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Comparative Analysis of Gene Editing and Patenting Laws: India vs. EU

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ABSTRACT

This paper provides a comparative analysis of the legal and ethical frameworks governing gene editing and patenting in India and the European Union (EU). Both regions welcome advancements in gene editing but impose stringent restrictions to maintain ethical compliance and public safety. The Indian Patent Act, with Sections 3(b), 3(c), and 3(j), and the EU's morality and ordre public doctrines limit the patentability of genetic modifications. While India permits gene editing in plant biotechnology, biomedical research faces tighter regulations under the Indian Council of Medical Research (ICMR) and the Department of Biotechnology (DBT). Similarly, the EU's regulatory bodies maintain strict oversight to prevent unethical practices. This paper discusses the evolving guidelines, including India's 2020 draft by DBT and CDSCO, and the EU's established frameworks, highlighting their approaches to balancing innovation and ethical integrity. By comparing these regulations, the paper elucidates how both regions navigate the complexities of gene editing to foster advancements while safeguarding societal values.

Keywords*: gene editing, patent law, public order and morality doctrine, critical analysis, legal ethics, IPR.*

I. INTRODUCTION

The role of patent law is to incentivise innovations that are useful to the society and that will benefit the society, but sometimes society might not consider certain innovations to be socially acceptable. There may arise questions of whether such innovations are to be encouraged further, either by way of protection through granting patents, or providing funding through government institutions. There may arise situations where the society is hesitant to the usefulness of the innovation. Some innovations can be gravely new, radical, and mysterious to the society as the long-term effects of the innovation are unknown, and the innovations themselves can bring out the scepticism among society.[2]

But through the years society has become more accepting of innovations though there is still a

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[2] One major example of this is the invention of *in vitro* fertilisation (IVF). When it was first introduced in 1978 and proven to be successful in helping childless parents, the society in general was against the concept. The tabloids resorted to calling the test tube baby "artificially made" and "Franken", after the character Frankenstein.

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long way to go. With the advent of technology, the pace at which innovations are brought into society has grown manifold and the legal system and the public require time to understand the importance, usefulness, implications, and the long-term effects of such innovations. Examples of innovations that have brought up the scepticism of the public and the legal system include stem cell and clustered regularly interspaced short palindromic repeats (CRISPR) technologies. Such innovation bring up ethical and moral questions that need to be addressed before bringing them into society.

II. THE WARF DECISION[3]

The first time human embryonic stem cell (hES cells) research was questioned under the law was in 2008 in the Wisconsin Alumni Research Foundation, Decision G-2/06 (WARF decision).[4] The case was decided by the European Patent Office (EPO) where it provided a broad definition of what an embryo is. There was no room left for purposive or creative interpretation of the term. The case was regarding pluripotent hES, at the time of application in 1996, required the destruction of embryos. Rule 28(c) and Article 53(a) were applied, and the application was rejected under the grounds laid down by the provisions.[5]

While Rule 28(c) states that patents for biotechnological inventions shall not be granted for when concerned with the "use of human embryos for industrial and commercial purposes", Article 53(a) states that "patents shall not be granted for inventions the commercial exploitation of which would be contrary to *ordre public* or morality."[6] Additionally, as per the EU Biotechnology Directive, the industrial and commercial uses under this question are to be read as against theoretical and diagnostic use for the benefit of the embryo. This is also to be read in line with the concerns of a legislator to prevent the misuse of innovation through the modification of the embryo.[7] The essential element considered by the EPO before coming to this decision was to protect the human dignity of the embryo.[8] The entire decision was taken to benefit the embryo to avoid its destruction.

Though the provisions mentioned were introduced post the application, the EPO held that the provisions will be applied retrospectively.[9] It further emphasised that there can be no protection to either the product or process by which a human embryo is destroyed as this is in direct

[3] European Patent Office, 'G-2/06: Use of embryos/WARF, (2009), Official Journal of the European Patent Office.
[4] J Thomson, Primate Embryonic Stem Cells, International Patent Application Publication Number WO96/22362 (Geneva: World Intellectual Property Organization, 1996).
[5] Rule 28(c) and Article 53(a), European Patent Convention.
[6] Ibid.
[7] Ibid.
[8] Ibid.
[9] Ibid.

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violation of the Rule. As for the Article, the EPO read a literal interpretation of it and stated that it was not necessary to discuss further about the wording of the Article or investigate balancing the benefit of the public with the right of the embryo or discuss when the *ordre public* and morality argument are to be assessed. It just stated that there is "no room for manoeuvre."[10] Hence, both, the Rule, and the Article, were applied to the case using the intent of the legislators that was interpreted to hold the case within the ambit of the provisions.

(A) The Brüstle v Greenpeace Decision[11]

This decision was further elaborated, and a more in-depth analysis was provided. In the Brüstle v Greenpeace case, the court dealt with the patenting of isolated neural precursor cells, the production of embryonic cells, and therapeutic use of the same.[12] The same questions arose in this case and the ECJ provided a broad definition of an "embryo". While the WARF decision was silent on the definition of the term, this case made clear the standing of the European courts regarding the issue of patenting products or processes that involve the destruction of a human embryo. The ECJ provided with a legal definition of an embryo rather than an ethical one as the latter would lead to controversy among different groups in the public.

The court held that if cells could transform into fully formed human beings, the destruction of such cells would constitute as a violation of the Rule and Article, and additionally the provisions under Patentgesetz, that has similar provisions. The ECJ reiterated that the cells must have an "inherent capacity" to be able to develop into a human being by itself.[13] It further reiterated the decision of the EPO in the WARF decision regarding the applicability of Rule 28(c) and denying the patent application on the rationale that the process involved the removal of stem cells from an embryo leading to its destruction. Here too, the court prioritised the protection of the dignity of the embryo over incentivising useful research moving towards an ontological approach. Hence, the destruction, and the method of destruction were not protected under a patent.

While it can be commended that the court is looking to protect the rights of a human embryo, the above decisions raise question regarding the balancing of rights between societal and research factors. By aiming to protect the embryo, the courts have ignored the rights of the diseased, who are alive and suffering. By bringing in an ethical notion to the debate on the destruction of embryos, there arises ethical questions on the suffering of the diseased who have

[10] Ibid.
[11] European Court of Justice, Oliver Brüstle v Greenpeace e.V., 18 October 2011, C-34/10.
[12] Ibid.
[13] Ibid.

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the right to better health.[14]

III. CRISPR CAS9 TECHNOLOGY

An additional issue that has arisen through the years is CRISPR technology. Prior to CRISPR, zinc finger nucleases (ZFNs) and transcription activator-like effector nucleases (TALENs) were used.[15] While ZFN and TALEN focus on the editing of targeted DNA sequences, CRISPR is different and more advanced in that it targets the editing of DNA and RNA sequences. This makes the entire process simpler and less time consuming. While stem cell research was focused on acquiring certain cells that can only be derived from embryos and destroying them in the process, gene editing technologies bring up similar questions relating to the morality and ethics of the practices.

The first and foremost issue is that there is no universal commonality with how countries deal with the issue of gene editing. Each country has its own laws regarding the matter. This remains a superficial issue, as countries have differences in what is considered as patentable subject matter. Hence there is no uniformity across the globe.[16]

CRISPR and other gene editing technologies are already being licensed and used by several companies in the agriculture sector as well as for therapeutic applications in the medical sector.[17] This is the case though there has been a patent dispute on the technology between University of California, Berkeley, where Professor Doudna collaborated with Professor Charpentier, and Harvard and Broad Institute MIT, where Prof Feng Zhang worked with a research team.[18] The main points of contention in this case are regarding the priority and novelty of the inventions and the disputes are mainly in the context of EU and USA laws.[19] It is necessary to understand that the laws in the jurisdictions vary and the outcomes of the cases will have an impact on the licensing and any future use of the invention.

The advantages of using gene editing technology are well known, but major issues arose since

[14] Article 25, Universal Declaration of Human Rights.
[15] Li, H., Yang, Y., Hong, W. et al. Applications of genome editing technology in the targeted therapy of human diseases: mechanisms, advances, and prospects. Sig Transduct Target Ther 5, 1 (2020). https://doi.org/10.1038/s41392-019-0089-y
[16] Athreye, S., Piscitello, L. & Shadlen, K.C. Twenty-five years since TRIPS: Patent policy and international business. *J Int Bus Policy* **3**, 315–328 (2020). https://doi.org/10.1057/s42214-020-00079-1
[17] V.M. de Grandpré and F. Lozon, 'Making Sense of the Battle for the CRISPR-Cas9 Patent Rights', Osler (15 March 2021), available online at www.osler.com/en/resources/critical-situations/2021/making-sense-of-the-battle-for-the-crispr-cas9-patent-rights
[18] Matthews, D., Minssen, T., & Nordberg, A. (2022). Balancing Innovation, 'Ordre Public' and Morality in Human Germline Editing: A Call for More Nuanced Approaches in Patent Law, European Journal of Health Law, 29(3-5), 562-588. doi: https://doi.org/10.1163/15718093-bja10073
[19] V. Lin, 'What Is a Patent Priority Claim?', Patent Trademark Blog/IP Q&A, available online at www.patenttrademarkblog.com/patent-priority-claim/

the shift to germ line gene editing. Prior to this, it was majorly used for gene editing in somatic cells (like normal liver cells).[20] With advancements in the biomedical fields and the scientific steps like the cloning of Dolly the sheep, and as discussed, the destruction of human embryos for stem cell research, more public attention was diverted to the sector as the inevitable questions of ethical implication of such practices arose widely.[21]

One could argue that the process of cutting into ones DNA sequence, removing a part of it, and altering it, is not a simple one, though it may seem simple to researchers working in laboratories. Bringing such changes into the society has major implications not just on humans, but for future generations and the legal system. There may be unknown consequences of gene editing that are unpredictable which will lead to future generations suffering.[22] And if one counters this by stating that is the current generation could create change in human genes with or without understanding the consequences of it, the future generations will be smart enough to reverse any changes made. This argument is arrogant.[23] Just like there is no way of understanding the consequences of current actions, there is no way of knowing what the future generation will be capable of.

IV. THE INDIAN PERSPECTIVE

Indian legislations have been conservative when it comes to the use of embryos and gene editing techniques in the country. While the development of gene editing techniques have been a welcome change, there have been several roadblocks in the Indian legal context.

There are pre grant conditions in place that set out items and processes that can be patented. Section 3(b) of the Indian Patent Act restricted the grant of patents for an invention for which the primary/ intended use or commercial exploitation of which could be contrary to public order or morality, or which causes serious prejudice to human, animal or plant life or health or to the environment.[24] This is similar to the morality and *ordre public* doctrine used in the EU.

Gene patenting refers to the "patenting of the process of manipulating DNA and chemical substances related therewith, gene sequences and fragments of gene that are not present in their natural state in nature."[25] Section 3(c) of the Act states that a "discovery of a scientific

[20] John J. Mulvihill and others, Ethical issues of CRISPR technology and gene editing through the lens of solidarity, British Medical Bulletin, Volume 122, Issue 1, June 2017, Pages 17–29, https://doi.org/10.1093/bmb/ldx002
[21] Ibid.
[22] Ibid.
[23] Ibid.
[24] Indian Patent Act, 1970.
[25] R., Archana, 'Gene Patenting: An India Perspective', Mondaq (2021) https://www.mondaq.com/india/patent/1085392/gene-patenting-an-india-perspective.

principle" cannot be considered an invention, and hence cannot be patented. This issue arises when considering the patentability of human genes that are found in their natural state and are edited to enhance their performance.[26] Further, section 3 (j) of the Indian Patent Act, 1970 includes objection to plants and animals, in whole or any part thereof, other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals to be patentable.

Specific to gene engineering and gene editing in the plants biotechnology sector, The Indian Ministry of Environment, Forest and Climate Change has permitted the use of gene edited products using the SDN-1 and SDN-2 techniques. This allows the products to bypass the assessment of the Genetic Engineering Appraisal Committee (GEAC) and shifts its jurisdiction to the Indian Seeds Act.[27] Plant products edited using the stated techniques are not considered genetically modified (GM). This opens the possibilities of adopting new breeding techniques (NBTs) and other gene editing techniques like CRISPR-Cas9.[28]

While Indian legislators have been more open to permitting gene editing techniques for plants and seeds, there have been several restrictions when it comes to the use of such techniques in biomedical research. The Indian Council of Medical Research (ICMR) is responsible for the regulation of biomedical research. In the 2006 Ethical Guidelines for Biomedical Research on Human Participants (Guidelines), ICMR laid down rules for conducting clinical research using gene therapy and related techniques.[29] It clearly stated that using gene therapy for enhancing certain characteristics in humans as unethical. In 2017, ICMR and the department of biotechnology released a new set of guidelines, National Guidelines for Stem Cell Research[30], that were updated to include the use of gene editing techniques like CRISPR-Cas9. It restricts the use of genetic editing research to *in utero* studies. Additionally, the embryos used for the research should be spare ones, and the genes used should not be kept for more than 14 days of fertilisation of primitive streak.[31]

Hence, the 2017 Guidelines had been made more liberal than the 2006 Guidelines. While the 2006 Guidelines took a stricter stance due to the lack of information, the 2017 Guidelines permit the use of stem cells and gene therapy for certain research purposes. There continue to

[26] Ibid.
[27] R., Sanjiv, 'India eases gene editing regulations', S & P Global (2022) https://www.spglobal.com/commodityinsights/en/ci/research-analysis/india-eases-gene-editing-regulations.html.
[28] Ibid.
[29] Ethical Guidelines for Biomedical Research on Human Participants, 2006.
[30] National Guidelines for Stem Cell Research, 2017.
[31] Bhattacharjee, K., & Arpit Singh, K., (2020). Regulation of Genome-Editing Technology in India, Journal of Legal Studies and Research, Vol., issue 2, 2455 2437, https://thelawbrigade.com/wp-content/uploads/2020/04/Koninika-Kunwar-Arpit-JLSR.pdf

be complexities in the use of gene editing techniques and newer regulations are required for more clarity.

This has led to the release of draft guidelines in 2020 by the Department of Biotechnology (DBT), in collaboration with the Central Drugs Standard Control Organisation (CDSCO).[32] The draft guidelines mentions that gene editing, and gene engineering cannot be used for modifications or enhancement purposes. It clearly states that germline gene editing cannot be conducted since the changes can be inherited by future generations, leading to genetically modified human beings. This is considered a social taboo and are claimed to be unsafe due to the lack of information on the same.[33] The draft also mentions that germline gene editing may be used to induce unnatural advantages in future generations. The draft says, "All such applications are prohibited unless scientific or ethical justification can be provided which is acceptable under socio-ethical norms and the laws of the land".[34] The draft also proposes to set up a new committee called the Gene Therapy Advisory and Evaluation Committee (GTAEC) to evaluate the ethical and regulatory aspects of gene editing.

There already exist guidelines and procedures for clinical trials of pharmaceutical products. Gene therapy will include a new form of drugs called nano-pharmaceuticals, and the draft guidelines will apply to the latter form of drugs.[35] The draft proposes to maintain the clinical trial period at five years and recommends a follow up of ten years after marketing. The draft has been made post the study of several international regulatory framework for gene editing. The focus on permitting research for gene editing is to aid in the development of drugs for conditions like sickle-cell anaemia, thalassemia, haemophilia, and more abnormal conditions

The new draft guidelines are a welcome change in the field of biomedical and biotechnological research. This can help in the research and development of drugs and other forms of medication in abnormal health and genetic conditions. An application has already been submitted for the trial of gene therapy for haemophilia by a DBT institute.[36] Bringing in new regulations for gene therapy will help understand the complexities of the issues and lay down better regulations for the same. Most countries already have said regulations in place, and introducing new guidelines will bring India a step forward in the right direction.

[32] Draft Document on Genome Edited Organisms: Regulatory Framework and Guidelines for Risk Assessment, 2020.
[33] Dutt, A., Gene editing: Medical board drafts new laws, Hindustan Times (2019) https://www.hindustantimes.com/india-news/gene-editing-medical-board-drafts-new-laws/story-WXR5RjSoMWPDcnhu9yZOtK.html.
[34] Ibid.
[35] Ibid.
[36] Ibid.

V. IMPLICATIONS OF GENE EDITING TECHNOLOGIES

Scientists must not be careless in using gene editing and stem cell technologies though there is a general understanding of the benefits it might hold in tackling genetic diseases and eradicating them altogether. Such technologies can also help in the better understanding of the human body and why and how certain people are more likely to susceptible to certain diseases. But it must be kept in mind that there are far reaching implications of carelessly using gene editing technologies.

Chinese scientist Jiankui He of Southern University of Science and Technology registered a clinical trial where he had implanted genetically modified embryos using the CRISPR Cas9 technology.[37] He had genetically edited the CCR5 gene relating to HIV/AIDS in the embryos. Two baby girls, namely Lulu and Nana, were born from this clinical trial.[38] He had not received approval to conduct the trial and had taken a gigantic risk without any ethical considerations. Post the investigation of his work, it came to light that the two embryos were edited in different ways. While the process used was the same, the product was different. One of the embryos was said to have lost five proteins due to the editing which could have seriously affected her immunity. The consequences of this were drastic.[39]

There is also the possibility of mosaicism. This can lead to a myriad of problems that can be inherited by future generations as well. A few mutated cells in the body can lead to diseases and sometimes, a single cell might develop a tumour and the consequences cannot be treated until the affected cell or cells are destroyed.[40] In addition to this, there can be off- target effects of gene editing that can sometimes be missed even after thorough screening.[41]

(A) Ethical concerns

Ethically speaking, germ line gene editing poses a huge problem when it comes to several factors of the society. Firstly, the matter of consent of future generations when their parents have the autonomy to edit their genes to enhance certain traits in their children. This can be problematic when considering the rights of the child who might later question the decisions of

[37] Regalado A. EXCLUSIVE: Chinese scientists are creating CRISPR babies. MIT Technology Review (28 November 2018) https://www.technologyreview.com/s/612458/exclusive-chinese-scientists-are-creating-crispr-babies/

[38] Marchione M. Chinese researcher claims first gene-edited babies. AP News (26 November 2018) https://apnews.com/4997bb7aa36c45449b488e19ac83e86d

[39] Ibid.

[40] Rothschild J. Ethical considerations of gene editing and genetic selection. Journal of general and family medicine, 21(3), 37–47. (2020). https://doi.org/10.1002/jgf2.321

[41] Ibid.

the parent.[42] It is understood that parents still are the decision makers of their children's life till they become majors, but providing parents with the option of gene editing seems extreme. There is already criticism around procreative autonomy through non- gene editing modifying options that are available to parents (like IVF, pre- natal testing, and other methods) to help them decide which children they would like to have.[43] Providing such a power to parents will lead them to choosing between "desirable" and "undesirable" qualities in their children.[44] In case of possible disabilities in children, the said disability can be eradicated with gene editing. While these methods can help parents in their decision making, they still pose harm and risk factors that need to be considered.[45]

This can also lead to eugenics where parents will resort to genetic pre- testing as every other parent is doing so.[46] This will lead to discrimination against certain characteristics in the embryos by parents choosing one trait over another. This can also lead to superiority and inferiority among parents and children alike and will eventually lead to inequalities in the society, i.e., there already exist economic inequalities in the society, with the prevalence of gene editing, there will arise other forms of inequality and introduce new forms of discrimination in the public.[47] The economic inequalities will, in fact, lead to other forms of inequalities as parents from the upper class will have accessibility to new forms of technology, while parents from the lower class will not have the option to do so. Hence, accessibility to the invention also becomes an issue, unless TRIPS flexibilities like compulsory licensing are resorted to.[48]

Additionally, there may arise issues regarding the "hierarchy of diseases", what diseases are more important to be treated or prioritised over others.[49] There can be situations where certain diseases are to be prioritised over others and concluding on what diseases are to be treated first can lead to additional issues. Moreover, the diseases prioritised in different countries can be different due to the history, geography, habits, and other aspects of the country.[50] This can be a problem as the gene that is responsible for diseases might not be known to scientists even though it is a serious one.

[42] Myrisha S. Lewis, *Is Germline Gene Editing Exceptional?* 51 Seton HALL L. REV. 735 (2021).
[43] Ibid.
[44] Rima Kundnani, 'Protecting the Right to Procreate for Mentally Ill Women', Southern California Review Law and Society (2013).
[45] Julia D. Mahogany and Gil Siegal, 'Beyond Nature? Genomic Modifications and the Future of Humanity', Law and Contemporary Problems (2018).
[46] Ibid.
[47] Ibid.
[48] Article 31, of TRIPS Agreement.
[49] Ibid.
[50] Ibid.

One of the major ethical issues that arise from gene editing is the moral value and status of embryos. There are religious arguments in place that state the germ line gene editing is giving too much power in the hands of parents or scientists and leading them to "act like God" or taking the role of God.[51] This can also be construed as a naturalistic perspective to the issue as gene editing is going against the nature of how humans are formed. The issue of dignity for the embryos is also brought up. Gene editing, some believe, can lead to the devaluing of humans and raising expectations for humans to be a certain way, if it becomes too prevalent.[52] The religious scholars base their arguments on the belief that through the introduction of germ line gene editing, there will be a discrimination between naturally born humans and genetically edited humans, that will eventually lead to the devaluation of naturally born humans.[53]

Secular view of the dignity argument is based on the notion that it is against the genetically edited human as they will be the ones directly facing the consequences of the changes made to them.[54] Moreover, the changes are being made without their consent, and in that act, taking away their autonomy over their own body.[55] Gene editing can also lead to the commodification of humans as certain characteristics will be preferred over another, maybe even the advertising of the same can be bound to happen if there are no proper checks in place.[56]

The regulations should rather focus on making gene editing accessible only to eradicate deadly diseases, be it genetic or otherwise. While one wants to focus on the eradication of diseases, there arises question of what diseases are to be eradicated, and in what way. Is the germ line editing of the disease enough to eradicate the disease, or is the destruction of the embryo necessary (to prevent children with the disease from being born)? Where to draw the line? This is also a slippery slope.[57] Germ line gene editing can be used for benevolent and eventually malevolent uses.[58] What is to say that gene editing will eventually be used to enhance human beings to have better traits than what is already prevalent (like increasing height, enhancing intelligence and athletic abilities)?

VI. FURTHER ANALYSIS OF *ORDRE PUBLIC* AND MORALITY DOCTRINES

All these issues, and more, bring up ethical and moral considerations that are to be answered

[51] Ibid.
[52] German Ethics Council.
[53] Ibid.
[54] R. Alta Charo, 'Who's Afraid of the Big Bad (Germline Editing) Wolf?' Perspectives in Biology and Medicine (2020).
[55] Ibid.
[56] Karen Busby and Delaney Vun, 'Revisiting the Handmaid's Tale: Feminist Theory Meets Empirical Research on Surrogate Mothers', Canadian Journal of Family Law (2010).
[57] Eugene Volokh, 'The Mechanisms of the Slippery Slope', Harvard Law Review (2002).
[58] Ibid.

by the law. Introducing limitations and exceptions to the use of gene editing and stem cell technology is one way to introduce the practice into the society. Under the TRIPS Agreement, countries have the power to have national legislations that cater to their needs as per the TRIPS flexibilities. There are pre and post grant limitations available to countries.[59]

While pre grant limitations could be in the form of exemptions to certain activities, processes, and products that will not fall under the ambit of patent law, post grant limitations are the laws that can be used to regulate the introduction of the new technology into the market. One major example of pre grant limitations is *ordre public* or the morality provisions under Article 27(2) and (3) of the TRIPS Agreement.[60] Questions under these provisions arise especially in the case of gene editing and stem cell technologies.

Under post grant limitations, products and processes continue to be under scrutiny in case they are against the law. This is especially the case where the standards and efficacy of the products needs to be checked. In any case the product does not perform well, it can be removed from the market and prohibited from being commercialised. The pharmaceutical and medical sector is where this practice is most prevalent as the products can be tested at a larger range once it is distributed in the market. Regulations around the accessibility and the availability of the drugs is also most important.

The TRIPS Agreement clearly provides that certain inventions can be excluded from being patented when they go against public order and morality. This was introduced keeping in mind the larger interests of the society, i.e., "to protect human, animal or plant life or health or to avoid serious prejudice to the environment."[61] Inventions that pose as danger to the interests of the society at large are to be excluded from patent protecting and they are not eligible to fall under the patentable subject matter. The main aim of this provision is to promote public welfare,[62] but as patent law is nationalised, certain countries have a narrow interpretation of the morality and *ordre public* provisions depending on the social and economic factors.

Some jurisdictions do not have the morality and *ordre public* provision in their national legislations, like the US. Though there is no mention of morality in the statutes, the courts in the US have considered the issue in the utility doctrine to protect the human body from being patent eligible.[63] The courts have discussed the issue through several landmark judgements by

[59] Ibid.
[60] UNCTAD-ICTSD Project on IPRs and Sustainable Development, Resource Book on TRIPS and Development (Cambridge: Cambridge University Press, 2005).
[61] Article 27, TRIPS Agreement.
[62] WTO, Canada — Patent Protection of Pharmaceutical Products, Report of the Panel, WT/DS114/R (17 March 2000) www.wto.org/english/tratop_e/dispu_e/7428d.pdf
[63] T. Minssen, 'Patenting Human Genes in Europe — and How It Compares to the US and Australia'

prohibiting the patenting on medical methods,[64] isolated human genes (differentiating them from cDNA)[65] and narrowing the definition of what can be protected under the law.

This is not the case in Europe, where several countries have included the said provisions in their national laws, even prior to the TRIPS Agreement.[66] As mentioned previously, Article 53(a) of the EPC holds similar provisions to Article 27(2) of TRIPS Agreement. Though there is no clear definition of *ordre public* and morality, the same can be understood from what is not patentable. The provisions or this can be found in the EU Biotechnology Directive.[67] The meaning of the terms has developed through the years through case laws. From the Oncomouse case to the Brüstle jurisprudence, the meaning of the terms has developed. In Relaxin, the court held that the morality assessment depended on the invention being abhorrent to the standards and culture of the society,[68] and the Plant cells case held that the concept of *ordre public* is present to the public welfare, security, and integrity of everyone.[69]

VII. CONCLUSION

The law can apply precautionary principles and exercise caution in cases where there is lack of evidence on the part of science (while permitting research without applying it to society in case of lack of evidence on the efficacy of the invention). It is also important to bring in procedural fairness for clinical trials in to make sure that there is proper research being conducted, that is not against the law. It is always better to weigh in the benefits and risks and the possibility of the results of an invention before making it applicable to society.

Science and technology continue to develop constantly, but the law and society cannot keep up with the pace of development. It is necessary that the law imbibes the values and cultures of the society in regulating new and unique inventions and to consider questions of *ordre public* and morality while regulating the research as laws are being made for the society. It is important for law to bring a balance between the welfare of the society while also keeping in mind the scientific advancement cannot be stopped to fulfil the demands of the society. A complete ban on the gene editing and stem cell research is impossible, hence, it is for the legal system to

[64] Mayo Collaborative Servs. v. Prometheus Labs, Inc., 132 S. Ct. 1289 (2012).
[65] Association for Molecular Pathology, et al. v. Myriad Genetics, Inc. 569 US 576, 133 S. Ct. 2107 (2013).
[66] L. Bently, B. Sherman, D. Borges Barbosa, S. Basheer, C. Visser and R. Gold, 'Exclusions from Patentability and Exceptions and Limitations to Patentees' Rights', WIPO Standing Committee on the Law of Patents SCP/15/3 Annex I (2010) https://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex1.pdf
[67] Articles 5 and 6 provide what is patentable and what is not. While the former makes it clear that human body, parts, and the whole of it are not patent eligible as they are mere discoveries of nature, the latter makes it clear that certain inventions like cloning human beings, processes for modifying the germline of human beings, and the use of human embryo for industrial and commercia purposes is ineligible to be patented.
[68] European Patent Office, T 0272/95 (Relaxin/HOWARD FLOREY INSTITUTE) of 23.10.2002.
[69] European Patent Office, T 0356/93 (Plant cells) of 21.2.1995.

bring in regulations to protect both sides.

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