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EXCLUSIONARY CRITERIA IN GENE PATENT

AUTHORED BY - POULAMI DAS

1. Introduction:

Over the last decades, genetic research is being more and more practically oriented with the application of gene patenting, where certain rights are given to institutions to use specific genetic sequences and technologies. This sharp uptrend in gene patenting can be traced to biotechnological development, heightened business interest, and the prospect of being rewarded well. Whilst gene patents, including a patent of a human genetic material, may grant respective developers an incentive and become a measure to attract investment, they also raise severe issues.

Contrary to the public understanding of gene patenting, the intellectual property over genetic information could determine the eligibility of genetic materials to the ownership of a patent holder and offer access to the genetic information to a limited number of people. These criteria define the choices that pertain to who enjoys control over specific genetic sequences or technologies and who is barred off from having access to what they require.[1] The most they have done is pushing the frontiers of scientific inquiry globally, evolving new therapies and health care delivery which in one way or another have a cascade effect to all corners of the globe.

Gene patenting that includes particularly is not limited to just laboratories and courts, but also raises questions of equity, rights, and justice in the provision of healthcare services.[2] The implications are not limited to scientific research and information sharing, but include dissemination of research results and scientific advancement as well.

Gene patents and exclusionary criteria frame the movement and equitable distribution of genetic materials, therefore, an appropriate position on both innovation and access to genetic resources is necessary.[3] Through a critical evaluation of exclusionary criteria, we can allow

[1] See Human Genome Project information at http://web.ornl.gov/sci/techresources/ Human Genome/index.shtml.
[2] http://www.genengnews.com/insight-and-intelligenceand153/gene-patents-in-europe-relatively-stable-despite-uncertainty-in-the-u-s/77899385/
[3] http://www.smh.com.au/national/brca1-gene-patent-ruling-to-be-appealed-20130304-2fg1f.html.

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scientific achievements to be directed to uplifting mankind instead of being looked at as belonging to a privileged group or motivated by profit making.

2. Research Question:

What are bioethical and legal disputes relevant to gene inclusion criteria, and how do they affect innovative activity, use of healthcare services, and welfare of the population at large?

3. Historical Background of Gene Patenting:

Gene patenting germinated a bit after the 1970s, a time when the world experienced dazzling discoveries that regenerated the process of molecular biology and genetic engineering. It was during this epoch that scientists achieved a momentous milestone: the procedure of eliminating the initial gene to be followed by the cloning of a new one.[4] It opened up the mystery of the genetic code to us, but this progress wrongly suggested that a new era has just dawned on our exploration, bringing all golden opportunities for medical research and biotechnology.

In the wake of this watershed moment, the landscape of genetic research underwent a profound transformation, as stakeholders grappled with the implications of commercializing genetic discoveries. Youthful by the prospect of financial rewards and the surge into biosciences helped the budding field of gene patenting to materialize and take the shape. To this end, striking a balance between the fuss that science has generated and the capitalistic drive saw the world's patent offices become the target of a growing inflow of patent applications that sought exclusive rights to genetic sequences and technologies.

The gene patenting craze grew even stronger after the missing link in the legal intricacies was filled in through the **Diamond v. Chakrabarty** judgment that was passed in 1980 in the USA legal system.[5] At the crux of this judicial showdown lay a fundamental question: could living things which have been altered genetically be similar to abstractions for instance a math formula and thus eligible for patent? From now on, the court decision will be recognized as one of the pillars on the ground of the genetical engineering law, science, and commerce, and it broke in favor of selling modifications.

[4] Zuhn D. "Gene Patenting Debate Continues". *PatentDocs: Biotech & Pharma Patent Law & News Blog*.
[5] Diamond v. Chakrabarty 44 U.S. 303 (1980).

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The Chakrabarty decision in fact has quite an impactful and extended reach, challenging the boundaries that genetic research has been placed into, on a general scale.[6] The questionable ruling granting patent protection to genetically modified organisms ("GMOs") ushered in a tempestuous wave of changes in the concept of intellectual property by laying the foundation for the patenting of human genes and genetic sequences.

Similarly, the rise of gene patenting was not without its skeptics and detractors who saw it as the introduction of intellectual monopoly in the field of genetics. Critics raised a number of issues challenging the ethical and societal outcomes of DNA commercialization, advocating among others for the prevention of monopoly, creative space, and free access to inheritable genetic gears. So, although sequence patents have really stimulated scientific progress and actually called for investment in genetic research, they still lead to very fierce debates among people concerned about the question of commercial benefits vs their own good.

In brief, the track of human gene patenting has become an integration of scientific breakthroughs, the influence of the courts and market haste. On one hand, it indicates the infinite desire of humanity for knowledge and innovation, but unfortunately, it also stands for the genetic data commercialization dilemmas as well as the societal discords.[7] Keeping pace with the dynamic revolutionary forces shaping the realm of genetics and biotechnology, it is imperative that we take measures to avoid repeating the mistakes of the past while at the same time, breaking new grounds in harnessing the power of genetics for the well-being of the human race.

4. Exclusionary Criteria in Gene Patenting:

Such exclusionary patent language accumulates to a specific set of criteria streamlined by the patent owners to inhibit those who are not a part of the patent holders community from using, improving or exploiting newly created inventions.[8] These standards are an unbreakable weapon against the patent holders using which they ensure control over their property as well as the dominance over the genetic inventions.

These restrictions are mostly in the form of a range of conditions such as the ripe of the licenses,

[6] *Ibid.*
[7] *Ibid.*
[8] *Ibid.*

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imposition of the research constraints and imposition of the diagnostic testing barriers. This resolution is equivalent to packing 3D printers, amputation kits, and medications into a backpack or a similar case.[9] Therefore, indigenous people get easier access to modern medicine when search and rescue forces arrive at disaster areas.

This implies that the physiological influence of gene patents extending outside the laboratory ripples far and wide, impacting scientific findings, medical ability, as well as the health of patients. Through creating barriers to entry and through strangling competition, the genetic patency restriction has a potential to restrict the speed of scientific discovery, delay the creation of novel medications, and dampen the innovative ardour of the genetics field, which is the main force of the progress in this field.

5. Ethical Implications of Exclusionary Gene Patents:

The implications derived from gene patents being exclusive with respect to justice, accessibility, and individual autonomy are like a twine that interwoven many areas, thereby provoking debates.[10] This patenting of genetic tests and therapies is the major barrier for the equitable distribution of healthcare, as it mostly leads to the insanely high prices of genetic tests and presented therapies which are out of reach for the poor class of society. Hence, the racial disparities in healthcare access are widened due to gene intangibles. The poor would now have to stay with their stipulated upper limit, whilst the rich would continue to enjoy the luxury of a customised health treatment or even personalised medication based on their DNA.

In addition to that, the monopolistic potential which is created by gene patenting is one of the major ethical problems that regulators need to address because gene patenting can stifle competition and lack of innovation in the biotechnology field as well. As a result of conferring narrow property rights, gene patents create a gate for small players to be shut off of the market, which leads to the absence of discovery, growth, and evolution in science. Not only does it influence market characters, it also under specialists in the field who have different parts of the same idea.

The freedom of the individual to exercise their patient autonomy is additionally violated in this

[9] http://www.smh.com.au/national/brca1-gene-patent-ruling-to-be-appealed-20130304-2fg1f.html.
[10] Caulfield, TA; Gold, ER (2000). "Genetic Testing. Ethical Concerns, and the Role of Patent Law". *Clinical Genetics*. **57** (5): 370–75. doi:10.1034/j.1399-0004.2000.570507.x. PMID 10852371. S2CID 40855297

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organizing principle through the described encroachment of gene patents on genetic information. Under such circumstances, individuals may be shut out from gaining access to vital facts about their genetic makeup, thus rendering them incapable of making personal healthcare choices which are pivotal in determining their personal health and well being.[11] The loss of patient autonomy results not only in a violation of the rights of the individual but also in undermining public trust in the healthcare system being the reason for that culture of paternalism and secretiveness contrary to the ethics of medical practice.

Who owns the gene is a question plaguing IP law in particular, which becomes acute when a certain gene is patented, thus posing a moral dilemma to lawmakers worldwide.[12] Through the pursuit of transparent policies, encouraging competition and protecting patients' rights when it comes to genetic innovation, policymakers have the opportunity to work towards a tomorrow where genetic technologies will accomplish the greater good and avoid being steered by the demands of profit makers. If ethical concerns are not resolved by joint activities, it is difficult to build up an acceptable strategy of genetic component of research and health care supply.

6. Legal Frameworks and Regulations:

Patents linked to genetics and the setting up of specific restrictions on the resources are within a pluralism of laws according to which each country is distinct legally. However, the U.S. which is a leading country and most likely has followed a liberal regime by granting the legal status of genes, has a completely different system in the European Union, where there are more restrictive laws.[13] These different approaches are a true indicator of the different thoughts that might come to the surface concerning the commercialization of gene discoveries across different ethnic, moral and economic considerations among the policymakers.

In the USA, the legal framework of gene patenting has, as can be put succinctly, adopted a fairly lenient approach, where patent offices have commonly been in the position of deliberating the granting of patents of genetic sequences and technologies under a rather liberal eye. This facilitative trend crowned when the major case of Association for Molecular Pathology v. Myriad Genetics, the Supreme Court's most memorable judgment, shed doubtful

[11] "Patenting Antibody-Based Biologics In Canada - Intellectual Property - Canada". *www.mondaq.com*.
[12] See Human Genome Project information at http://web.ornl.gov/sci/techresources/ Human Genome/index.shtml.
[13] See Human Genome Project information at http://web.ornl.gov/sci/techresources/ Human Genome/index.shtml.

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light on the morality of patents of genes. The Court's attempt to negate Myriad Genetics' patent assertions concerning the isolated human genes was indeed to ambitiously permit a thorough review of the existing attitude towards gene patenting, with the aim of ensuring that the criteria for patentability be interpreted as tailored as possible for this type of invention.

Contrastingly, the European Union countries follow a more preventive method to genetic patenting, with legal structures that are explicit on the need for public health and also the promotion of innovation.[14] Also they also give due care to copyright issues which enable everyone to access genetic resources. This set of legislations is incorporated, as in the directives like Directive 98/44/EC on legal protection of biotechnological inventions, and poses demands on patentability, which entails more genuine technological innovation and industrial effect.

The latest jurisprudence in the invention of Myriad Genetics, courtesy of the Supreme Court, is a real impetus for initiatives concerning the revisioning of the gene patents world and the consequences of such a move for scientific progress and the public good. The fact that gene patents have been proved to be invalid for some and their associated exclusionary requirements have been scrutinised, the legal cases that preceded and sparked debates of the appropriate balance between incentivizing innovation and safeguarding access to information of genetic nature.[15] While the task of policy makers is gaining a better understanding of the intricacies of these situations, a harmonized and equitable approach to gene patenting is what is needed, which will mesh the concept of intellectual property with the overall imperatives of society.

7. Case Studies: Impact on Innovation and Access to Healthcare:

While the European Union countries push for the researching and caring of public interests and innovation by having explicit laws governing the use of genetic patents, the United States stick to the savings patents method which in most cases compromises human welfare.[16] The same thing they also do take care of copyright relations, thanks to which you will get the chance to use genetic resources belonging to all. The legislations given are an example of the legal directive such as Directive 98/44/EC on the legal protection of biotechnological inventions, and as such they pose demands on the patentability which means that the new technology and industrial impact is more and more mentioned.

[14] http://archive.epo.org/epo/pubs/oj009/05_09/05_3069.pdf
[15] *Ibid.*
[16] *Ibid.*

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The new jurisprudence on the invention of human genes provided by the recent adjudication of Myriad Genetics by the US Supreme Court serves as an amazing impetus for a plan to reconsider the old practices in patenting of human genes and to contemplate its implication toward the scientific enhancement and public welfare. Not only is the invalidation of gene patents for some and correspondingly the scrutiny on their exclusive requirements candidates, but also the legal cases that started these opinions and the disputes over equilibrium (encouragement of innovation with safeguarding of information of genetic nature) prove these things. However, the onerous duty of policy-makers is to avoid getting lost in the details of these situations and instead to forge ahead with a fair and just approach to the governance of genes which will integrate the complexity of intellectual property norms with the overarching rights of society.

In the same manner, regular patenting of genetic testing technology for the interpretation of rare diseases has caused a lot of ethical and practical concerns, especially when the rare disease patients check on affordability and availability of the diagnostic kit.[17] On several occasions, the imposition of criteria that are not inclusive enough have been the reason that the genetic tests are costly thereby the patients can't afford them when they are struggling with the rare illnesses that they are battling with. These subtleties are deep, as the situation only makes it worse for those who have rather poor access to good doctors, thus they are finding themselves at the mercy of chance and even luck.

By analyzing these scenarios with a critical mindset, the stakeholders accomplish the task of understanding the different problems emerging from the use of patents to limit certain genetic information. They reveal the complex dance of intellectual property rights, health care delivery and science productivity which urges a rethink of the current patenting practices with respect to the implications for overall health of a society.[18] The policymakers and practitioners are presented with a chance not just to move simultaneously with the way that these complexities are being navigated, but also to complete an equitable and morally defensible system of law where more attention is being paid to the needs of the community rather than individual commercial interests.

[17] *Ibid.*
[18] iPS Cell Technology Spurs Biological Patenting in Japan (PDF), World Intellectual Property Review.

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8. Socioeconomic Considerations:

The inter-sectoral picture of the gene patents which are exclusionary transcends mere healthcare inequities which are only healthcare; national healthcare systems will be further bridled by them; and this will affect especially low- and middle- income countries where access to medicine and medicinal technology is already limited. In this regard, patent monopolies, conferring sole ownership of genetic innovations, are equipped to maintain an economic system that is already unfair while preventing those in difficult situations from getting hold of drugs that can prolong their lives and forming a cycle of poverty and sickness in society.

Moreover, the promotion of commercial genetics investigations set out by financial goals can, paradoxically, lead to the denominations of public health concerns by monetary creations.[19] This result-driven mechanism of exploration may stimulate inattention to those diseases which are predominantly present among the marginalized groups that cannot initiate proper monetary stimulation in their research and development. As a result, these communities, in that case, are more likely to be curved down in the realm of diseases, without any support for carrying out successful prevention and cure. Hence, the issues do not receive the required attention and resources.

The repercussion of such gene patents is not convoluted within the laboratory structure, as the problem creates acute social injustice, and finally widening the economic gap around the globe. In the course of this intricate struggle, it becomes clear that we need to develop a comprehensive system of laws that will address the foundation of social injustices in the age of commercialized genetic research and create a progressive regulatory environment that values fairness and equal treatment of everyone regardless of social status or geographical location.[20]

9. International Perspectives:

The issue of gene patenting is not only domestic but is international, so it's required for it to be handled by having collaborative efforts and aligned policies on an international level. It is important to note that while some jurisdictions have chosen to pass a moratorium entirely on developments in gene patenting, others continue to issue patents for genetic sequences and

[19] Zuhn D (9 Jun 2009). "Gene Patenting Debate Continues". *PatentDocs: Biotech & Pharma Patent Law & News Blog*.
[20] Caulfield, TA; Gold, ER (2000). "Genetic Testing. Ethical Concerns, and the Role of Patent Law". Clinical Genetics. 57 (5): 370–75. doi:10.1034/j.1399-0004.2000.570507.x. PMID 10852371. S2CID 40855297

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technologies marking a stark dissimilarity in terms of intellectual property rights and biomedical innovations.

Achieving the same level of harmony among patent laws of different nations will constitute a substantial step in the direction to fighting the negative effects of the exclusionary use of gene patents. The creation of a framework that is aimed at improving consistency and coherence of the legal framework, is one of the ways policymakers can ensure that this type of technology is facilitated on a level playing field. Additionally, it helps ease equitable access to genetic resources and technologies.

Moreover, the improvement of patenting process transparency will go on to provide accountability and build up public trust in the management of the genotype code.[21] Transparency measures can be employed like public gene patent registries and disclosure requirements for patent holders so that when such patent holders are forced to publicize their information it would create greater scrutiny as well as inclusivity fostering a transparent environment for proper genetic research and innovation.

If no global coalition is built to tackle the problems caused by genetic patents, it can only be assumed that the discussed issues will continue to be seen, undermining the attempts to further scientific development, public health, and fairly address the health gap across the globe.[22] Through incorporating a cooperation model based on mutual respect and mutual responsibility, the international community may find a way to create a just and sustainable future in which genetic technologies happily coexist with this.

10. Conclusion:

The issue would be to clearly understand the complexity of the exclusionary criteria of gene patenting, which will ambivalently contribute to the ethical and the legal dilemmas. Therefore, practical solutions should be employed, which will handle the issue well.[23] Connecting all the different parties into conversation will definitely help and protecting the patenting process as transparently as possible will be one more step forward to resolving these issues so that we would use genetic research at its full potential for domestic improvement.

[21] *Ibid.*
[22] Sharples, Andrew. "Gene Patents in Europe Relatively Stable Despite Uncertainty in the U.S.
[23] *Ibid.*

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Having dialogue that is frank and includes everyone makes it easier to uncover shared values and concerns, which subsequently leads to collaboration and consensus towards a sustainable solution that favors everybody. Transparency in patenting process – it is an accountability and trust enrichment factor for stakeholders to inspect and challenge if exclusivity claims affect negatively in scientific progress or limit availability of important healthcare interventions.

Additionally, through the enactment of policies encouraging the public interest rather than narrow profit orientations, policymakers and industry leaders play a role of cultivating an ecosystem that promotes innovation alongside distribution of benefits obtained through genetic research on an equitable basis.[24] This calls for regulation and enforcement of policies that support open and controllable access to gene tests as well therapy that is also low cost, especially the poor who otherwise might be exempted from the non-inclusive practices.[25]

By following a broad and long-term approach with an ethical sharp focus and social responsibility, we can utilize genetic research to improve public health and human well-being and our society as a whole while at the same ensuring the principles of equity and justice.[26] The collective efforts can move us into the future which would be able to take care of the people of all the social categories, even at those extreme economic and geographic situations.

[24] *Ibid.*
[25] Caulfield, TA; Gold, ER (2000). "Genetic Testing. Ethical Concerns, and the Role of Patent Law". *Clinical Genetics*. **57** (5): 370–75. doi:10.1034/j.1399-0004.2000.570507.x. PMID 10852371. S2CID 40855297
[26] iPS Cell Technology Spurs Biological Patenting in Japan (PDF), World Intellectual Property Review.