the Transplant Network in Slovakia.

The sessions during the second day of the conference were chaired by project partner *Torbjörn Tännsjö* from the Stockholm Bioethics Centre. First *Lukas Prudil*, associate professor at the Department of Social Medicine and Health Care Administration, Medical Faculty, Masaryk University, Brno, Czech Republic gave a country analysis of the Czech Republic. Extensive human subject research is conducted in the Czech Republic, however a corresponding legal framework is missing. Rules applicable to biobanks, research conducted on cells and tissues, and anonymization requirements cannot be found in a single legal document. Although there is no comprehensive document, the field is governed by a number of general pieces of national legislation and international instruments.

István Peták from the Hungarian Biotech Association, KPS Molecular Treatment Solutions and the Semmelweis Medical University presented the Hungarian country analysis. Among the ten EU accession countries, Hungary had the first biotechnology association founded in 2002. Hungary has a solid record of attracting and conducting international clinical trials, with over 250 clinical trials performed each year, which is outstanding especially if seen in light of Hungary's population. Core research areas in Hungary are medicinal chemistry, plant genomics, bioinformatics and infobionics, clinical trials, biomarkers and diagnostics, absorption, distribution, metabolism and excretion (ADME), molecular biology and vaccines. Hungary has a number of strengths, making it a leading state in the biotech industry.

Professor *Zoltán Alexin*, senior lecturer at the University of Szeged, Department of Software Engineering, addressed the specific topic of the workshop, anonymization of health care data in Hungary. Dr. Alexin first formulated his own position concerning privacy, which corresponded to the Hungarian Constitutional Court's view – especially as laid down by its decision 36/2005. Zoltán Alexin acknowledged that a democratic society may restrict the right to self-determination by law, referring to legal, economic or national security reasons, or the vital interests of others. In his view, a society may not restrict the right to self-determination simply by referring to general health reasons, but rights intrusions may only be justified in exceptional cases, in the higher interests of the society (that is clearly demonstrated by a law). One exception is that data processing for medical research may be done without consent (if obtaining consent is not feasible), but this does not mean a restriction to self-determination: the patient may object to the processing of data afterwards, may require access to, copying, rectifying or deletion of data, i.e. he or she may withdraw the presumed consent. Dr. Alexin concluded by saying that the solutions cannot be found either in mathematics or in law. All problems are questions of respecting people's personal rights and human dignity. He proposed that consent should be the moral and ethical basis of medical research – as also recommended by the Nurnberg Code and the Oviedo Convention.

Josef Kure, Professor at the University Centre for Bioethics and Department of Medical Ethics, Masaryk University, Brno talked about the ethics of biobanking. Professor Kure first gave an overview of the various types of biobanks; second, he presented the ethical concerns; third, he addressed the 'stored tissue issue concerns'; and fourth, he listed some positive scenarios.

The session during the last day of the workshop was chaired by project partner *Claudio Tamburrini* from the Stockholm Bioethics Centre. In this session *Ioana Berindan Neagoe*, Head of Functional Genomics De-

partment and Assistant Professor of Immunology from the Ion Chiricuta Cancer Institute in Cluj Napoca, Romania addressed the issue of tumor banks and their use in functional genomics studies in Romania. Her talk was based on a paper co-authored by her and her colleagues *Liliana Policiuc*, legal advisor, and *Ovidiu Balacescu*, principal investigator.

At the end of the workshop *Judit Sándor* and *Petra Bárd* summarized the findings of the workshop. After a summary of the main thoughts given by different participants of the workshop, in the second part of her presentation Petra Bard addressed a topic not explored during the workshop: forensic biobanks. She stated that while the lack of definitions, uniform standards and problems of interconnectivity might have drawbacks from the point of view of research and efficiency in case of classical biobanks, in case of forensic biobanks these problems cause Member States to be in contravention of the law. Petra Bárd concluded by saying that although a number of issues had been discussed, and researchers agreed on many, there are plenty of issues left to be discussed in Stockholm at the next anonymization workshop under the guidance of Torbjörn Tännsjö and Claudio Tamburrini.

As it is apparent from the above, the workshop was also an opportunity for Central Eastern European scholars to meet, where many experts from all around Europe shared their thoughts with each other and with the Tiss.EU partners. During the workshop, participants of several similar EU-funded projects could exchange ideas in person and by the distribution of materials. An example of collaboration was the leaflet published and sent to Tiss.EU participants by the organizers of the Sixth Framework Programme project called "Privileged" on privacy in law, ethics and genetic data. As the CELAB team pointed out, while there is an agreement on the need for common standards and there are some minimum requirements on which there seems to be a Europe-wide agreement, there are a number of ethical, legal and technical issues left for future discussions.

2.1.6. Bio-Ethical and Legal Database

To improve the management of CELAB's bioethical and legal database, the CELAB team has decided to develop it based on the projects carried out in the research center. Each team working on a certain topic is responsible for updating the database with legal and policy materials in the respective field. In this way, *Petra Bárd*, *Enikő Demény* and *Judit Sándor* contribute to the biobanks section of the bio-law database; *Enikő Demény*, *Péter Kakuk* and *Judit Sándor* to the nanotechnology section; *Violeta Beširević* to the euthanasia section; *Enikő Demény*, *György Kovács*, *Judit Sándor* and *Márton Varju* to the stem cell research and intellectual property regimes sections. *Enikő Demény* is responsible for the overall management of the database.

Since in many CELAB projects, the bulk of the work is to collect and analyze various legal instruments in the field of biomedicine, the biolaw-database is a practical resource to store the data collected during research. We hope that the database proves to be a good research tool not only for CELAB researchers but also for all those colleagues who are conducting research on these topics. Statistical data shows that the database is searched from a variety of countries, and the number of returning visitors is increasing year by year.

Webpage: http://www.biolaw-database.com/

2.2. POLICY ACTIVITY IN CELAB

2.2.1. Developing Models of Implementation of UNESCO Bioethical Instruments

CELAB received a UNESCO grant for developing models for implementation of UNESCO Bioethical Instruments (Grant No: 375423 08 HUN).

With this project, CELAB sought to contribute to the increasing international awareness of the existence of these UNESCO declarations. We believe that reflections on and interpretations of these documents should be an integral part of ethics education, policy-making, national legislation and international research and that translating these documents into the official languages of the Member States is one of the best ways to spread the idea of bioethical thinking and disseminate the results of policy-making at UNESCO. Therefore our goal was to arrange authoritative and accessible translations of the three UNESCO declarations on bioethics: the Universal Declaration on the Human Genome and Human Rights (1997), the International Declaration on Human Genetic Data (2003) and the Universal Declaration on Bioethics and Human Rights (2005).

The importance of these translations is that this is the first time that Czech, Croatian, Italian, Hungarian and Serbian readers can read in their mother tongue a compilation of the three main international declarations drawn up and adopted in the field of bioethics, recognized by most states in the world. The booklets have been sent out for free and without any commitment to decision makers, ministries, medical universities, faculties of law, libraries and ethical committees. Those involved in this project hope that the translations will serve as practical tools to promote the implementation of the key UNESCO instruments on bioethics.

Local, Regional or International? Laws, Standards and Codes for Biotechnology – An International Workshop

The lessons, experiences and results of the project have been discussed in the framework of a joint workshop organized on November 7–8, 2008 in Budapest, entitled: *Local, Regional or International? Laws, Standards and Codes for Biotechnology*. The workshop was opened by the CEU Rector *Yehuda Elkana*'s welcome speech, followed by a talk by *Péter Gresiczki*, who represented the Hungarian UNESCO Committee. The participants debated the importance of international bioethical norms and the specific concerns in the lawmaking processes of individual countries.

In the first day of the workshop, the lectures covered such broad topics related to the UNESCO Declarations as the relationship between bioethics and human rights, bioethics and cultural diversity or the right to health care. The first session was chaired by *József Kovács*, Associate Professor, Deputy Director, Head of the Department of Bioethics of the Semmelweis University, Institute of Behavioral Sciences.

The first lecture was offered by *Judit Sándor*, on the topic "Bioethics and Law: Competitors or Allies?" In her lecture, Professor Sándor framed the debate around the UNESCO bioethics instruments in the context of the relationship between law and bioethics. She argued that ethics and law cannot be separated. A strong criticism based on ethical considerations should not be simply swept aside based on the fact that it is a different discipline. And vice versa, an ethical code that disregards law and does not even provide the minimum protection that the law already provides would not be acceptable in a society.

The next lecture was offered by *Lukas Prudil*, Associate Professor at the Department of Social Medicine and Health Care Administration, Medical Faculty, Masaryk University, Brno, Czech Republic, who addressed the topic "Access to Health Care." The third lecture of the morning panel was offered by CELAB Researcher *Enikő Demény* on the issue of "Bioethics and Cultural Diversity". In the first part of her presentation, Demény outlined the main provisions on the issue of cultural diversity of the major UNESCO instruments. According to Article 12 of the Universal Declaration on Bioethics and Human Rights, the importance of cultural diversity and pluralism should be given due regard. However, such considerations shall not to be invoked to infringe upon human dignity, human rights and fundamental freedoms. To achieve this, UNESCO aims to foster multidisciplinary and pluralistic dialogue about bioethical issues between all stakeholders and within society as

a whole. In the second part of her presentation, Demény discussed the possibilities of such interdisciplinary dialogue in the context of knowledge production characteristic of the new converging technologies (biotechnology, nanotechnology, information technology and cognitive sciences). She focused her attention on the relationship between bioethics and anthropology and pointed out that the applications of biotechnology raise fundamental questions about human existence. These are questions that are relevant not only for professional ethics or for the anthropology of science and technology. This "science and technology" that is employed in biotechnology might alter also the "subject of anthropology": the human being and its relationship to its environment. Taking all this into account, Demény argued that anthropology can offer meaningful insights to bioethics.

The lectures were followed by a round table discussion on the process of translation, difficulties in implementation and the role of the Declaration in the different national legal systems. The round table discussion was moderated by *Violeta Beširević*, Associate Professor at Belgrade University, Research Associate at CELAB. Participants at the roundtable were: *Petra Bárd*, CELAB Researcher; *Enikő Demény*, CELAB Researcher; Professor *Imre Hronszky*; Professor *Josef Kure*; Professor *Miomir Matulovič*; *György Kosztolányi*, Medical Doctor, Full Professor of Medical Genetics at the University of Pécs, Member of the Hungarian Academy of Sciences, president and former president of various professional organization of human genetics in Hungary; Judit Sándor, CEU Professor and Director of CELAB and CEU students.

In the second day of the workshop the lectures were focused on a more specific topic, namely on ethics and genetics, a topic that is closely related to the UNESCO bioethics declarations. The session was chaired by *Josef Kure*, Professor at the University Centre for Bioethics and Department of Medical Ethics, Masaryk University, Brno.

The first lecture was offered by *Violeta Beširević*, Associate Professor, Union University Law School Belgrade, Research Associate at CELAB and was entitled "Basic Norms of Bioethics: Informed Consent and UNESCO Instruments." The purpose of her presentation was to assess the informed consent requirements in the Universal Declaration on the Human Genome and Human Rights, the International Declaration on Human Genetic Data and the Universal Declaration on Bioethics and Human Rights. These requirements represent recent international attempts to give informed consent central to ethically and legally acceptable medical and research practice. Beširević showed that the given standards are minimal and that the drafters failed to make con-

sent and consenting rigorous and fully specific. Yet, while some national laws have gone beyond these standards, the author reminds that in most countries legislation addressing the social implications of biotechnological developments is either unsystematic or nonexistent. Hence, although not fully determined and included in legally non-binding instruments, the authoritative statements concerning informed consent in the UNESCO declarations represent a very

helpful what-to-do list. Moreover, the declarations are the most thorough global initiative thus far to consider human rights implications of biomedical sciences and as such, represent an important step in protecting human rights in the area of bioethics.

The second lecture was entitled "Human Genome and the Protection of Human Rights in Croatia" written by Prof. *Nenad Hlača*, Chair of Family Law, Law School University of Rijeka, Rijeka, Croatia. Since Professor Hlača had to cancel his participation at the workshop, his paper was presented by Professor *Miomir Matulovič*, Dean of the Faculty of Law at the University of Rijeka and a Full Professor of the Theory of Law and State and the Philosophy of Law, University of Rijeka, Croatia. The aim of Professor Hlaća's paper was to analyze if and how human rights are protected within the legal framework and the practice of DNA testing in Croatia.

The session was closed by *Péter Kakuk*, Research Assistant in the University of Debrecen, Medical and Health Sciences Centre and CELAB Research Associate's presentation on "Genetics and the Concept of the (Common) Heritage of Human(kind)ity: An Instrument under Construction." His talk was based on documents that reported the birth and construction process of UNESCO'S Universal Declaration on the Human Genome and Human Rights (1997). Kakuk highlighted that one of the fundamental questions in the construction process was whether the declaration aims to protect the rights and dignity of human beings or it protects the biological integrity of the human species, or both. According to him the approved or final formulation of the Declaration seems to oscillate between the two aims, and is an approach to undertake both tasks. As a result, the Declaration embraces an ambivalence regarding the moral relevance of the genome. It advocates that the value of a person is independent of his or her genetic characteristics, but hardly avoids sanctifying the biological aspects of human beings with giving an intrinsic value to the human genome itself.

Following the lectures, in a roundtable discussion the participants of the workshop debated the possibilities of the applications of UNESCO declarations in the process of bioethics education. The roundtable was moderated by *Professor* Judit Sándor. Participants were *Violeta Beširević*, *Nada Gosič*, Associate Professor of Medical Ethics, Bioethics and Healthcare Ethics, Medical School in Rijeka, Department of Social Science; *Imre Hronszky*, Full Professor at the Budapest University of Technology and Economics (BUTE), Faculty of Economics and Social Sciences; *Josef Kure*, Professor at the University Centre for Bioethics and Department of Medical Ethics, Masaryk University, Brno; *József Kovács*, Associate Professor, Deputy Director, Head of the Department of Bioethics of the Semmelweis University, Institute of Behavioral Sciences; *Péter Kakuk*, Research Assistant in the University of Debrecen, Medical and Health Sciences Centre, Research Associate at CELAB, *Miomir Matulovič*, Dean of the Faculty of Law at the University of Rijeka and a Full Professor of the Theory of Law and State and the Philosophy of Law, University of Rijeka, Croatia; *Ivana Rodič*, Adviser at the Ministry of Health of the Republic of Serbia; *Judit Zeller*, Senior Lecturer at Department of Constitutional Law, Faculty of Law of Pécs, University of Pécs and CEU students.

We hope that the research and policy partnership established in the course of the project between academic institutions, universities, research centers and government ministries in the five countries will continue in the future.

2.3. TEACHING

CELAB's staff and fellows are involved in teaching both at CEU and at other universities in Hungary and other countries in the region. They offer courses that are in close connection with CELAB's main fields of inquiry. One of CELAB's goals is to develop a teaching network for bioethics and biolaw in the region.

2.3.1. Teaching at CEU

Judit Sándor

Department of Political Science and Gender Studies

Reproduction and Gender

The course deals with the social impact of human reproduction technologies on gender relations, family, and society. The new and alternative forms of human reproduction have created challenges to the disciplines of ethics, law, and gender studies. The social impact of reproductive medicine today is much more extensive than the simple relief of emotional frustration among infertile couples. By creating alternative forms of parenthood and supplanting sexual intercourse as a means of reproduction, this branch of biomedicine has unwittingly created a wide array of third-party effects. While legal theorists have spent considerable time of exploring the human body as property or as a part of personhood, feminism's responses to reproductive technologies and their regulation center around the criticism of the concept of the individualized human body, and it rejects the biomedical model in science. The course integrates both legal and feminist approach to the contemporary issues of body and reproduction.

Human Rights and Biopolitics

This course deals with the status of, and current challenges to, human rights. By analyzing relevant texts and landmark cases, different generations of human rights will be explored. The course will focus on recently emerged thematic issues within the domain of human rights, such rights as privacy and security, women's rights, and politics of life. Contemporary human rights encompass increasingly important norms in areas of biopolitics; policy issues related to reproductive and end-of-life decisions; biodiversity and environmental protection; genetic testing, biobanks, and storage of genetic data, among others. This course will develop skills in the analysis of normative texts and cases that contain elements from both the human rights and biopolitical discourses.

Department of Legal Studies

Privacy Rights and Data Protection

This course provides an introduction to different concepts of privacy from comparative legal aspects. Though the legal scope of the right to privacy is highly contested, the right to seclusion and the control of information about oneself (privacy as secrecy) are considered to belong to privacy rights in most legal systems. The course also includes the discussion of recent efforts to extend privacy principles in order to respond to the challenges the ever expanding internet and the rapid biotechnological advances pose. Both fields require special consideration with regard to transnational data transfer.

Patients' Rights in the Twenty-First Century

Patients' rights represent a complex and dynamically changing legal field. Some of the patients' rights belong to international human rights (the rights mentioned in the European Convention on Human Rights and Biomedicine, such as the right to dignity and equal treatment) while others have originated from personal rights (such as the right to consent and refusal) or simply derived from health care law (right to complain, access to services). During the course the students will analyze normative texts and cases that contain elements from both the human rights and bioethics perspectives. The Reader and the attached bibliography shall provide the basic literature for further studies. The course will develop legal and policy skills in the students who will have the opportunity to discover a new and

rapidly developing field of contemporary patients' rights.

Petra Bárd

Department of Legal Studies
EU Constitutional Law
EU Fundamental Rights

2.3.2. Teaching and Lecturing at Other Institutions

Enikő Demény

Family and Identity in the Age of Genetics
Foundation of Gender Studies
MA Courses at the Faculty of Political, Administrative and Communication Sciences, Babes-Bolyai University, Cluj, Romania

Petra Bárd

European Union Law
European Business Law
Courses at ESSCA, Budapest, Hungary

Violeta Beširević

Medical Law Courses
Union University Law School Belgrade: BA/Medical Law
Specialized Studies in Medical Law/Law and Ethics in Biomedicine
Specialized Studies in Medical Law/Patients' Rights
Liability of Physician for a Patient's Death Caused by Omission
Association for Promotion and Protection of Patients Rights, Belgrade, January 31, 2009.

Péter Kakuk

Bioethics Seminars
General Medical Program, Medical and Health Science Center, University of Debrecen
Bioethics
Medical Diagnostics and Laboratory Analyst, Medical and Health Science Center, University of Debrecen
Dental Ethics
Faculty of Dentistry, Medical and Health Science Center, University of Debrecen
Pharmacy Ethics
Faculty of Pharmacy, Medical and Health Science Center, University of Debrecen
Health Care Ethics
Health Care Management, Medical and Health Science Center, University of Debrecen

2.3.3. PHD Defenses

On 29 April, 2009, *Péter Kakuk*, CELAB Research Associate received his doctoral degree from Health Sciences at the Debrecen University with a summa cum laude evaluation. The title of his dissertation was: "The Bioethical Problem of Genetic Information and Discrimination: The Doctrine of Genetic Exceptionalism in Policy Debates" and can be reached at: http://hdl.handle.net/2437/80508

On September 3, 2009 *Judit Zeller*, CELAB Research Fellow defended her PhD at the University of Pécs, Hungary with the dissertation entitled "A testen kívül létrejött embriók morális és jogi státusa a reprodukcióhoz való jog és a tudományos kutatás tükrében [The Moral and Legal Status of the In-Vitro Embryo in Light of the Right to Reproduction and Scientific Research]". Her supervisor was *Prof. Antal Ádám* and her opponent *Prof. Judit Sándor*, Director of CELAB.

On September 16, 2009 *Éva Földes*, PhD student of *Professor Judit Sándor* at the Department of Legal

Studies, defended her PhD dissertation entitled "The Emerging Mandate of EU Law in Health Care: A Legal Analysis of the Influence of Internal Market Implementation on Access to Health Care in Hungary and Slovenia" at the CEU. The members of the Doctoral Committee were Profs. *Herman Nys* (University of Leuven), *Gábor Juhász* (ELTE), *Csilla Kollonay-Lehoczky* (CEU), and *Judit Sándor* (CEU) as Supervisor. The Chair was Prof. *Anton Pelinka* (CEU).

2.3.4. Internship

During the month of August in 2009 *Péter Buzás*, an undergraduate law student at ELTE, conducted a research internship at CELAB on the topic: "Bioethics in International Law: A Special Case of Stem Cell Research."

2.4. PARTICIPATION IN KEY EVENTS AND NETWORKS IN THE FIELD OF BIOETHICS AND BIOLAW

2.4.1. The Inter-university Francophone Network in the Field of Bioethics's meeting in Kyoto

In 2007 based on the idea of *Prof. Brigitte Feuillet-Liger*, an inter-university network was created in the field of bioethics. After a preparatory meeting held in Paris, the first workshop was organized in 2007 in Rennes. The third meeting, organized in collaboration with the Faculty of Law took place on January 5–6, 2009 in Kyoto, Japan. This Francophone network includes mainly lawyers but also social scientists who work in the interdisciplinary field of studies of biomedicine, family law, and ethics. In the framework of this cooperation, thematic sessions and publications aim to explore legal and cultural differences in bioethics. The Kyoto workshop focused on the topic of "Adolescents and Medical Treatment". Members of the network are: *Brigitte Feuillet-Liger*, *Pénélope Agallopoulou*, *Amel Aouij-Mrad*, *Stéphane Bauzon*, *Thérése Callus*, *Maria-Claudia Crespo-Brauner*, *Françoise Furkel*, *Ryuichi Ida*, *Dominique Manai*, *Kristina Orfali, Véronica San Julian*, *Geneviève Schamps*, and *Judit Sándor*. Professor Judit Sándor has been a member of the Advisory Board and the network since the beginnings. She delivered a paper in Kyoto and in Rennes.

2.4.2. ELPAT: European Platform for Ethical, Legal, and Psychosocial Aspects of Organ Transplantation

Webpage: www.elpat.org

Professor Judit Sándor and CELAB Reseacher Enikő Demény took part in the activity of the ELPAT Working Groups: *Organ trafficking, tourism and paid donation* and *Legal boundaries*.

The Working Group on Organ trafficking, tourism and paid donation aims to address the following questions: Is the current legislation of European countries efficient in preventing and prohibiting human organ trafficking and tourism? If not, what are the loopholes and what improvements can be proposed? What outreach can be given to actual vendors or victims? What actions can be taken to diminish vulnerable populations' and groups' risk of being targeted as donors or vendors? The working group also aims to study how providing medical, legal and psychosocial support to actual organ vendors or victims can improve their condition and the negative outcomes of their selling an organ; to study how information, education and awareness campaigns can prevent vulnerable populations from being targeted as vendors. Regarding the use of internet for soliciting of paid donation and advertising the need of transplantation, the working group will explore if legal measures can be proposed and adopted for prohibiting internet solicitation and advertising.

A working paper on „Internet Use in Organ Solicitation in Romania and Hungary" was submitted by Enikő Demény and presented at the 2nd ELPAT meeting in Juan-les-Pins, France, November 13–15, 2009.

As an outcome of the working group activities, a project was prepared and submitted to the European Commission entitled "The European Platform for Ethical, Legal, and Psychosocial aspects of Organ Transplantation." The project has been positively evaluated in the first round and will start in 2010 if it receives the final approval from the Commission.

2.5. PARTICIPATION IN CONFERENCES

During the 2008–2009 academic year, CELAB staff and fellows took part in the following academic and scientific events:

Biotechnology and Law
Conference organized by the Legal Forum
Presentation by Judit Sándor: "Biotechnology and Human Rights in Europe"
October 10, 2008, Budapest, Hungary

Local, Regional or International? Laws, Standards and Codes for Biotechnology
CELAB-UNESCO Workshop
Presentation by Judit Sándor: "Bioethics and Law: Competitors or Allies?"
Presentation by Enikő Demény: "Bioethics and Cultural Diversity"
Presentation by Violeta Beširević: "Basic Norms of Bioethics: Informed Consent and UNESCO Instruments"
Presentation by Péter Kakuk: "Genetics and the Concept of the (Common) Heritage of Human(kind)ity: An Instrument under Construction"
November 7–8, 2008, Budapest, Hungary

Second Privileged Project Workshop
CELAB Participant: Judit Sándor
November 12–15, 2008, Coimbra, Portugal

Conference on Nanotechnology
Presentation by Péter Kakuk and Enikő Demény: "The Social, Ethical and Legal Aspects of Nanotechnology"
November 20, 2008, Veszprém, Hungary

Scientific meeting of the Hungarian Society for Bioethics
Presentation by József Kovács: "Bioethical Issues in Psychiatry"
December 3, 2008, Budapest, Hungary

International Sessions Commemorating the 60th Anniversary of the Universal Declaration of Human Rights and the 10th Anniversary of the Valencia Declaration of Human Duties and Responsibilities (An Euro-American Project)
Presentation by Violeta Beširević: "Human Rights in the Twenty First Century: Euthanasia as a Universal Right to Die?"
December 9-12, 2008, Valencia, Spain

New Technologies and Human Rights
Organized by European University Institute, Faculty of Law
Invited speaker: Judit Sándor on "Human Rights and Genetics"
December 15–16, 2008, Florence, Italy

3rd Meeting of the Francophone Network of Lawyers in the field of Biomedicine
Thematic Focus on "Adolescents and Medical Treatment"
CELAB Participant: Judit Sándor "Adolescents' Rights in the Hungarian Medical Law"
January 5–6, 2009, Kyoto, Japan

Methodological and Methodical Issues in Bioethics Today
International Regional UNESCO Conference
Presentation by Petra Bárd: "The Forensic Use of Genetic Information: Ethical and Legal Concerns" and
Presentation by Enikő Demény: "Bioethics, Social Sciences and Biotechnology: The Challenges of Interdisciplinarity in the Policy Context"
January 21–22, 2009, Prešov, Slovakia

RemediE Project 2nd Workshop
Presentation by Judit Sándor and Márton Varju "Intellectual Property and Cultural Difference: Research Methodology"
January 22–23, 2009, York, United Kingdom

Guest Lecture at the International Hereditary Cancer Center (IHCC) and Biobank
Invitation by the Department of Genetics and Pathology, Pomeranian Medical University and Read-Gene SA
Chaired by Professor Jan Lubinski
Lecture by Judit Sándor: "DNA in Bank? Fallacies and the Art of Regulating Biobanks"
February 20, 2009, Szczecin, Poland

2nd International Conference of European and Comparative Law
Presentation by Petra Bárd: "The Fight Against Terrorism: Data Protection Standards versus the Establishment of Surveillance Society"
March 19–20, 2009, Portorož, Slovenia

Second Nanoplat Project Workshop
Presentation by Enikő Demény and Péter Kakuk: "Nanotechnology and Deliberative Processes: Country Report on Hungary"
March 26–27, 2009, Istanbul, Turkey

Tiss.EU Project Workshop: Anonymization and Pseudonymization as Means of Privacy Protection
CELAB Participants: Judit Sándor, Petra Bárd and Enikő Demény
Concluding remarks by Judit Sándor and Petra Bárd
April 6–8, 2009, Budapest, Hungary

Nanotechnology: Risk Assessment and Legislation Initiatives in the European Union
Seminar organized by Hungarian Food Safety Office
CELAB participant: Enikő Demény
April 7, 2009, Budapest, Hungary

Responsible Development of Nanotechnology: Governance Challenges – High Level Workshop
Organized by Budapest University of Technology and Economics
Presentation by Enikő Demény and Péter Kakuk: "Situated Challenges and Opportunities for Nanotechnology in Hungary"
April 17, 2009, Budapest, Hungary

RemediE conference in conjunction with the UK Social Science Stem Cell Initiative
Presentation by Judit Sándor and György Kovács: "Regenerative Medicine: Duality of Legal Norms"
May 7–8, 2009, London, UK

Days of Bioethics at the Medical School in Rijeka
Organized by the Department of Social Sciences at the Medical School of the University of Rijeka, the Croatian Society for Clinical Bioethics and the Rijeka Branch Office of the Croatian Bioethics Society
Presentation by Petra Bárd: "The Force of Law: Genetic Data Protection in Central and Eastern Europe"
Presentation by Enikő Demény: "Universal Values, Contextualization and Bioethics"
May 14–15, 2009, Rijeka, Croatia

GeneBanC Final Conference
CELAB Participants: Judit Sándor and Petra Bárd
Plenary Session Presentation by Judit Sándor "From Private to Public? Legal Concepts of the Rights to Privacy and Ownership in the Legal Regulation of Biobanks"
Presentation by Petra Bárd: "Genetic Databases in the Forensic Context – A European Perspective"
May 18, 2009, Brussels, Belgium

GeneBanC Stakeholders' Conference: New Challenges for Biobanks. Ethics Law and Governance,
Organized by the Catholic University of Leuven
CELAB Participants: Judit Sándor and Petra Bárd
May 19–20, 2009, Leuven, Belgium

17th Annual Conference on 'The Individual vs. the State': Arguments that Work
CELAB Participants:
Judit Sándor chairing the session "Seen from the Bench"
Petra Bárd presenting in the session "Arguments in Social Panic"
June 12–13, 2009, Budapest, Hungary

Privileged Project Stage 3 Workshop
CELAB Participant: Judit Sándor
June 22–24, 2009, Vilnius, Lithuania

Tiss.EU Project workshop
CELAB Participants: Judit Sándor and Petra Bárd
June 24–25, 2009, Paris, France

Nanoplat Project – Final workshop
CELAB Participants: Enikő Demény and Péter Kakuk
June 25–26, 2009, Brussels, Belgium

Joint Biobank Symposium
Keynote speach by Judit Sándor: "Are There Any Recipes for Making a Good Law on Biobanks? Lessons Drawn from the Previous Law-Making Projects"
July 8–9, 2009, Graz, Austria

Second International Conference of the Tiss.EU project: Privacy, Confidentiality and Personality Rights in Biobanking and Genetic Research with Human Tissue
Organized by Department for Medical Ethics and History of Medicine, Göttingen University
Presentation by Judit Sándor "Private Tissues?"
July 16–18, 2009, Göttingen, Germany

NICLAS International Constitutional Law Summer School
Presentation by Petra Bárd: "Whose Justice? Disability Related Aspects in the Field of Human Rights"
July 16, 2009, Vienna, Austria

PEC meeting, Steering Committee Meeting of the NMD-Chip project
CELAB Participant: Judit Sándor (Member of the Advisory Board on Ethics)
August 31–September 2, 2009, Stockholm, Sweden

GeneBanC Project final conference
CELAB Participants: Judit Sándor and Petra Bárd
September 8–9, 2009, Geneva, Switzerland

EACME Annual Meeting: Multiculturalism, Religions, and Bioethics
Organized by Fondazione Lanza (Padua), "Ca' Foscari" University of Venice, and the European Association of Centres of Medical Ethics (EACME)
Presentation by Petra Bárd: "Forensic Genetics and Data Protection – A Central Eastern European Perspective" and Presentation by Enikő Demény: "Universal Values, Contextualization and Bioethics: Knowledge Production in the Age of Genetics"
September 10–11, 2009, Venice, Italy

Tiss.EU Workshop Focal Theme A: "Procurement, Storage and Transfer of Human Tissue and Cells for Research"
CELAB Participants: Judit Sándor and Petra Bárd
Paper by Petra Bárd: "Forensic Genetics and Data Protection – A Central Eastern European Perspective" presented by Professor Renzo Pegoraro
September 24–26, 2009, Padova, Italy

2.6. MEDIA EVENTS

The Director and Fellows of CELAB took part in many media events contributing to the awareness-raising on current ethical dilemmas in the field of bio-medicine and had the opportunity to make CELAB more widely known in the media.

"Méltóság az élet végén"
[Dignity at the End of Life]
Round-table discussion series with the participation of László Bitó, Alaine Polcz, Miklós Beer, Margit Bulkai, Ferenc Fejtő, György Bárándy, József Böjte, Ferenc Kásler, László Lukács, Róbert Frenkl, Pál Gergyely, Ágnes Heller, Ferenc Oberfrank, Ferenc Glatz, Judit Sándor, Pál Tamás and Imre Wiener.
Duna TV (Television)
January 5, 12, 19, 26, and February 2, 2009.

"A genetikai tesztelés etikai kérdései"
[Ethical Questions in Genetic Screening]
Interview with József Kovács, reporter and editor: Dorottya Vizi
"Közelről" [Close-up] Program, MR1 Kossuth Radió (Radio)
February 4, 2009.

"Az eutanázia etikai kérdései"
[Ethical Questions of Euthanasia]

Interview with József Kovács
"Tények-vélemények" [Facts and Opinions] Program,
Klub Rádió (Radio)
February 13, 2009.

"A fogyatékosság etikai kérdései"
[The Ethical Questions of Disability]
Interview with József Kovács by Szilvia Bíró
"Szempont" [Point of view]
Program, MTV, m1 (Television)
February 19, 2009.

"Viták az agyhalál körül"
[Debates on Cerebral Death]
Interview with József Kovács by Anikó Köbli
Medical Tribune, 7(4): 1 and 8–9.
February 26, 2009.

"Genetikai szűrés a lombikban – hol a határ?"
[Genetic Screening in the Test Tube
– Where is the Limit?]
Interview with József Kovács
by János Nemes
Népszabadság (Daily)
April 14, 2009, p. 12.

"Az aktív és a passzív eutanáziáról"
[On the Active and Passive Euthanasia]
Interview with József Kovács,
reporter and editor: Ilona Mélykúti
Klub Rádió (Radio)
April 16, 2009.

"Molekuláris Tajgetosz:
veszélyesek a neten megosztott
egyéni genetikai adatok"
[Genetic Tests Sold on the Internet]
Written by Tamás Simon,
including a contribution from Judit Sándor
Origo (Online News Site)
June 14, 2009.

"Physicians and Medical Malpractice"
Talk Show, participant Violeta Beširević
"Uvećanje" Program, B92 TV, Belgrade
July 15, 2009.

"Criminal Investigation Related to Stem Cell
Therapy in Hungary"
Interview with Endre Czeizel, Judit Sándor
and Balázs Sarkadi,
reporter and editor: Judit Diós
MR1 Kossuth Radió (Radio)
July 29, 2009.

"Az emberen végzett kutatás etikai feltételei"
Interview with József Kovács by Mária Géczi
"Déli Krónika" Program, MR1,
Kossuth Rádió (Radio)
July 29, 2009.

"Kiszolgáltatottság kontra orvosi érdekeltség"
[Being at Someone's Mercy vs. Doctors' Interests]
Interview with József Kovács
by Anna Danó
Népszabadság (Daily)
July 30, 2009, p. 3.

"A reménység piaca: Az őssejt kutatás, a jog és az
etika" [The Market of Hope: Stem Cell Therapy,
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Written by Judit Sándor
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August 6, 2009, pp. 20–22.

2.7. PUBLICATIONS

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3. BUDGET

3.1. REVENUES IN AY 2008/09

Approved Budget from CEU for AY 2008/20009:	42,082 €
External Funding in AY 2008/2009:	241,378 €
• GeneBanC project:	89,852 €
• GeneBanC project overhead:	1,967 €
• RemediE project:	49,818 €
• Remedie project overhead:	15,774 €
• Nanoplat project:	54,883 €
• Nanoplat project overhead:	1,151 €
• Tiss.Eu project:	34,410 €
• Tiss.Eu project overhead:	523 €

3.2. SPENDING IN AY 2008/09

C-5036 CELAB main budget code

Budget category	Amount in Euro
Personnel	41,362
Web-page design	720
Total	42,082

C-8340 REMEDIE project

Budget category	Amount in Euro
Personnel	48,144
Other costs	1,674
Total	49,818

C-8239 GeneBanC project

Budget category	Amount in Euro
Personnel	75,509
Other costs	14,343
Total	89,852

C-8341 TISS.EU project

Budget category	Amount in Euro
Personnel	19,565
Other costs	14,845
Total	34,410

C-8336 NANOPLAT project

Budget category	Amount in Euro
Personnel	46,652
Other costs	8231
Total	54,883