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Legal Limitations on Genetic Research and the Commercialisation of its Results*

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1. Preliminary Remarks

About two years ago in a public discussion on precisely the subject of our debate a prominent French scientist rose and literally shouted at the audience: “All you have to do is to provide us with the means we need for our research. For the rest, it is solely our task and right to decide how to proceed.” And just a few months have passed since a study published in Great Britain by a group of scientists explicitly deplored the predicament generated by an obviously excessive and unbalanced reference to human rights and data protection. Moreover, the same study qualified requests for extensive information to be given to research subjects as a time-consuming, contra-productive fiction and pleaded for a new approach reviving “implied consent” as the one and only acceptable point of reference.¹ No doubt, statements equally clear but expressing a definitely contrasting position can also be readily found, such as, for instance, the repeated appeals to reject once and for all any direct or indirect attempt to legalise embryonic research and to underscore the ban by severe sanctions.

It is precisely these obviously different, not to say incompatible positions that are mirrored by most of the national reports and it is their particular merit to have given us such a vivid picture of the actual state of the debate. Therefore, I want first and foremost to thank the national reporters for their substantial contribution to our discussion. Let me however add a

* Session IB. National reports received from: Croatia, J. Mutabžija & I. Kunda; Denmark, M. Hartlev; Finland, L. Walin; France, F. Bellivier, L. Brunet, M.-A. Hermitte, C. Labrusse-Riou & Ch. Noiville; Germany, J. Taupitz; Greece, G. Koumantos; Italy, E. Resta; Japan, E. Maruyama; The Netherlands, M. H. M. Schellekens; Serbia, G. Vukadinović; UK, S. Millns; US, M. J. Malinowski & R. Rao.

¹ Report by J. Gillott, Genetic Interest Group, Human Rights, Privacy and Medical Research – Analysing UK Policy on Tissue and Data 3, 5, 13 (2006).

brief remark on my rather awkward situation. We are expected to deal with an unquestionably most complicated subject in an evidently far too short a time. Under these circumstances and in view of the equally limited time for my introductory remarks, you will certainly understand that I can neither try to bundle the national reports nor even attempt to present a general report covering every aspect of a definitely very intricate issue. All I can do is, first, address some of the most salient challenges, and, secondly, outline a few characteristic reactions.

2. Challenges

2.1.

None of the questions we face are “national”. They, in other words, do not address genuine national problems that reflect issues typical for a particular national context and therefore can only be dealt with within the frame of an equally national approach. What we are in fact confronted with are national reactions to a clearly international challenge: the growing possibilities to influence, to put it mildly and carefully, the probably most determinant element of a human being, its genetic constitution. Never before in the history of mankind have the odds been seemingly so favourable to eliminate deficiencies of the human organism as early as its creation and to efficiently combat later fatal risks mostly exemplified by illnesses such as Parkinson’s and Alzheimer’s, the apparently inevitable marks of a rapidly ageing society.

Consequently, it comes as no surprise that the constant advances in biosciences, such as, for instance, in the case of stem-cell research, question the very foundation of any legal reflection on the status of the individual, in the words of the European Union’s Charter of Fundamental Rights (Chapter 1, arts. 1 and 3), the duty to respect her or his dignity and to protect her or his integrity. Differences as far-reaching as those between the responses of the various national laws to the implications of biotechnology, conflicts as sharp as those over the research programme of the European Commission and the ensuing debates in the European Parliament, or the, to say the least, astonishing assumption that German scientists involved in embryonic research in Manchester and intending to pursue their activities in Frankfurt may be prosecuted for infringing criminal law, mirror the profound uncertainty caused by an increasingly quicker developing biotechnology.

2.2.

The dilemma shaping the actual discourse can best be described by three quite different examples:

2.2.1.

The first illustration may appear rather surprising. It refers to a by now well-established practice, acknowledged, though often only conditionally, by a large number of laws: in vitro fertilisation. Nothing fits apparently better into a concept that over centuries has dominated both the societal and legal perception of familial relations. Procreation was seen and treated as a natural and therefore indispensable feature of any family, as the long list of divorce or even annulment provisions and the many cases definitely transcending national frontiers show. Consequently, in vitro fertilisation was hailed as an antidote to childlessness, restoring womens' natural role and, lastly, also eliminating the difficulties and risks of adoption.

However, the short, but noticeably successful history of assisted procreation is equally a record of an ongoing radical review of the traditional family perception. The birth of children ceases to be a purely natural gift and becomes an increasingly solvable technical problem. Hence, the issue overshadowing all other questions is no longer how to cope with the impact of childlessness on both the individual and family life, but how to best comply with the wishes of potential parents. For precisely this reason, the American Gynaecological Society in an advertisement published in major newspapers assured all women over sixty that they would henceforth not have to renounce the birth of a child.

In vitro fertilisation initiates, in other words, a process in the course of which children are progressively perceived as a construct intended to respond to the conditions set by the particular circumstances of the procreation and the wishes of the potential parents. Therefore, the measure of success of artificial procreation is finally not the mere birth, but the characteristics of the child. As a result, in vitro fertilisation, as different as its motives and aims may be, inevitably paves the way for a selection process. It is nevertheless misleading, if not improper, to simply speak of "design babies". Such a description may be understandable whenever, in circumstances as those indicated in the *Haschmi* decision of the Court of Appeal,² the birth of "saviour siblings" is deliberately sought. The pre-implantation diagnosis, exemplifies however a procedure that surely is not part of a "design" process, at least in the term's generally accepted sense, but certainly promotes and conditions a choice. Their primary function – to help parents find out whether or not they should opt for assisted reproduction – necessarily entails a decision as to which embryos should be destroyed or cryoconserved. Moreover, since the birth of a genetically deficient or handicapped child can, thanks again to a pre-implantation diagnosis, be ascertained in time and thus prevented, potential parents are free to determine all further steps. Finally, rising health costs have either led, as in the case of insurance companies, to precautionary information being given

² R (Quintavalle) v. Human Fertilisation and Embryology Authority [2003] 2 FCR 193 (CA); R (Quintavalle) v. Human Fertilisation and Embryology Authority [2003] 2 All ER 105 (HC, Admin).

to potential parents as to the financial burden ensuing from the birth of genetically deficient children, or, as in a series of proposals in the United States, to the demand for an obligatory pre-implantation diagnosis.

Despite a growing readiness to consider “artificial” procreation as an adequate alternative to “natural” birth, its legal assessment still differs remarkably. “Artificial” procreation is to a large extent treated in precisely the same way as an equally non-natural parenthood, such as adoption, was dealt with. While “natural” procreation, as a rule, never presupposes a particular qualification, a thorough evaluation is, as is illustrated by the British experiences, widely expected in connection with “artificial” procreation. Thus, a “dubious” past may not inhibit procreation as long as it is “natural”, but will exclude, like in the case of adoption, an “artificial” production of children. Besides, whether or not the “naturally” born children of genetically deficient or handicapped persons are absolutely healthy is of no importance. However, if the same persons insist on a pre-implantation diagnosis in order to ensure that they have children with precisely the same deficiencies or handicaps as their parents, the reaction is nearly unanimously negative. In sum, the legality of artificial procreation may be increasingly confirmed. But the many, sometimes far-reaching conditions attached to its acceptance underline the high degree of reticence which remains concerning this treatment.

2.2.2.

My second example is the escalating proliferation of genetic information. Genetic data were for a long time thought to be purely medical items. Therefore, most Data Protection Authorities, and in particular the French Commission Informatique et Libertés, deliberately limited their considerations to medical aspects. Similarly, the 1995 Directive of the European Commission on the Protection of Personal Data³ did not list, because of the explicit reference to health data (art. 8), genetic information among the “sensitive data” the use of which is subject to distinctly restrictive conditions. However, as important genetic information for medical treatment or research may be, other purposes play an increasingly relevant role. Labour relations, insurance contracts, health policies and “papa tests” are some of the currently most discussed examples.

Employers have an indeed evident interest in genetic data related to both future and actual employees. This knowledge, in the employers’ view, permits them to calculate the risks of a labour contract more accurately, especially in the case of long-term employment. But, almost everywhere, legislators and courts have determined clear limits to the employers’ requests for information. The binding measure is the specific employment context. Therefore, questions

³ Directive 95/46/EC of the European Parliament and of the Council on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data, of 24 October 1995, OJ No. L 281, 23.11.1995.

concerning genetic data are only legitimate as long as the particular employment necessitates their awareness. Even then, access to such data must be restricted, as was stated, for instance, by the German National Ethics Council. Genetic information indicates, in the majority of cases, certain risks that will generally not occur (if at all) before the employees in question reach the age of fifty or even sixty. Employees are consequently only obliged to disclose genetic data if their implications already or imminently endanger the fulfilment of specific employment tasks. It is against this background that the International Labour Organisation has demanded that genetic screening should be either prohibited or limited to cases expressly mentioned by national law⁴ and thus it has also rejected all attempts to legitimise access to genetic information with the consent of the employees concerned.

Insurance companies have an equally outspoken interest in the genetic data of their future or actual customers. The decisive motive is once more a timely discovery and prevention of risks. Genetic information is in the insurers' opinion the key to a correct evaluation of financial consequences, especially in relation to life or health insurances. But, as with employers, the genetic data as such do not justify a particular treatment of the persons concerned. Whether it is appropriate and from when onwards depends on the age of the persons in question, their actual state of health and the usual course of the particular illness. Moreover, an uncritical acceptance of the insurers' expectations could seriously affect the possibilities of those threatened by genetic deficiencies to insure themselves, not to speak of the repercussions for the social security system. Especially the latter factor intensified the demands, in countries like Germany, for a law that would guarantee protection for the persons concerned and at the same time ensure adequate insurance conditions. Thus, one of the proposals foresees that higher contributions can only be demanded if the insurance policy exceeds a certain sum.

Reactions such as those by insurers are not unique. Genetic deficiencies and their consequences are an equally crucial cost-factor in the case of health and social security agencies. The result is increased pressure to collect and process genetic data nationwide. But in contrast to other similar attempts, the efforts of these agencies are also and mainly prototypical for the shift to clearly preventive policies. The data form the basis of measures intended to combat rising costs by changes in individual behaviour, thereby permitting such risks to be controlled and reduced.

The more the attention, both within or outside Government, focuses on prevention, the more the importance of supportive research is accentuated. A particularly characteristic concomitant is the establishment of biobanks. They may seldom be as broadly conceived as the British Biobank, but even when they concentrate on particular diseases, such as, for instance, Alzheimer's, the collection of genetic data is supplemented by detailed information

⁴ Protection of workers' personal data, ILO Code of practice (1996), art. 6.12.

especially on professional and family life, as well as on the individual experiences and habits of the persons affected. As a result, biobanks possess very complete personal profiles of a growing number of persons. Thus, what at first was conceived and regarded solely as a means of research, has progressively developed into an information source which may be used for purposes as different as insurance contracts, health policies and security activities.

2.2.3.

My third example is a study by the French Institut national de la santé et de la recherche médicale (Inserm) on the Behavioural Difficulties of Children and Juveniles published last autumn. Its main object is the diagnosis of latent aggressiveness in children up to three years of age and in embryos. The authors do not content themselves with an affirmative answer to the question of whether aggressiveness can already be identified in the embryonic stage. They recommend that the development of the embryo and, later on, the newborn child should be closely followed at least in the case of very young mothers, parents who are drug users or families with a criminal or psychiatric history. Signs of excessive motor movement, impulsive behaviour or a lack of empathy should also be meticulously registered and carefully evaluated, and, if necessary, this should trigger treatment combining psychotherapy and medication.

In a way, considerations such as these are reminiscent of earlier French attempts to complement medical reports on newborn children by making use of social reports or the more recent proposals by Scotland Yard to regularly observe the children of persons serving a long prison sentence in order to discern criminal tendencies in good time. And as in the case of the health sector the apparently strict “objectivity” of research incites and justifies long-term policies with far-reaching social consequences. In fact, security is next to health the most prominent example of demands and measures deliberately seeking to instrumentalise especially the advances in genetic research for a broad range of purposes ranging from identification to observation and prevention. The by now self-evident use of DNA or the growing utilisation of biometrics are the typical results of these efforts.

All in all, genetic data have ceased to be an information source more or less reserved for research purposes and have become a source of knowledge routinely exploited for very different aims. But every step in this direction also changes the background and the impact of research. Thus, for instance, embryonic research by now contributes in a double sense to the “making of man”. It fundamentally alters the circumstances of procreation and at the same time increasingly urges interventions restructuring individual behaviour. Consequences such as these explain the quest for rules covering the purposes of and the conditions for research

as well as the possible uses of its results. The already mentioned debates in the European Parliament or the proposals for the reform of French legislation concerning stem-cell research illustrate both the dimensions and the ambivalences of these expectancies.⁵

3. Reactions

3.1.

3.1.1.

Any regulation in the field of biosciences and especially biotechnology is subject, irrespective of the standpoint taken, to the reservation determined by increasingly rapid changes. Genetic research demonstrates day after day that achievements which only a short time ago were dismissed as foolish speculations have not only been realised but meanwhile surpassed. In reality, the experience with information and communication technology, marked by rapidly increasing progress from the huge databanks of the 1960s to the personal computers of the 1970s, the notebooks of the mid-1980s and the transformation of mobile telephones into an all-embracing information and communication means since the 1990s, is repeated.

However, this parallel not only applies to the remarkable speed of development. It equally underscores the experiences already evident with regard to information and communication technology: the unstoppable erosion of laws intended to restrict the processing of personal data and thus to protect the persons concerned against a limitless proliferation, commercialisation and instrumentalisation of their data. The continuous alteration of the technological context undermines the possibilities to implement existing regulations. Hence, the advances in biosciences subject all regulatory attempts, as in the case of information and communication technology, to an unrelenting review process.

Most legislators have nonetheless chosen not to question their traditional approach: laws should set timeless rules. There have certainly been exceptions. But they were generally restricted to provisions concerning temporary issues. In all other cases the sole reserve was the legislator's freedom to reconsider and decide anew at any time, irrespective of whether major codifications or merely responses to definitely less demanding issues were at stake. Therefore, the readiness to proceed in precisely the same way with regard to regulatory interventions related to biosciences and biotechnology seemed perfectly normal, all the more so since laws such as the 1990 German Act on the Protection of Embryos as well as similar regulations in Austria or Italy openly claim to affirm and protect basic constitutional principles.

⁵ See P.-L. Fagniez, *Cellules souches et choix éthiques*, Rapport au Premier Ministre (2006).

The need for a different perception has nevertheless not been ignored. There are at least two examples that illustrate the intention to take into account the constant evolution of biosciences and biotechnology and thus enable the law to adjust as quickly as possible. The first model, a deliberate combination of legislative demands and administrative interventions, has, for instance, been practised in Great Britain, Finland and France. Here the legislator's mostly rather vague demands are complemented by the establishment of one or more Authorities. As a result, the statutory regulation still provides the necessary framework, but a particular Agency oversees its interpretation and application. Consequently, the accent increasingly shifts towards a casuistic application, exemplified by the decisions of the Authorities or their constantly reviewed Codes of Practice. Each of these instruments has a double function. On the one hand, it determines, for instance, whether specific research can be carried out and, if so, under what conditions, and it nourishes, on the other hand, the hope that notably flexible reactions might help to better assimilate the implications of an evolving biotechnology.

However, controversies such as those surrounding pre-implantation diagnosis or therapeutic cloning also reveal the drawbacks of this model and its difficulties in fulfilling its intentions. Certainly, an "overhasty drafting which moral panics commonly provoke", to quote Dr. Millns' national report, may, as in Great Britain, have hindered a truly consistent application. But the final decisive handicap is a structural obstacle. Even a distinctly pragmatic and therefore predominantly casuistic response cannot change at will the interpretation of statutory provisions, especially where, like in the case of biotechnology, new achievements also have unprecedented consequences. A review of the prior provisions, as undertaken by the British 2001 regulation, does not end the debate. At best, it only bridges the time until a next reassessment becomes necessary.

The second model, promoted by regulations such as those in France and Japan, opts for a purely procedural approach. Thus, the 2004 review of the 1994 first French bioethics law added a provision authorising embryonic research, but only for a period of five years. In other words: the legislators combined their resolution allowing the research with an obligation to reexamine their actual position at an already fixed date. One can assume, as our French colleagues remark in their report, that a return to a negative attitude is indeed improbable. Nonetheless, provisions such as those in the French law of 2004 radically change the structure of the parliamentary debate on biotechnology issues. The decisions taken are no longer final reactions, but elements of an ongoing discussion. Parliament does not desist, for an unlimited time, from further considerations. On the contrary, it engages in a continuous debate against the background of the evolution of biosciences and biotechnology.

Already in the 1990s the Norwegian Parliament, in order to ensure that it can intervene both in good time and adequately in the case of information and communication technology,

persuaded the Norwegian legislator to similarly link the adoption of the data protection law to an acknowledgment of the need to rediscuss it after a clearly predetermined period. Apprehensions, as those expressed in the German Parliament, that such provisions could be used as a pretext to bypass or even abandon the leading principles contained in certain regulations neither hindered the French or Japanese legislator in opting for a specific time-limit in connection with their demands concerning biosciences, nor did they deter a growing number of Parliaments from following the example of the Norwegian data protection model, even if in certain sectors only, such as, for instance, telecommunications. A convincing legitimisation of both the guiding principles and the rules which crystallize them depends not the least on their ability to successfully confront the advances in technology and their potential consequences.

The 2002 Dutch Embryo Act also sets a time-limit, though in a rather peculiar way. The Act categorically forbids the creation of embryos for scientific research or purposes other than bringing about pregnancy, but simultaneously empowers the Government to end this prohibition by means of a decree. However, the Government's plan must be discussed in Parliament and announced before September 1, 2007. Hence, the time-limit does not initiate a critical review of an existing regulation without prejudicing its outcome. What the Dutch provision intends is, as our Dutch colleague, Dr. Schellekens, stresses in his report, to ensure a prior debate in Parliament, irrespective of the Government's right to alter the conditions for embryonic research. Consequently, the Dutch regulation cannot be compared with the limitations in France or Japan. The readiness to follow and evaluate the development of biotechnology may in both cases be evident. Nonetheless, the Dutch reaction only amounts to a belated acceptance of a decision on embryonic research which was initially postponed.

3.1.2.

Comments on legislative techniques inevitably analyse and evaluate the instruments of national legislators. However, both the range and the form of their interference decisively depends, as far as Member States of the European Union are concerned, on the competences and activities of the European Commission. Its interest in biosciences and biotechnology is manifest. The Commission's research programmes have repeatedly emphasised the importance of this particular field, also with regard to the European Community's competitive power, and have consequently expressly encouraged and supported research.

However, experience shows that the conflicts caused by the European Commission's policies in the research sector as well as by the no less passionate controversies surrounding the patenting of human genes are lastly the preliminary stage of Community-wide rules on biosciences and biotechnology. And, indeed, if the capacity of the European Union to

implement its repeatedly acknowledged common values and thus to safeguard its credibility is not confirmed in a field which is as socially and politically crucial as this, then answers to questions such as those on the premisses of embryonic research or the conditions determining access to genetic data and the limits to their use can no longer be left to manifestly deeply-divided national legislators.

Directives of the European Commission, in contrast to any international agreement, have an immediate effect. They displace national regulations and substitute them with rules adopted by the European Union. However, as far-reaching as its regulatory powers are, the European Commission can neither ignore national debates on the risks caused by a direct or indirect instrumentalisation of human beings for research purposes or an equally indirect or direct commercialisation of their genetic data, nor disregard the national experiences with an obviously obsolete and therefore ineffective legislative technique. Its explicitly acknowledged duty to ensure that all its decisions are compatible with the European Union's Charter of Human Rights and its obvious interest in the efficacy of the measures taken imply a decision process which is determined by both aspects. Only then can doubts such as those expressed in the Netherlands with regard to the rigidity of European regulations be convincingly rebutted.

3.2.

Research in the genetics field, just like any other research activity, is governed and covered by the researchers' fundamental right to freely define the object, the scope and the means of their research. Biosciences are nevertheless also one of the most impressive examples of the need to ensure both the transparency of research and a timely knowledge of its potential consequences. Society can neither tolerate experiments with human beings in the name of research nor ignore the implications of research directly or indirectly devoted to eugenics. Statements such as those in the 1947 Nuremberg Code, the Council of Europe's Convention on Human Rights and Biomedicine⁶ and the Helsinki Declaration⁷ certainly do not by now mirror an increasingly irrelevant past, all the more so since the prohibition of eugenic practices has been explicitly reiterated and confirmed by the European Union's Charter of Fundamental Rights (Chapter 1, art. 3).

However, censorship is equally inadmissible. Prohibitions such as those in the Charter do not provide *carte blanche* for *ad lib* interventions. The alternative in these circumstances, is as also stressed in particular by the Finnish and Italian national reports, a broad public debate

⁶ Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, Oviedo, 4 April 1994, European Treaty Series No. 164.

⁷ World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, first adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and last amended by the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000, with a Note of Clarification on Paragraph 29 added by the WMA General Assembly, Washington 2002.

ensuring not only the transparency of research but also an intensive exchange of views on its impact. The establishment of National Ethics Commissions or other similar Committees reflects precisely this expectation. Hence, both the French and the German Commissions have primarily a double task: to comment, especially at the request of the national Parliaments and Governments, on regulatory intentions, and to initiate and maintain a public debate on the actual state of and potential developments in biosciences. The already mentioned attempts to arrange a continuous parliamentary debate by providing a binding time-limit for reviewing regulations concerning biotechnology are thus complemented by an equally uninterrupted public discussion. The social and legal framework of research is in other words redesigned. Respecting the researchers' freedom to determine the object and the means of the research has its price: involvement in a public debate which always allows the public at large to be aware of the social and political repercussions of their work.

The importance of a public discussion animated by the opinions of the National Ethics Councils is exemplified by the experiences with regard to stem-cell research or "therapeutic" cloning. In both cases the need for a broader approach, terminating in evidently one-sided support for research projects exclusively concentrating on the use of embryos and assisting the search for alternative means was extensively argued. And it is again the National Ethics Commissions, as the statements of the French Commission especially demonstrate, that have warned against an equally one-sided substitution of embryonic stem-cells by adult stem-cells and emphasised the need to thoroughly examine the possibilities and limits of a carefully differentiated use of stem-cells, a demand corroborated most recently by the research results of the *Schoeler* team at the University of Munster. But each of these public debates has also affirmed that Committees such as the National Ethics Commissions can only fulfil their tasks if their independence is unconditionally acknowledged and they do not therefore run the risk of being regarded as a mere antechamber of Parliament or an expert group confined to answering questions put by third parties.

A different, but no less important limit on researchers' freedom to determine the object and means of their research has been illustrated by the experiences with biobanks. The legitimate expectation to extend the collection and processing of personal data to information clearly transcending both the genetic and the medical field permits, as mentioned, extremely refined and therefore rather unique profiles of the persons concerned to be set up. Consequently, biobanks may have a distinct purpose that explains and justifies their claim to the information they store, but the data they dispose of are, as was also indicated, of eminent interest to a growing number of parties. Hence, access to the data cannot only depend on their relevance for the specific research. It must, on the contrary, equally be determined by the reliable exclusion of this data as far as aims other than research are concerned. As long as this

condition is not satisfied, the researchers' access to the data is in conflict with one of the most elementary requests in data protection –restricting the use of the data to purposes unequivocally defined in advance – and must therefore not be permitted.

It is certainly correct that data protection laws, despite their readiness to guarantee a strictly purpose-bound use of personal data, did finally admit regularly renewed exceptions intended, in particular, to protect the “public interest”, to safeguard the “public” or “state security”, or to “prevent, detect and prosecute criminal offences”. Each of these provisions, deliberately phrased in an extremely abstract way, is literally predestined to be invoked whenever personal profiles such as those stored in biobanks provide a truly “ideal” information for aims as different as the realisation of cost-cutting health policies, or a long-term reduction of criminal activities. For exactly this reason, the German National Ethics Council proposed to complement the data protection statutes with a “research-secret” that would unequivocally reduce the use of the data to purely research purposes and opposed the establishment of new biobanks as long as the necessary legislative measures to acknowledge such a “secret” are not in place.

3.3.

A few closing remarks on a mostly rather reluctantly discussed subject: the commercialisation of research. The signs of its impact can hardly be overlooked. Thus, the systematic collection of genetic data in Iceland relied on substantive support from the pharmaceutical industry. Similarly, universities in a growing number of countries are by now either closely cooperating with private firms especially interested in medical products to treat diseases with high incidence rates, or progressively establish non-profit corporations and create foundations in order to financially benefit from research activities in biosciences. Biopatents are, as particularly the report of our American colleagues Professors Malinowski and Rao⁸ shows, another no less significant sign of expanding commercialisation. Attempts such as the intensive effort to secure the admissibility of gene patents do not simply mirror the typical concerns of specific parts of the industry. Biopatents were and still are also a strong incentive for many researchers. And as in the case of industry, an intentionally broad application of patents reflects the interest in profiting as much and as long as possible from the research results by a clearly strategic patent, a habit which has been strongly criticised by the German National Ethics Council. Results such as those of a study published in March 2005 in *Science* demonstrating that nearly three-quarters of the patents examined contained problematic claims,⁹ confirm precisely this tendency.

⁸ 54 *American Journal of Comparative Law* 2701, 2703 *et seq.* (2006).

⁹ J. Paradise, L. Andrews & T. Holbrook, *Patents on Human Genes: An Analysis of Scope and Claims*, 307 *Science* 1566 (2005).

An increasing commercialisation may, as illustrated by the frantic race for the \$1000 genome, offer considerable economic advantages to both the researchers and their academic institutions. But it also affects the structure of as well as the conditions for research. The potential uses prove more and more to be the lastly decisive criterion for the research objectives. A university that assigns research to non-profit entities inevitably modifies its perception of the various research projects and their evaluation. Besides, once the accent is placed on the applications of the research and consequently on its profitability, researchers increasingly tend to shift their activities to private firms set up by themselves and therefore totally devoted to their own ambitions and expectations.

Biopatents establish, finally, a monopoly that empowers their owners to determine all the uses of the research results for the immediate future. Further developments, especially in fields as critical as the treatment and prevention of diseases, may thus be hindered. Many patent laws therefore contain, in contrast to for instance US legislation, a research clause allowing the use of patented findings for research purposes without authorisation from the patent owner. Furthermore, experience shows that biopatents not only reduce the communication between researchers and thus impede scientific discourse, but also induce their owners to organise access to their findings so as to enable them to closely follow and control all subsequent uses. However, the more the effects of a legally guaranteed monopoly are realised, the more the claim for compulsory licences is intensified. They counterbalance the negative consequences of patents and should therefore, as for example demanded in the Netherlands or by the German National Ethics Council, be systematically granted especially in the genetics field.

Commercialisation also has consequences for persons being tested. Consent plays a role which is probably more important than ever before. It already helps to bypass barriers such as those established by data protection laws, as stereotyped consent forms demonstrate. Moreover, where, as in the case of genetic research, the interest focuses on data generally considered to be sensitive, consent is an indeed ideal means of access. The readiness of test-persons to provide every bit of information requested eliminates all objections. It is their will that not only guarantees virtually unlimited access, but also best shields researchers from doubts and criticism.

However, a highly formalised consent more then ever raises the question of whether the persons concerned are, particularly in the case of minors and other incapable persons, really given an opportunity to understand both the background and the purposes of the research. The mere reference to the consent of parents or guardians distracts from the need to secure the participation of the persons concerned. Therefore, instead of insisting on a procedure that ignores them, researchers must, as some of the National Ethics Committees have explicitly demanded, adapt their language as well as their ways of communication to the specific

situation of minors and incapable persons and thus secure a genuine reaction. Consequently, consent should be deformed and the communication methods redefined in accordance with the specific features of the context in which the cooperation of the persons affected is sought.

Finally, where, as in the case of data protection, the primary objective of all regulations is to ensure the respect of the persons concerned and hence to prevent any attempt to transform them into mere objects for the researchers' plans and activities, a thorough review of the modalities of consent is not sufficient. The still widely used national and international provisions that openly bypass the need to demand consent and which legitimise research as long as a particular interest or special advantages for a concrete group of children can be confirmed, instrumentalise once more the persons affected and infringe their integrity. Procedures that lastly confer upon researchers the privilege of deciding internally whether these conditions have been fulfilled do not have a sufficient corrective function. Here, as elsewhere, legislators must strive for criteria which are as context-oriented as possible and pave the way for a public discussion on the purposes as well as the potential effects of research.

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