5th International Focus Programme Essay Competition
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Biotechnology and health care

Regulation, limits, controversies

Motto: *"Man's mind, once stretched by a new idea,*
never regains its original dimensions."[1]

Introduction

Biotechnology[2] is considered to be one of the greatest technological breakthroughs for this new millennium.[3] Embedded in this professed rush to make law to meet the emergency of technology, there is a tendency to claims of uniqueness or newness. The emergent technology is cast as a novel situation which calls for law in an original sense, a need for new law to meet the radical newness of technology.[4] This social science of regenerative medicine is mainly governed by law and bioethics, norms which establish the boundaries of human activities and social interactions following socially recognised value-based considerations.[5]

In biomedicine, law is responsible for translating into binding rules social and policy expectations of progress and innovation, the demands of commercial stakeholders in the "*bioeconomy*", the concerns relating to risk and hazard in human interference with biological matter, and in particular, the boundaries of human activity in biosciences as indicated in bioethics. These rules may contain prohibitions and threaten the breach of those prohibitions with sanctions, require human activities to be licensed, screened, monitored, and reviewed, indicate how the market may penetrate into scientific activity and how scientific activity may benefit from the existence of a market, offer incentives for scientific progress, and generally, provide a clear and predictable framework for actors and stakeholders. A potential shortcoming of law and the legal process is that its coverage may not be comprehensive and may lag behind scientific developments.[6] While all new technologies are received in the moment as new, they soon become mundane, both in everyday life and in institutional responses. Legal forms and legal institutions routinely transform popular worry about a technology into law and regulatory structures.[7] However, law may fail to offer a normative solution for novel scientific and technological developments, or may focus on technologies rendered outdated by new advances in science and technology. Law may also struggle with translating permeable and moving boundaries negotiated extra-legally and with accommodating a plurality of non-exclusive viewpoints on what constitutes good (ethically acceptable) and bad development.[8]

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[1] Oliver Wendell Holmes;

[2] Broadly defined in Article 2 from the Convention on Biological Diversity as "*any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.*";

[3] Francesco Francioni, "Genetic Resources, Biotechnology and Human Rights: The International Legal Framework", *EUI Working papers*, Law No. 2006/7, p. 1;

[4] Barton Beebe, "Law's Empire and the Final Frontier: Legalizing the Future in the Earlyorpus Juris Spatialis", *108 Yale Law Journal* 1737, 1999;

[5] Marton Varju, Judit Sandor, "The Multiplicity of Norms: the Bioethics and Law of Stem Cell Patents", June 2012, p. 2;

[6] Marton Varju, Judit Sandor, "The Multiplicity of Norms: the Bioethics and Law of Stem Cell Patents", June 2012, p. 2;

[7] Kieran Tranter, "Biotechnology, Media and Law-Making: Lessons from the Cloning AND Stem Cell Controversy in Australia 1997-2002", 2010, p.2;

[8] Idem 9, p.2;

As scientists "*remake Eden and play God*"[9], much legal and ethical analysis has already been written on the subject and much writing remains, yet this paper will focus mainly on the legal concerns and challenges focusing on human rights in health care. Therefore, in addressing these premises, the information is structured in three parts: the first one identifies the general, relevant regulations in this field, the second one analyses only the incidence of human rights while the last part is more specific, describing the global standards for the patenting of biotechnological inventions and the controversies that may arise in practice.

Relevant regulations

A closer relationship between the development of biotechnology and human rights can be found in a number of international instruments adopted in the last fifteen years in the field of biotechnology applied to human genetic resources.[10] The apparent success of international and regional human rights instruments, such as the Universal Declaration of Human Rights and the European Convention on Human Rights, fuelled an agenda aiming to secure the benefits of international human rights law for bioethics, to "*subsume*" bioethics to the advanced legal, political and governance framework of the international human rights community.[11]

This global context of high interdependence plus great inequalities means that international efforts to control biotechnology are a vital supplement to efforts at local, national and regional levels. UNESCO has been at the forefront of an ambitious programme aimed at setting legal and ethical standards applicable to the human genome, expressing a clear intention to "*unite these two streams*" and "*establish the conformity of bioethics with international human rights law*".[12] The results of this programme are, for the time being, four important soft law instruments: the 1997 *Universal Declaration on the Human Genome and Human Rights* (UDHG), the 1999 *Guidelines for the Implementation of such Declaration*, and the 2003 *International Declaration on Genetic Data* and the 2005 *Universal Declaration on Bioethics and Human Rights* (UDBHR). The UN General Assembly endorsed the UDHG in 1998 and in the past three years has been engaged in the negotiation of a new convention designed to restrict human cloning. At the regional level, the Council of Europe has, since 1997, adopted a variety of legal instruments setting ethical standards in the field of biomedicine and biomedical research, including the *Oviedo convention on human rights and biomedicine, the additional protocol on the prohibition of human cloning*, the 2002 *Additional Protocol on transplantation of organs and tissues of human origin*, and the 2005 *Additional Protocol on biomedical research.*

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[9] The President's Council On Bioethics, Beyond Therapy: Biotechnology And The Pursuit Of Happiness, 1-2, 2003, available at http://bioethics.georgetown.edu/pcbe/reports/beyondtherapy/chapter1.html#section7, last visited on 22 February 2013;

[10] Francesco Francioni, "Genetic Resources, Biotechnology and Human Rights: The International Legal Framework", *EUI Working papers,* Law No. 2006/7, p. 3;

[11] Faunce, Thomas, "Will International Human Rights Subsume Medical Ethics? Intersections in the UNESCO Universal Bioethics Declaration", *Journal of Medical Ethics*, 2005, 32: 173-178.

[12]UNESCO: *Universal Declaration on Bioethics and Human Rights* 2005, paragraph 12, available at http://unesdoc.unesco.org/images/0013/001390/139024e.pdf, last visited on 22 February 2013;

A database with the specific and most significant regulations in biotechnology can be found in the Genomic Monitor[13], a study which not only identifies them but also analyses the entire legal frame. The conclusion was that most of them have a different historical background, few common principles, don't share a single international organisation, there is a lack of clarity over which rules are applicable, "*which leads to uncertainty over rights and obligations, and affects predictability as states are uncertain which rules others will apply*"[14], lack of awareness of the full range of rules, the problem of duplication of provisions, different dispute settlement mechanisms, all of these creating a problem in means that a "*key part of the control of the biotechnology revolution is significantly flawed at the present time and this is something which the international community urgently needs to address*"[15].

Human rights: the limits of biotechnology?

Human rights reside in the fact that obligations are not reciprocal, like most classic customary international law obligations, they are integral owed to the international community as a whole, operating "*erga omnes"*. Thus, the assumption that any State has an interest in the respect of basic human rights as a matter of international public policy has contributed to the "*constitutionalization*" of a core of fundamental human rights norms in terms of "*jus cogens"*, endowed with inherent normative strength so that no single state may dispose of them at will. In this respect, Francesco Francioni considers *"jus cogens"* the most powerful legal tool to support supports the concept of "*international community*", as a collective entity that transcends the sovereignty of states, encompassing them *"uti universi"*. [16]

In assessing the impact of human rights on biotechnology, I will consider the following rights: human dignity, non-discrimination, self-determination, rights pertaining to the human body such as life, integrity and health, economic and social rights, including intellectual property rights and sustainable development.

Human dignity[17] is the broadest human right concept invoked in the context of biotechnology. As an ethical justification, it may support the legitimacy of cutting edge scientific research in the field of medicine and genetic therapy for hereditary or otherwise incurable diseases, and generally in promoting participation in scientific progress consistent with Article 27 paragraph 1 of the Universal Declaration of Human Rights. The potential benefits of such progress, especially for people who suffer, or may be born suffering, from severe diseases and disabilities of a genetic nature constitute a powerful ethical and human rights argument to counter-balance the cultural or religious objections of those who are opposed to playing with a matter of life or the design of

[13]As identified in the Genomics Monitor, written by Catherine Rhodes, November 2006, available at: http://www.brad.ac.uk/acad/sbtwc/gateway/monitor/genomicsmonitorissue1.pdf, last visited on 22 February 2013;

[14] Idem 14, p. 10, where it is given as an example the therapeutic human cloning, which appears to be permitted under the Universal Declaration on the Human Genome and Human Rights, but not in the United Nations Declaration on Human Cloning;

[15] Idem 14, p. 11;

[16] Francesco Francioni, "Genetic Resources, Biotechnology and Human Rights: The International Legal Framework", *EUI Working papers*, Law No. 2006/7, p.12;

[17] The 1948 Universal Declaration refers to it in the Preamble as "… *the foundation of freedom, justice and peace in the world*" and incorporates it in Article 1, which states that *"… human beings are born free and equal in dignity and rights*".

nature.[18] Similarly, in the field of agriculture, respect and protection of human dignity can be an important factor in adopting a policy favourable to the introduction of genetically modified crops or the distribution of genetically modified food when this represents the most effective way to deal with situations of severe poverty, famine or malnutrition that endanger the dignity, subsistence and the very life of people.

In particular, respect for human dignity entails that biotechnological applications in the field of medicine shall: 1) respect the uniqueness and diversity of human beings and, accordingly, avoid a reduction of individuals to their genetic characteristics; 2) respect the free and informed consent of interested persons, in accordance with the modalities established by law; 3) avoid eugenic practices, especially those aimed at the selection of human beings; 4) be based upon the principle that the human genome and parts of the human body may not be disposed of for monetary gain; and, 5) shall conform to the basic prohibition of reproductive human cloning.[19]

The problem is that the standards continue to diverge, thus, it is very important to consider the national legislation. Some relevant examples concern the lack of consensus on questions like: Where human life begins? Whether embryos are protected under the principle of human dignity? Whose consent should be considered?. These questions are important in regulating abortion, genetic manipulation, embryonic stem – cell research and human cloning. Nowadays, doctors can also inject replications of certain genes in order to predetermine some traits. Would it be fair to interfere in such way?! DNA may provide information regarding a person's life and health potentials. Who should have access to this information and under what conditions and restrictions. Who should make the initial decision for testing?[20]

In Vo[21] the Strasbourg court, echoing an earlier decision that found no evidence that the parties to the ECHR had agreed to a particular solution regarding the right of an unborn child to life (Bruegemann), declared that the question from what point in the biological existence of humans the right to life begins belongs to the discretion of individual Contracting States[22]. In the same vein, while the "*potentiality"* of human embryos and their "*capacity to become a person*" was recognised under the right of respect for human dignity, recognising a full moral status of human embryos was deferred to the jurisdiction of individual Contracting States[23]. The lack of a "*clear common ground among the Member States"* prevents the European Court from imposing European boundaries in areas characterised by "*fast moving medical and scientific developments*"[24].
Another important human right with great impact on biotechnology is *non – discrimination*. One of the positive consequences, in moral and social terms, of genetic science, and in particular of the Human Genome Diversity Project (HGDP), is the production of scientific evidence that there is

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[18] Campiglio , "Human Genetics, Reproductive Technology and Fundamental Rights", *XIV Italian Yearbook Int*., 2005, p. 83.
[19] Francesco Francioni, Genetic Resources, " Biotechnology and Human Rights: The International Legal Framework", *EUI Working papers*, Law No. 2006/7, p. 14;
[20] Marion Hilligan, Nelson P. Miller, Don Petersen and Chris Hastings, "Superhuman – Biotechnology's Emerging Impact on Law", *Thomas M. Cooley Law Review*, Vol. 24, No. 1, 2007, p. 17;
[21] ECtHR: Vo v. France, App. 53924/00, 08/07/2004, ECHR 2004-VIII, paras. 83-85;
[22] ECommHR: Brueggemann and Scheuten v. Germany, 1981, 3 EHRR 244.;
[23] ECtHR: Evans v. UK, App. 6339/05, 10/04/2007, paras. 54 and 56;.
[24] ECtHR: S.H. and Others v. Austria, App. 57813/00, paras. 68. 69, 74;

no biological basis for the concept of "*race*" and that persons belonging to the same racial - ethnic group may indeed have a more diverse genetic patrimony than people who may be profiled as belonging to different racial groups.[25]

In practice, this principle played an important role European Patent Office, where there was an example of race utilization in patent specification. Myriad Genetic claimed a patent relating to a gene probe "*for diagnosing a predisposition to breast cancer in Ashkenazi Jewish women*". The relevant gene mutation related to ovarian and breast cancer and was found to be prevalent in Ashekenazi Jewish population in the order of 1% as compared to 0.1% of the general population. The European Society of Human Genetics strongly opposed diagnostic targeting of a racial group in a gene patent application. In particular, it argued that genetically discriminating considerations are contrary to public morality. The European Patent Office decided to up-hold the patent in amended form, stating that it "*relates to use of a particular nucleid acid carrying a mutation of the BRCA 2-gene, which is associated with a predisposition to breast cancer for in vitro diagnostic of such predisposition in Ashkenazi Jewish women*". Belgian geneticist Professor Gert Matthijs commented that *"there is something fundamentally wrong if one ethnic group can be singled out by patenting*", adding "*women coming to be tested for breast cancer will have to be asked whether they are Ashkenazi Jewish or not*", though, the Myriad patent amounts to "*discrimination*", and is also impractical, since many people of Ashkenazi descent don't know their ancestry.[26]

But the area where the risk of discrimination on a genetic basis is the highest and most disturbing is that of insurance and employment. The following questions arise: 1) whether insurers and employers may be allowed to require genetic tests as a condition of insurance or employment; 2) whether insurers or employers may require disclosure of prior genetic tests by the applicant; and 3) whether insurers or employers may give weight for business purposes to genetic information voluntarily provided by applicants. Prima facie, the answer to these questions appears to be negative in the light of the norms contained in universal and regional instruments on bioethics. For example, Article 11 of the Council of Europe Convention on Biomedicine stipulates that "*any form of discrimination against a person on grounds of his or her genetic heritage is prohibited*".[27]

Self – determination, originally conceived as the right of people to accede to self – government translates into biotechnology as the sovereign right of all people to freely pursue economic, social and cultural development, including biogenetic resources within their territorial jurisdiction. This right also entitles States to pursue economic policies aiming at protecting their population against the damaging impacts and unwanted risks of biotechnology applications.[28]
In an experiment on cell lines, the respect for human dignity, a right to personal integrity, and the individual and collective right to maintain control over genetic heritage, were challenged because when taking of human tissues from a small and fairly remote tribe of indigenous people from Papua New Guinea, in order to study their unique characteristics and their possible application in

[25] Francesco Francioni, "Genetic Resources, Biotechnology and Human Rights: The International Legal Framework", *EUI Working papers*, Law No. 2006/7, p. 14;
[26]"Slimmed down breast cancer gene patent upheld", June 2005, available at http://www.bionews.org.uk/page_12415.asp, last visited on 22 February 2013;
[27] Idem 29, p.15;
[28]Idem 29, p.18;

the early detection and eventual cure of adult leukaemia and other degenerative disorders, they didn't asked for their consent in order to make the DNA experimentation.[29] On this matter, the Declaration carefully balances freedom of scientific research against the need to safeguard human rights and the general interest of humanity against possible abuses. Besides proclaiming the human genome "*the heritage of humanity*", the declaration establishes, in Article 5, that research, treatment or diagnosis affecting a person's genome must be undertaken only on the basis of *"… the prior, free and informed consent of the person concerned*". More important, the same article provides that when *"… a person does not have the capacity to consent, research affecting his or her genome may be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law*"[30]. This formulation leaves ample margin of appreciation for national law-makers to decide when and under what specific conditions research and technological applications affecting someone's genome are permissible.

Controversies regarding patent law

Patent law is a traditionally ethically "*sterile*" area of law where the main function is to channel the innovation to the market.[31] Related to biotechnology, controversies arise as it deals not only with legal and technical questions, but relates even more strongly to ethical and societal issues.

The key international standards with regard to patents were established by the *Trade-Related Aspects of International Property Rights* (TRIPS Agreement)[32], which introduced a worldwide framework of minimum standards with regard to the grant, scope and use of patent rights.[33] However, as these regulations are very broad, countries have the flexibility to limit what constitutes patentable subject matter. US patent law remained faithful to its purposes stated in the US Constitution, that of securing the successful commercialisation of inventions. Patent laws in the biotechnology powerhouses of Asia recognise that the patent system may be closed for inventions on public morality grounds[34], there is not much indication that the public morality clause would incorporate the boundaries established in bioethics and that it would be applied to exclude from patentability inventions consisting of or containing human biological material.

The European Union Directive 98/44/EC it is considered to be the most comprehensive incorporation of ethical principles relating to the treatment of the human body and human

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[29]"The Human Genome Diversity project", *GenEthics News*, issue 10, available at http://www.hgalert.org/topics/personalInfo/hgdp.htm, last visited on 22 February 2013;

[30] Universal Declaration on the Human Genome and Human Rights, Article 5, available at http://portal.unesco.org/en/ev.php-URL_ID=13177&URL_DO=DO_TOPIC&URL_SECTION=201.html, last visited on 22 February 2013;

[31] Marton Varju, Judith Sandor, "The Multiplicity of Norms: the Bioethics and Law of Stem Cell Patents, The Global Dynamics Of Regenerative Medicine: A Social Science Critique", A. Webster, ed., Palgrave, 2012;

[32] The provisions relating to patents are put forward in Articles 27-34 of TRIPS. The general principle is laid down in Artile 27(1), which provides that patents should be available for any invention, whether products and processes, in all fields of technology, provided that there are new, involve an inventive step and are capable of industrial application. TRIPS stresses that patents shall be available, and patent rights enjoyable without discrimination as to the place of invention, the field of technology, and whether products are imported or locally produced.

[33]Daniel Wüger, Thomas Cottier, "Genetic Engineering and The World Trade System", *Cambridge University Press*, 2008, p. 77;

[34]Article 5 of Patent Act in China, Article 3b of the Patent Act 1970 in India, Article 32 of the South Korean Patent Act and Article 32 of the Patent Act 1959 in Japan.

biological material as objects of utility and of commercial relevance by the patent system. The Directive posits that neither the human body at the various stages of its formation and development, nor the simple discovery of one if its elements including the sequence or partial sequence of a gene, can constitute a patentable invention, whereas an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.[35]

However, with all these international efforts in coordinating the patents in the biotechnology domain, serious issues arise in connection with the access to health care. A relevant and controversial example is also the case of *Myriad Genetics*, mentioned previously. The company obtained several European and US patents for the screening of breast cancer genes, but licensed the test exclusively to a limited number of commercial genetic laboratories within specific geographical regions. This highly restrictive licensing policy gave rise to a strong and worldwide reaction and triggered the contemplation of measures for preventing highly restrictive exercise of patent rights. In order to reduce any potential harmful effects of bio-patents and unreasonable behaviour of patent holders, Belgium introduced a compulsory license for public health and France established an ex-officio license to supply the domestic market and some other states are debating the introduction of a compulsory licence system.[36]

Conclusions

As seen from above, in the global context of high interdependence and great inequalities means, the regulation in this domains is inconsistent, there is a lack of clarity over which rules are applicable, lack of awareness of the full range of rules, a duplication of provisions, different dispute settlement mechanisms and this may affect the health care systems. Biotechnology companies may speculate these inconsistencies, choose to *"treaty shop"* and to locate to the jurisdictions with the most favourable legislation for their research purposes. All these may affect human rights, as access to medicines and health care.

This domain implicates the full spectrum of human issues, from personal health to familial and social relationships to national and world demographics, and it will force a choice among distinct worldviews that many of us are not prepared to make.[37] Sovereignty may be at stake but so is what it means to be human.

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[35]The European Union Directive 98/44/EC, Article 5(1)(2);

[36]Geertrui Van Overwalle, Biotechnology and Patents: Global Standards, European Approaches and National Accents, 2008, p. 105;

[37] Marion Hilligan, Nelson P. Miller, Don Petersen and Chris Hastings, "Superhuman – Biotechnology's Emerging Impact on Law", *Thomas M. Cooley Law Review*, Vol. 24, No. 1, 2007, p.1;