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Patenting Related to Human Genetic Engineering and Eugenics: An Analysis of European Patent Law and Normative Policies

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Abstract

Humanity has been under serious threat in some way or the other in some point in history. Many a time, it has been man's own inventions that have wronged human beings. Progress in technology and a better understanding of science is a dangerous tool if it falls into the hands of those holding malicious intent or is subjected to wrong institutional policies fueled by bigotry and discrimination. In this respect, from biological science and genetic traits to insight into nature's most intrinsic molecule, the DNA, have all been prone to abuse by those with a eugenic mindset. The dark side of eugenics has evidently plagued humanity since the progress of biological science unlocked deeper insights into the study of genetics. The fact that certain individual characteristics are inheritable in families makes their division into 'good traits' and 'bad traits' inevitable. Under such conditions, the credibility of a patenting regime weighs heavily on the policy-makers, lawmakers, and European patenting authorities to ensure harmonizing the patent practices with European values and normative approach.

Key words: Eugenic, genome editing, GMOs, Gene Patenting, Bioethics, genetic apartheid, racial discrimination, *reproductive and genetic technologies*, genetic diversity

Introduction

Patent is the key to innovation and a tool to protect the intellectual property rights in any invention, granted for either novel products or processes. With the advent of genetic engineering biological technology has taken a revolutionary turn, unfolding new vistas of scientific advances

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in synthetic biology. Simultaneously, the leap forward in new technologies has generated a controversial debate surrounding bioethical issues. One such issue is that of *eugenics* literally meaning 'good birth', which is defined in Cambridge Dictionary as: "The idea that it is possible to improve humans by allowing only some people to produce children." The concept is to improve humans genetically and is carried out via the process of reproduction, having both positive and negative aspects. The former is aimed at reducing the transfer of undesirable genes; say inheritable diseases from parents to off-springs by promoting reproduction among those with healthy genes. Also, it is associated with free consent, respecting pluralist values, non-discrimination, and scientific awareness of genetics for the sake of good births. Measures taken by governments may be family planning, tax incentives, family allowances, and child care to promote positive eugenics. Negative eugenics is, however, a venomous notion to block persons with undesirable traits from breeding, perceived as being unfit to reproduce,[1] in order to enhance the chances of desirable transmittable hereditary traits in a population. Negative eugenicists are thus characterized by discriminatory practices. Thus, the skeptics of eugenics are construing the patenting of human genetic engineering technologies such as recombinant DNA, genetic screening, and genome editing (or gene editing) as a potential weapon in the hands of neo-eugenic exponents. The vile history of misuse of eugenics is alive in the memoirs of mankind, and may well be a warning for the future.

The *eugenic* movement, which was rooted in *'*Social Darwinism*',* emerged in the last decades of the nineteenth century. 'Social Darwinism' applies Darwinian biological theories of 'natural selection' and 'survival of the fittest' as well as the wisdom derived from the rediscovery of Mendel's laws of inheritance in politics. 'Eugenics' is defined by Francis Galton, known as a pioneer supporter of eugenics and one who elaborated its scope and aims, as a 'science which deals with all influences that improve the inborn qualities of a race'.[2] The proponents of the 'eugenic movement' advocated that state should pursue coercive plans of human breeding to reduce quantity of unfit and undesired segment in a population, asserting that unfit races were the root cause of social and economic ills. Eugenics popularized in Western Europe and North America, and was adopted by

[1] Philippa Levine. 'Eugenics: A Very Short Introduction'. OUP, New York, 2017. Page 7

[2] Francis, Galton. Eugenics: its Definition, Scope and Aims. The American Journal of Sociology, Vol.10, No.1(Jul.,1904) 1-25

fascist regimes in the first half of the twentieth century. Adolf Hitler regarded the Nordic and German races as the ideal race and tried to eliminate genes that he considered biologically inferior to his race. Resultantly, genocide and atrocities were committed by the Nazi regime employing selective breeding human schemes, concentration camps, and medical experiments[3]. Hitler's Eugenic ideas were expressed in his autobiography *Mein Kampf.* The Third Reich's internal policy was based on Nazism, which was defined by Rudolf Hess, the deputy of Hitler, as 'applied biology'. The discipline of eugenics was made a compulsory course in educational institutions and medical schools. The Max Planck Society (then called Kaiser Wilhelm Organization) championed eugenic racial research.[4] The 'Law for the Prevention of Genetically Diseased Offspring' was enacted for compulsory sterilization of any citizen who suffered from a genetic disorder and for the establishment of Genetic Health Courts. Alan Cassels points out that Holocaust and even Hitler's external policy and foreign politico-military adventurism was motivated by the same hatred racial policies.[5]

In North America, the growing influx of poor immigrants from Eastern Europe was unsettling for the Anglo-Saxon section of the population. This resulted in campaigns and an outpour of literature which attributed human traits of feeble-mindedness, insanity, and criminality to inheritance in certain families and races. The anti-immigration laws[6] were enacted to curb immigration and legitimize eugenic techniques of sterilization. About 60,000 became victims of coercive sterilization in majority of US states.[7] The ruling of US Supreme Court in *Buck v. Bell* [8] upheld not only the State of Virginia's forced sterilization of unfit and intellectually disabled, but it also validated eugenic sterilization laws in the United States. Only punitive eugenics was declared as unconstitutional by the US Supreme Court in the *Skinner v. Oklahoma* [9] case (1942). The reasoning laid down in the

[3] Stanford Encyclopedia of Philosophy <http://plato.stanford.edu/entries/eugenics/>

[4] Israel W. Charny (Ed.). *Encyclopedia of Genocide, Vol.1*. Jerusalem: Institute of Holocaust and Genocide, 1999. page 215

[5] Alan, Cassels.*Ideology and International Relations in the Modern World*.London: Routledge, 1996.

[6] Jonson Immigration Restriction Act of 1924

[7] Edwin Black. *War Against the Weak: Eugenics and America's Campaign to Create a Master Race*. 2012

[8] *Buck v. Bell* 274, U.S.200 (1927)

[9] Skinner v. Oklahoma ex rel. Williamson 316 U.S. 535 (1942)

Supreme Court ruling echoed during the Nuremberg Trials of 1946-1947 when those accused of committing war crimes of forced sterilization of millions of citizens justified their acts by referring to the precedent set by *Buck v. Bell.*[10] Although the forced sterilization was mostly abandoned after the Second World War after the US Supreme Court ruling in *Skinner v. Oklahoma* (1942), the Eugenic Board of North Carolina continued the practice and during the period of 1958-1968 committed genocide in guise of involuntary sterilization.[11] The eugenic sterilization laws were finally abolished in 1979.[12]

The eugenic practices have been linked to racial discrimination and apartheid. Sir Paul Nurse, Nobel Laureate once warned that genetic testing could result in 'genetic apartheid'.[13] The linkage of eugenics to apartheid is substantiated by empirical evidence produced during the South African Truth and Reconciliation Commission (TRC) proceedings when Wouter Basson, notoriously known as 'Dr. Death', was prosecuted for running his 'Project Coast'. He was the personal physician of Prime Minister Botha who was a staunch supporter of apartheid Rhodesian administration facing guerrrella insurgency. The Project was a covert bioweapon initiative which developed biological weapons including sterility vaccines to target people belonging to anti-apartheid insurgent movement[14], and organize assassinations against activists of anti-apartheid movement including detainees of SWAPO in Namibia and of ANC in South Africa. One of the witnesses testified during the Reconciliation Commission that he was contacted by Basson to invent a serum which could render a black woman infertile.[15]

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[10] Gina M. Wingood, Ralph J. Di Clemente (Ed.). Handbook of Women's Sexual and Reproductive Health. Kluwer Publishers, 2002. Page 13

[11] https://www.arpejournal.com/volume-15-number-one/did-north-carolina-economically-breed-out-blacks-during-its-historical-eugenic-sterilization-campaign/

[12] [Washington Post 25 April, 2018 https://www.washingtonpost.com/national/health-science/california-lawmakers-seek-reparations-for-people-sterilized-by-the-state/2018/04/25/2a873578-4869-11e8-8082-105a446d19b8_story.html>]

[13] Tim Radford, "Fear of Genetic apartheid" The Guardian (UK) March 4, 2003.

[14] Kathy Wilson Peacock. *Biotechnology and Genetic Engineering*. New York: Infobase Publishing, 2010.

[15] Chronicle of the Truth and Reconciliation Commission: A Journey through the Past and Present into the Future of South Africa, Piet Meiring, Carpe Diem Books, 1999. page 352.

From Eugenics to neo-eugenics in the era of Genetic Engineering Patents

The scientific and technological advances in genetics and gene patenting have opened promising vistas for humanity's welfare, capable of improving human hereditary traits. However, genetic engineering has also contributed to the re-emergence of neo-eugenics or liberal eugenics. The phenomenon of genetic engineering techniques, in opinion of Jeremy Rifkin, author of *The Biotech Century*, 'is exactly what eugenics is all about', because precise choices have to be made in the laboratory by molecular biologists as to which genes should be preserved as 'good genes' and which ones should be altered or erased as 'bad genes'.[16]

The author of book, *The New Eugenics: Selective Breeding in an Era of Reproductive Technologies*, Professor Judith Daar[17], employs the use of the term 'new eugenics' for these genetic technologies as the behaviors reflect the same pattern of 'old eugenics', which were associated with the victims of sterilization legislation as the sufferers. The sufferers included physically deformed psychotics, mentally retarded and recidivist criminals as well as those in a group termed as reproductively unfit. She argues that in the age of reproductive revolution and the Assisted Reproductive Technologies like *in vitro fertilization* (IVF) almost the same preconceived notion of exclusion continues to exist; as neither parents after knowing about the genetic disorder of their offspring would like to have them, nor the poor would have access to 'assisted reproductive technologies'. Professor Nicolas Agar defended the idea of human enhancement. In his book, he defends the acceptability of these technologies and says:

> "We have arrived at the conclusion that there is no objection against the principle of using genomics, cloning and engineering to enhance human beings. But this conclusion can only be a starting point for an investigation that dispenses with any pragmatic optimism, so as to

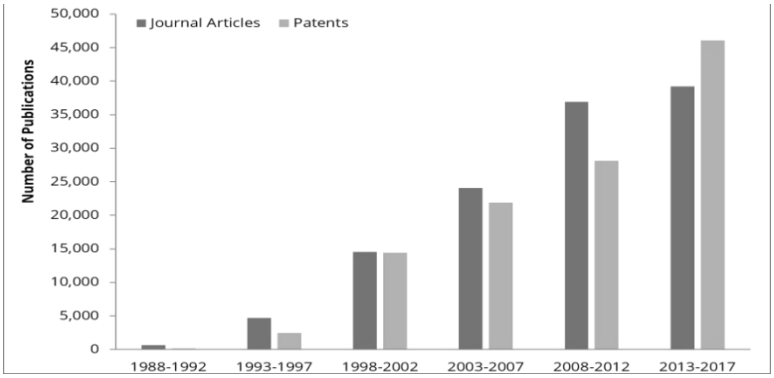
[16] Jeremy Rifkin. The Biotech Century: Harnessing the Gene and Remarking the World. New York: Penguin Putnam, 1998

[17] The New Eugenics: Selective Breeding in an Era of Reproductive Technologies. By Judith Daar. New Haven (Connecticut): Yale University Press. The Review published in The Quarterly Review of Biology Volume 92, Number 4. University of Chicago https://www.journals.uchicago.edu/doi/10.1086/694978

> address enhancement technologies as they really are, not as they might ideally be."[18]

Whatever Nicolas Agar says in the defense of these technologies, the dreaded past of eugenics appears to creep in with the advent of these technologies.

The Human Genome Project (October 1990- April 2003) gave a considerable impetus to the technological advances in the genetic field. The Project provided a blueprint of the human genome sequence, giving scientists a full picture of genetic material specific to the human species. The companies started huge investment in research and development (R&D) and resultant patenting of new genetic inventions and therapy techniques. Resultantly, an upsurge can be witnessed in applications for grant of patents related to genetic technologies. The CAS (Chemical Abstracts Service) a division of the American Chemical Society published an article which reported that 113,229 patent applications had been filed for the grant of genetic patents and cell therapies.



Source: CAS American Chemical Society website[19]

The patenting of new genetic technologies in recent decades include genome editing, genetic diagnostic testing, and gene and stem cell therapies for curing genetic disorders. Human germ line editing made it possible to alter the faulty DNA of embryos and reproductive cells,

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[18] Nicholas Agar. Liberal Eugenics: In Defence of Human Enhancement. Blackwell Publishing: Victoria, 2004. See chapter 8, page 158

[19] <https://www.cas.org/blog/gene-and-cell-therapy-rd-and-market-insights-you-need-get-competitive-edge> last accessed November 30, 2020.

followed by *in vitro fertilization* (IVF), after which the resulting embryos are artificially implanted. The genome editing techniques, namely CRISPR-CAS9 (with the option of error reversibility)[20], TALEN[21], ZAFNs[22], and HEGs[23] are milestones in the field of gene editing for therapeutic purposes aimed at improving the life-quality. However, various concerns have been raised regarding their use against the preservation of human dignity, human rights, and fundamental freedoms. The human germ line editing techniques could be used to make alterations other than those for gene therapy such as the physical appearance and intelligence of an individual. So-called 'designer babies' referring to the latter is the case in point. There is a fear that progress in genetics in gene therapy to edit human genome or to modify genetically the human embryo is making the dream of 'designer babies' a reality.[24] It is because the borderline between therapy and design is blurred, and designing enhanced functions may endanger child welfare and genetic identity of all humans and identity of the individual.

So, both uses are possible: by modifying genes to prevent diseases or to enhance normal traits. It is difficult to draw a sharp line between their uses.[25] There is more likelihood that the research was going beyond the treatment or prevention of disorders, and eugenics purposes likely to be served by 'engineering of desirable genetic characteristics', resulting in discrimination and injustice against certain individuals and groups.[26] In view of that risk, UNESCO International Bioethics Committee (IBC) called for a special procedure which should restrict the option of editing of human

[20] CRISPR-CAS9 (clustered regularly interspaced short palindromic repeats (Cas9), <https://patents.google.com/patent/WO2014093479A1/en>

[21] TALEN (Transcription activator-like effector nucleases) <https://patents.google.com/patent/US20140087426>

[22] ZFNs (zinc-finger nucleases) <https://patents.google.com/patent/US20120329067A1/en>

[23] HEGs (homing endonucleases or meganucleases. <https://patents.google.com/patent/WO2014121222A1/en>

[24] UNESCO panel of experts calls for ban on "editing" of human DNA to avoid unethical tampering with hereditary traits <https://en.unesco.org/news/unesco-panel-experts-calls-ban-editing-human-dna-avoid-unethical-tampering-hereditary-traits>

[25] Statement from the Danish Council on Ethics on genetic modification of future humans In response to advances in the CRISPR technology, Published by the Danish Council on Ethics 2016 https://www.etiskraad.dk/~/media/Etisk-Raad/en/Publications/Statement-on-genetic-modification-of-future-humans-2016.pdf

[26] Nuffield Council on Bioethics. Ethics review identifies top two challenges for genome editing https://www.nuffieldbioethics.org/news/ethics-review-identifies-top-challenges-genome-editing

genome to the extent of preventive, diagnostic or therapeutic purposes, and 'without enacting modifications for descendants'. Any other course of action, the UN panel warned would 'jeopardize the inherent and therefore equal dignity of all human beings and renew eugenics.' [27]

Other writers in literature feared that gene editing experiments may be conducted outside the regulated institutional laboratories, thereby, running risk of being hacked, namely 'genetic biohacking'.[28] For instance, individuals may use themselves the genome editing techniques giving rise to spike in bio-hacking services easily available in the market.[29] There is a likelihood of leaking of genetic information of individuals by 'eugenic-hackers', and that it may be misused for eugenic practices.

Initially, the controversy was around whether gene and DNA sequence found in nature would be eligible for patenting. Later, the legal question was raised for judicial determination whether the man-made complementary DNA (cDNA) and genetically modified living organisms were patentable. In 1980, the U.S. Supreme Court gave ruling in Diamond v Chakrabarty[30] that use of genetically modified organisms for the purposes of oil spill clearing is patentable by reason of it not being found in nature. The European Patent office granted patent on Harvard mouse and ruled that patentability of the genetically modified mouse was to be confined to transgenic mice only. In case of *Association for Molecular Pathology v. Myriad Genetics, Inc*.,[31] the patentability of the Myriad company's invented method of manipulating BRCA1 and BRCA2 was challenged, which was based on a naturally found DNA segment isolated from its naturally setting. The US Supreme Court ruled that being a product of nature, a DNA

[27] UNESCO panel of experts calls for ban on "editing" of human DNA to avoid unethical tampering with hereditary traits https://en.unesco.org/news/unesco-panel-experts-calls-ban-editing-human-dna-avoid-unethical-tampering-hereditary-traits OCTOBER 5, 2015

[28] Patricia J. Zettler, Christi J. Guerrini, and Jacob S. Sherkow. Regulating genetic biohacking. Science. 2019 Jul 5; 365(6448): 34–36. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7004414/

[29] Why we're not prepared for the genetic revolution that's coming. Robert Chapman. Independent, UK, Wednesday 30 May 2018 https://www.independent.co.uk/voices/genetic-revolution-marmite-genes-testing-disease-dna-biohackers-eugenics-a8375496.html

[30] Diamond v Chakrabarty -447 U.S.303, 100 S. Ct.2204 (1980)

[31] 569 U.S. 576 (2013)

segment is not patentable, but that the complementary DNA (cDNA) was eligible to be patented as it did not occur naturally.

Observed in 2002 by US President's Council on Bioethics, the issue of human cloning to produce children raised concerns about the possibility of eugenic cloning or genetic enhancement.[32] The Council went on to express that if society overstepped the line of therapy and entered unchartered waters of cloning, the irreversible journey would be without map, compass or even destination;[33] patenting of cloned human organs and IVF techniques might be a slippery slope towards human cloning and eugenics,[34] and if private eugenics allowed to the only parents claiming to have superior DNA and their right to replicate offspring through genetic techniques, the cumulative choices would finish up in altering human nature.[35]

The patentability of technologies related to human embryonic stem cells (HESC) has been seriously questioned. The patents for human embryonic stem cell (HESC) were initially granted in 1998 by the United States patent and Trade Office (USPTO) to James Thomson, and his team derived from earlier embryos.[36] The concern raised on the patentability of human embryonic stem cell as in the process human embryo was undermined.

A number of genetic screening techniques have been patented including SMA carrier screening patents for detecting recessive diseases which may facilitate parents to learn the risk of giving birth of offspring being affected by disorder and thus giving them a choice. The tests include examinations for BRCA (BRCA1 and BRCA2) mutations and non-intensive prenatal testing (NIPT). Some of these techniques have the potential for being abused for eugenic practices. For example, the latter technique named 'multiplexed parallel analysis of targeted genomics regions for non-intensive prenatal

[32] President's Council on Bioethics. Human Cloning and Human Dignity: An Ethical, Washington DC: July 2012 Inquiry page 107

[33] Calum MacKellar, Christopher Bechtel (edited). The Ethics of the New Eugenics, Beghahn Books: 2016. P- 119

[34] Kerry Lynn Macintosh. Human Cloning: Four Fallacies and Their Legal Consequences · 2013

[35] Ibid, page 89

[36] US Patent No. 5,843,780, 6,200,806, and 7,029,913

testing (NIPT)' was patented [37] in 2016. This technology can be used for prenatal screening with sex chromosome-associated disorders such as the Down syndrome, Edward syndrome, and Patau syndrome. This technique can detect a number of genetic variations, and, which is argued, can potentially be abused for eugenic purposes.[38] The application of carrier screening and prenatal testing techniques can lead to prejudice and intolerance against those who do not approve of these procedures.[39]

The use of pre-implantation genetic diagnosis (PGD) screening technique, which is generally considered as an improved form of parental testing and genetic selection, given its nature and outcome, in view of David S King, the editor of Gen-Ethics News argues, is eugenics. This will bring in prospects of 'consumer-driven form of eugenics' or *laissez faire* eugenics, far beyond the pre-existing eugenic practices.[40] It may lead us towards eugenic 'design babies', and the frequent use of such techniques will result in the child being valued for his genotype than inherent traits.[41]

Numerous other issues related to human dignity and fundamental freedoms which are argued to be arising out of the advances in genetic engineering techniques. These include inequality and discrimination, fear of coercion by governments to use these therapies, unwarranted interference in nature, right of the unborn child, the and issue of informed

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[37] Patent No. WO2016189388A1Multiplexed parallel analysis of targeted genomic regions for non-invasive prenatal testing WIPO (PCT) https://patents.google.com/patent/WO2016189388A1/en]

[38] Keeping the Backdoor to Eugenics Ajar? Disability and the Future of Prenatal Screening < Gareth M. Thomas, PhD and Barbara Katz Rothman. AMA Journal of Ethics https://journalofethics.ama-assn.org/article/keeping-backdoor-eugenics-ajar-disability-and-future-prenatal-screening/2016-04#:~:text

[39] Neil A. Holtzman. Eugenics and Genetic Testing Published online by Cambridge University Press: 26 September 2008 <https://www.cambridge.org/core/journals/science-in-context/article/abs/eugenics-and-genetic-testing/860BB629E8E7184BA07E14556DABCCB9>

[40] Pre-implantation genetic diagnosis and the 'new' eugenics David S King, Editor, Gen-Ethics News Journal of Medical Ethics 1999;25:176-182 <https://jme.bmj.com/content/medethics/25/2/176.full.pdf >

[41] Extending pre-implantation genetic diagnosis: the ethical debate: Ethical issues in new uses of pre-implantation genetic diagnosis. John A. Robertson. Human Reproduction, Volume 18, Issue 3, March 2003, Pages 465–471, Published: 01 March 2003 take from https://academic.oup.com/humrep/article/18/3/465/626048]

consent;[42] parental rights and obligations, human life and dignity; [43] social justice (benefit not shared equitably by rich and poor even if positive eugenics applied), protection of genetic diversity, fear that human genome editing coupled with social liberalism may lead to liberal eugenics chosen by parents instead of driven by state policy resulting in social division, in addition to the consumerisation of human biology.[44]

In the context, a report of European Academies Science Advisory Council urged the policy-makers and the scientist community to have a dialogue on the societal implications of the research in molecular biologic methods being used to edit human genome.[45]

European Legal landscape

The European patents are governed by both European as well as national laws. There are two ways to appraise the validity and legitimacy of granting the eugenic gene. The first is to look at its normative aspects in the light of the European and international laws, and the second is to examine the issue purely in the context of the European patent laws.

Let's first see the phenomenon from the normative perspective. The Charter of Fundamental Rights of the EU hails human dignity as inviolable which must be respected and protected.[46] It is because the European Union foundation of European spiritual and moral heritage is based on 'indivisible, universal values of human dignity, freedom, equality and solidarity'.[47] In the field of biology and medicine, the Charter prohibits the eugenic practices particularly those aimed at the selection of persons.[48] The UNESCO Declaration on the Human Genome and Human Rights (1998) obligates the respect for dignity and rights of everyone irrespective of their

[42] <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6454467/table/dey257TB4/?report=objectonly>

[43] The ethics of clinical applications of germline genome modification: a systematic review of reasons 2018 Sep 1;33(9):1777-1796. doi: 10.1093/humrep/dey257.Ivy van Dijke , Lance Bosch et. el. https://pubmed.ncbi.nlm.nih.gov/30085071/

[44] Nuffield Council on Bioethics London, 2016. https://www.nuffieldbioethics.org/wp-content/uploads/Genome-editing-an-ethical-review.pdf = Agar N (2004) Liberal eugenics: In defence of human enhancement (Oxford: Wiley-Blackwell)

[45] Genome editing: scientific opportunities, public interests and policy options in the European Union <https://scnat.ch/en/uuid/i/3c01b648-90d9-5831-92f9-d1a7fabcd663>

[46] Article 1

[47] Preambleof Charter of Fundamental Rights of the EU

[48] Article 3

genetic characteristics and to respect their uniqueness and diversity,[49] and prohibits discrimination based on genetic characteristics[50]. The UNESCO Declaration enjoins that research applications concerning human genome in the field of biology, genetics and medicine should not prevail over human dignity, human rights, and fundamental freedoms.[51] It also maintains that genetic research of an identifiable person, whether data stored or processed, must be kept confidential.[52] The States are obliged under the Declaration to respect and promote the practice of solidarity towards those who are affected by the disease or disability of the genetic character.[53] The Council of Europe Data Protection Convention (1981) safeguards the respect for right to privacy in the context of the increasing flow of information across the borders with regard to the automatic processing of personal data.[54] The Oviedo Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine prohibits discrimination based on genetic heritage.[55] The Oviedo Convention also prohibits medically assisted reproduction techniques in view of choosing the sex of the future child with exception to avoid serious hereditary sex-related disease.

For any clinical trial undertaken on medicinal products for human use, it was enjoined that the privacy and data protection rights shall be protected as per requirement of Directive 95/46/EC.[56] However for processing of personal data between member states, the directive leaves it at the discretion of each state to decide transaction with other member states keeping in view their level of protection to the rights and freedoms of individuals particularly the right to privacy.[57]

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[49] Article 2

[50] Article 6

[51] Article 10

[52] Article 7

[53] Article 17

[54] Preamble and Article 1

[55] Article 11

[56] Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use *OJ L 121, 1.5.2001, p. 34–44*

[57] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data *Official Journal L 281, 23/11/1995 P. 0031 - 0050*

Regulation (EC) No 1394/2007 on Advanced Therapy Medicinal Products requires to observe the principles and fundamental freedoms safeguarded in the EU Charter of Fundamental Rights, and other European treaties in the field of medicine and biology such as the European Convention for the Protection of Human Rights and Dignity of Human Being with regard to application of Biology and Medicine.[58] The law prohibits carrying out of clinical trials of gene therapy which cause modification to the subject's germ line genetic identity.[59] The agreed basis for conducting clinical trials, involving human and in respect of application of biology and medicine, has been declared as the protection of human rights and dignity of human being. Further, the law requires observance of stringent clinical pre-trial criteria to make sure procuring the consent of the person subject to clinical trial, special protection for persons unable to give consent, and risk assessment through toxicological experiments and screening by ethic committees/authorities.[60]

The ethical norms and fundamental rights have occupied central stage in all the innovative activities under the EU Horizon 2002 framework, particularly the rights of physical and mental integrity, data protection rights, right to privacy, and the non-discrimination right.[61] In line with this policy, the EU law prohibits research funding in the field of research which intends to modify genetic heritage of individuals in such a way so as to make these modifications inheritable or human cloning for reproductive use, and human stem cell research.[62] The recitals 16 of the Directive 98/44/EC of July 6, 1998 on the Legal Protection of Biotechnological Inventions, clarifies that 'patent must be applied so as to respect the fundamental of human dignity and integrity of the person' and that human body including germ cells and mere discovery of one of its elements or products including

[58] Regulation (EC) No 1394/2007 on Advanced Therapy Medicinal Products <https://eur-lex.europa.eu/eli/reg/2007/1394/oj >

[59] Directive 2001/20/EC

[60] Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use Official Journal L 121, 01/05/2001 P. 0034 - 0044

[61] Article 19.1 Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC Text with EEA relevance *OJ L 347, 20.12.2013, p. 104–173*

[62] Article 19.3 of Regulation (EU) No 1291/2013

sequence or partial sequence of a human gene cannot be patented. The recital 38 disallows the patenting of processes technologies which offend against human dignity. The Universal Declaration on Human Genome and Human Rights, Oviedo Convention and other human rights and bioethics related treaties and jurisprudence may be referred to.

European Patent Law, Patenting Criteria and Procedure in genetic engineering field

After this survey, let's see the phenomenon of eugenic genetic patents in the context of European Patent Laws on regional level's patent regime. The European regulatory landscape is of its own kind, influenced by the European public opinion regarding environment, public health, economic interests, and European values of fundamental freedom and human rights. The first source of patent law is *The Convention on the Grant of Patents 1973 (EPC) or European Patent Convention (EPC)*. The European Patent Office (EPO) is the central office established under the EPC for patent applications, applications' examination, opposition and grant of patents. The EPC is supplemented by the EPO Implementing Regulations and the EPO Guidelines for Examiners. The second source is the Directive 98/44 of July 6, 1998, passed by the European Parliament and the European Council. It is the key European framework for legal protection of inventions related to biotechnology and genetic engineering. The recitals of the Directive regard, for interpretation purpose, national patent laws as a useful source,[63] but not subject to present discourse. The EC Directive 98/44/EC was implemented into the European Patent Convention in 1999 so as to serve as supplementary means of construction in form of the Rule 26-29 of the European Patent Convention. As patenting procedures and practices are done at the patent office and they are main gatekeepers to examine patent application to avoid any misuse, therefore, the jurisprudence developed by the case-law of EPO Boards of Appeal and the Enlarged Board of Appeals is yet another source of understanding the legal aspect of genetic patent law.

The EPC provides a comprehensive legal mechanism for the grant of European Patent and lays down the patentability criteria in its Article 52(1), which describes that 'European patents shall be granted for any inventions, in all fields of technology, if they are new, involve an inventive step, and

[63] This is because Directive 98/44/EC, Article 1(1) allows the national laws to be adjusted where necessary in accordance with the provisions of the Directive.

are susceptible of industrial application.'[64] The word 'any field of technology' qualifies inventions in genetic engineering and biotechnology upon meeting the eligibility criteria.[65] For eligibility and non-eligibility of the patenting gene sequence, the Rule 29 is pertinent to look into.

In accordance with the Rule 29, sequence of a gene or partial sequence of a gene or human body at its various stages cannot constitute patentable invention; however, if produced by way of technical process or isolated from human body may eventually become a patentable invention, howsoever its structure appears identical to the natural one. Additionally, the sequence or partial gene sequence in order to be eligible for patentability would require disclosure of its industrial application.[66] In broader terms, the inventions are eligible for patenting if biological material in natural form when it is isolated from natural environment or is manufactured by a technical process.[67] In the specific field of human stem cell patenting (HESC), in contrast to the USPTO policy on grant of patent, the European public opinion, laws and practice have been against the human stem cell patenting (HESC).

Resultantly, there have been controversies and legal battles over the patenting of human embryonic stem cell. However, this controversy was not generated due to the reasons underlying eugenics rather on grounds of morality and human dignity. The patenting on human embryonic stem cell comes within the purview of Article 53(a) of the Convention (1973)[68], and corresponding Article 6 (2) (c) of the Directive 98/44/EC, which excludes from patentability criteria the inventions the commercial exploitation of which is repugnant to the *morality* or '*ordre public*'. The Rule 28 (c) of the EPC elaborates the clause Article 52(a) and disallows European patent on 'uses of human embryos for industrial and commercial purposes.' Upon the question referred to it, the Enlarge Board of Appeal (EBA) in Wisconsin Alumni Research Foundation case, decided the non-patentability of claims specified in the patent application, the method involving necessarily the

[64] Article 52(1) of EPC
[65] Article 57 of EPC
[66] Rule 29 (1), 29 (2), and 29 (3) of the EPC
[67] Rule 27 (a) of EPC
[68] Article 53(a) of EPC < https://www.epo.org/law-practice/legal-texts/html/epc/2016/e/ar53.html >

destruction of human embryo from which said products were derived, the method itself, nevertheless, was not part of the patent claims.[69]

In *Oliver Brustle v Greenpeace*, a reference for preliminary ruling came before the Grand Chamber of the Court of Justice of the European Union (CJEU) in respect of the patentability of 'Neural precursor cells, methods for their production as well as their use in neural defect therapy', and which were based on stem cell derived from human embryo resulting in destruction of the embryo involved. The matter in question was the European Patent No. 1040185 B1 issued to the German scientist Oliver Brüstle. The Court ruled that the inventions where 'prior destruction of human embryos or their uses as base material' involved, would be excluded from patentability within the meaning of Article 6 (2) (c) of the Directive 98/44/EC.[70] Consequently, the EPO Opposition Division revoked the said patent granted to Professor Brüstle in 2013.[71]

However, in a subsequent judgment the Grand Chamber of the CJEU, interpreting the said provision of Article 6(2) (c) of the Directive 98/44/ EC further elaborated what constitute a 'human embryo', and ruled that an unfertilized human ovum whose further development had been stirred by parthenogenesis, based on current scientific knowledge if not inherently capable of developing into human being, would not constitute 'human embryo'. The CJEU left this matter to the nation courts to determine judicially.[72] The Court findings are in line with the Directive 2004/23/EC, whereby the decisions relating to the use or non-use of any specific kind of germ cell and embryonic stem cells are left to the discretion of a member state to determine. In case a national legislation authorizes a particular use of such cells, the relevant State will have to protect public health taking in to view the specific risks as per provisions of the Directive and guarantee

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[69] G 0002/06 (Use of embryos/WARF) of 25.11.2008 < https://www.epo.org/law-practice/case-law-appeals/recent/g060002ex1.html >

[70] Oliver Brüstle v Greenpeace eV. Judgment of the Court (Grand Chamber) of 18 October 2011. – Case C-34/10. European Court Reports 2011 I-09821 https://eur-lex.europa.eu/legal-

[71] EPO revokes patent in the "Brüstle" case 11 April 2013 https://www.epo.org/news-events/news/2013/20130411a.html >

[72] Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks, CJEU, 18 December 2014, Case C-364/13 Judgment of the Court (Grand Chamber) CJEU. https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A62013CJ0364

respect for fundamental rights, though the risk associated with the cells should be assessed based on scientific knowledge.[73]

Regarding gene editing techniques, the CJEU in 2018 ruled that the organisms, obtained by way of mutagenesis techniques constitute GMOs within the meaning of GMO Directive 2001/18/EC (deliberate release into environment), and, therefore the obligation under the Directive would be applicable. The obligation ensures precautionary measures to make sure appropriate steps have been taken for protecting human health and environment as a result of placing the genetically modified organisms in the market.[74] The EU Implementation Regulation 503/2013 controls the risk. The European Patent Board of Appeal has revoked the patent (EP 2771468) related to the CRISPR gene editing technology on ground of devoid of novelty.[75]

On the issue of human cloning and interfering in human germ line, there is much clarity within the European Community. The patenting of 'processes for cloning of human beings' falls within the prohibitory clause of 'ordre public' and morality', and their commercial exploitation has been made unequivocally unpatentable. The corresponding Rule 28 EPC under Article 53(a) (a) of the EPC is applicable. A clear definition of 'process for cloning of human-being' and reasoning of such unequivocal prohibition is evidently clear specifically from the language of the recitals (40-41) of the Directive 98/44/EC.

The process for human cloning human being is defined as 'any process for cloning human beings may be defined as any process, including techniques of embryo splitting, designed to create a human being with the same nuclear genetic information as another living or deceased human being' and the reasoning for its exclusion of patentability was described as offending against 'ordre public and morality'.

[73] Article 3. 2(c.) of Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells OJ L 102, 7.4.2004, p. 48–58

[74] Court of Justice of the European Union, C-528/16, EU:C:2018:583.

[75] Decision in case T 844/18 on the CRISPR gene editing technology, 17 January 2020

For assessing Article 53(a) objection, the implied notion 'ordre public' was defined as "covering the protection of public security and the physical integrity of individual as part of society..." [76], whereas the 'morality' in assessment thereof was as the Board of Appeal ruled: there was "no single definition of morality based on e.g., economic or religious principles represent an acceptable standard in European culture." [77] On the same ground of being contrary to 'ordre public and morality', there is consensus within the European Community against the interfering in the human germ line, and it unambiguously prohibits the patenting of "processes for modifying the germ line genetic identity of human beings". [78]

In contrast to this the processes for modifying the genetic identity of animals is prohibited only to the extent that such processes are 'likely to cause them suffering without any substantial medical benefit to man or animals, and also animals resulting from such processes.' The reasoning for this given by the European Board of Appeal (EPA) is that practical examples under Article 53(a) EPC arise from the fact that not everything can be done to human beings which can be done to other living beings. For example, the avoidance of offspring which are unwanted, due to certain properties (sex, colour, health), for economic reasons, may be quite legitimate for domestic animals whereas when applied to human beings it would be contrary to "ordre public" or morality.[79]

The patentability of Oncomouse was opposed and the examiners at the EPO did not grant patent in 1985 on patent application 85304490.7 on method for producing transgenic animals on the ground of Article 53 (b) of EPC. However, ultimately, the Opposition Division's decision dated 16.01.203 to maintain the European Patent No. 0169672 in amended form was appealed to the Board. The Board remitting to the first instance ordered to maintain European Patent No.85304490.7, filed on 24.6.1985 with priority date of 22.6.1984.[80] In the same ruling of the Board of Appeal it was said that in such a case Rule 23(d) test is applicable which enjoins to take into consideration only such things: "animal suffering, medical benefit

[76] EPO Board of Appeal in T 356/93 (Plant cells) of 21.2.1995.
[77] T 0315/03 (Transgenic animals/HARVARD) of 6 July 2004. Para 6.1
[78] Article 6(2) (b) and Recital 40 of the Directive 98/44/EC read with Rule 28 EPC under Article 53(a) (a) of the EPC.
[79] Case No. G 0001/03 decided by European Board of Appeal on 08 April 2004
[80] T 0315/03 (Transgenic animals/HARVARD) decided on 6 July, 2004

and the necessary correspondence between the two in terms of the animals in question". However, the EPO Guidelines for Examination elaborates that the list of exceptions to patentability under Article 53(a) and Article 53(a) which is laid down in Rule 28, is 'illustrative and non-exhaustive, and is to be seen as giving concrete form to the concept of 'ordre public' and morality in this technical field', which indicates that decision under examination may vary from case to case.

Conclusion

The scholarship poured out by the exponents of eugenics appears fascinating in the first instance when it claims enhancement of human species and elimination of undesirable hereditary diseases and genetic disorders. The movement was associated with Hitler's fascism and with proponent of pro-apartheid policies that once prevailed in South Africa and Western Sahara. Europe and the United States were the birth places of eugenic movements. However, the European public opinion has changed after the Second World War.

Consequently, eugenic supporters lost the backing of the populace and public opinion drifted away from negative eugenics that propagated the notion that only those people with 'desirable genetic traits should be allowed to reproduce'. However, a tiny minority still carried the eugenic mindset. Huge research funding, robust regime for protection of intellectual property rights in patents, and the innovative and judicial decisions such as those in Diamond v Chakrabarty helped bringing in a revolution in genetic science and genetic inventions in the last few decades.

This, in turn, opened up tremendous opportunities for the eugenicists to realize their pipedream. A plethora of scholarship poured out in literature and media propaganda by eugenicists led to the emergence of new eugenics. Eugenicists camouflaged their agenda behind arguments that favor the incredible benefits arising from advances in genetics and engineering. The linkage of patent laws with international trade and its internationalization through the regime of TRIPS agreement coupled with the creation of diagnostic and therapeutic technologies have posed new challenges for policy-makers elsewhere in the world.

The European values and faith in respect for human dignity and fundamental freedoms is reflected in its policies and legal regimes. Both the European Union and Council of Europe normative regimes have been crystal clarity about the use or non-use of these genetic technologies. Also, the vigorous well organized European patent office appears strong enough to keep in check such eugenic tendencies through their robust patenting procedures. In practice, however, European policies and laws are fragmented in different institutions and inter-governmental organizations. We should not forget that more investment by the European companies in research and development (R&D) and the resultant rise of patent applications and grant of patents to protect their technologies influences European Union policies and patenting as well. The dynamics of internal market and tougher competition abroad with other economic and technological powers have also been contributing factors, which continuously shape and adjust the patent policies about protection of new genetic technologies. Pragmatically speaking, the European Community has to tradeoff between normative values and national and Community business interests. Notwithstanding all that, the EU, Council of Europe and the European Patent Office should coordinate their endeavors and establish institutionalized mechanisms to keep in check the new-eugenic tendencies for the sake of humanity and a better world ahead for new generations.