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OPTIMISING PATENT FRAMEWORKS-ENGINEERING LEGAL SOLUTIONS FOR GENOMIC SEQUENCING

Aradhana Singh[1], Mrs. Darshi Sharma Guhey*[2]
[1]LLM Student, 4th Semester, Kalinga University, Raipur, Chhattisgarh
[2]Assistant Professor, Faculty of Law, Kalinga University, Naya Raipur, Chhattisgarh
darshi.sharma@kalingauniversity.ac.in

ABSTRACT
This paper explores the complex connection between intellectual property (IP) and genomic sequencing, emphasizing the legal hurdles and ethical dilemmas that emerge as human genome research advances. It explores the contentious domain of gene patenting, the complexities of data ownership, and the consequences for research, healthcare, and society. The author evaluates different genetic patent aspects, such as technologies, materials, and products, and their eligibility for patents in various jurisdictions. The article also delves into important legal battles that have influenced the gene patenting field, including Diamond v. Chakrabarty and the Myriad Genetics case. Likewise, it discusses the ownership of genetic information, the involvement of data-sharing organizations, biobanks, and informed consent in the management of this data. It highlights the significance of fair availability of genetic technologies in low-resource areas and the influence of licensing practices on worldwide health results. The article ends by providing a global outlook on gene patenting, evaluating strategies in the US, the UK, Canada, China, Australia, Japan and India.

Keywords: Biobanks and Data Ownership, Ethical Considerations, Intellectual Property, Genomic Sequencing, Gene Patenting

1. INTRODUCTION
The connection between science and law is growing more complex, especially as scientists explore the secrets of the human genome, highlighting the significance of intellectual property rights. This article explores the relationship between intellectual property (IP) and genomic sequencing, covering topics like gene patenting, data ownership, and access. The combination of scientific investigation and legal concepts poses difficulties as well as possibilities, as demonstrated by the completion of the Human Genome Project in 2003. Nevertheless, this significant event signalled the start of a fresh chapter in genomic studies, as swift technological progress raised unique concerns regarding ownership, creativity, and availability of genetic data. In the 1990s, disputes over genetic innovation patents intensified, including concerns about extensive patent claims and unknown sequences. The Human Genome Project and Watson and Crick's DNA discovery paved the way for modern genetic research.

In this crossing, the author examines the intricate connection between science and law in the field of genomic sequencing. The goal is to improve society's understanding of the issues that arise in the genomic era by examining the challenges, opportunities, and ethical dilemmas that occur at this intersection. The close connection between science and law is clear, growing more complex as scientific progress reveals more about the human genome. Intellectual property rights, especially concerning gene patenting, play a crucial role in this area. The research delves into the intersecting fields of IP and genomic sequencing, specifically emphasising ownership of data and access outside of patents. This expansive landscape presents challenges and opportunities, requiring cautious navigation. Our expedition will explore the changing terrain where scientific discovery intersects with legal concepts, illuminating points of agreement and disagreement. The author aims to shed light on how science and law intersect in unlocking the full potential of the human genome through this exploration.

2. Navigating the Legal Genome: Exploring IP in Genetic Innovation
Gene patents primarily cover genetic technologies, natural and isolated genetic materials, and genetic products such as proteins. Twenty years after the initial genomic project, biotechnology has shifted its focus to patent

systems, particularly in genetics and related technologies. Genetic patents will include natural genetic materials, isolated genetic materials, genetic technologies, and genetic products for conciseness.

Let's look at the terminologies:

- Genetic technologies encompass tools and methods used in genetic research and healthcare, like DNA sequencing, genetic testing, and gene therapy. These technologies involve amplifying DNA through techniques like PCR and DNA cloning. Patenting new genetic technologies is typically less controversial than genetic material patents, as criteria like 'invention' and 'novelty' are more easily met.
- Genomic constituents, such as DNA, RNA, genes, and chromosomes, are considered ordinary in their original state. In Australia and many other countries, patent law distinguishes between natural genetic materials within living organisms and isolated genetic materials that have been purified through a specific process. Patent claims for DNA must demonstrate a clear distinction from naturally occurring materials. Stem cells and other genetic materials may be patented if isolated and cultured to create a cell link.
- Remote inherited resources like cDNA and genetic sequences are forms of genetic material that can include coding or non-coding sequences. Gene patents covering isolated genetic materials incorporate genetic sequences in the description of the patented invention. Extracted genetic material from complete genes or coding sequences. can be used for genetic condition diagnosis, therapeutic protein production, gene therapy, and other applications. Gene fragments, such as SNPs and ESTs, encode important protein regions, and patenting them could be controversial without information about their linked gene function.
- Genetic products, such as proteins and nucleic acid constructs, can be patented if they are isolated or synthesized. Proteomics, the study of proteins and their functions, is seen as the next frontier in genetic science. By utilizing genetic materials, new drugs and treatments could be developed, building on the groundwork of sequencing the human genome.

The patent system birthed over 400 years ago, has adapted to technological advancements, like gene patents in bioinformatics and nanotechnology. Challenges persist in determining the uniqueness and utility of genetic inventions, sparking legal concerns like Diamond v Chakrabarty and legislation like the Bayh-Dole Act. FDA's 1982 approval of the first recombinant DNA drug was a milestone, enabling genetically modified products in medicine and the growth of the biotechnology industry in the 1980s. Advancements in sequencing methods, as well as the approval of patents for whole creatures such as the 'Harvard Mouse', led to ethical discussions concerning the patenting of more intricate organisms. Genetically engineered animals have become highly beneficial resources for medical research.

2.1 CASE STUDIES

a. Diamond vs Chakrabarty 447 US 303 (1980)

Facts: During the 1970s, Ananda Mohan Chakrabarty, a microbiologist at General Electric, created a genetically engineered bacterium that can decompose crude oil, commonly referred to as "oil-eating" bacteria. Chakrabarty submitted a request for a patent with the USPTO for his genetically engineered bacterium invention. This particular bacterium, belonging to the Pseudomonas genus and identified as Pseudomonas putida, demonstrated significant potential in dealing with oil spills. Chakrabarty sought a patent for the live, artificially created microorganism, but the Patent Office rejected the request because they deemed the microorganisms as natural products and ineligible for patenting. The Board of Appeals upheld this ruling; however, the Court of Customs and Patent Appeals overturned it, resulting in a review by the United States Supreme Court.

Analysis

- Initial Refusal: Chakrabarty's patent application was initially turned down by the USPTO because living organisms were deemed ineligible for patents under Section 101 of the U.S. Patent Act, which only allowed patents for new and useful processes, machines, manufactures, or compositions of matter.

- The team worked together to complete the project on time. Chakrabarty filed an appeal with the Patent Office Board of Appeals after the rejection, and they upheld it by stating that living organisms, being products of nature, cannot be patented.
- Despite his best efforts, he was unable to solve the difficult math problem. Chakrabarty appealed to the CCPA, who overturned the Patent Office Board of Appeals decision, stating that the bacterium qualified as a "manufacture" or "composition of matter" under Section 101.
- An appeal was made to the U.S. Supreme Court, which agreed to hear the case to determine whether living organisms, specifically genetically modified microorganisms, were eligible for patents in the Section 101 of the Patent Act.

Verdict: The U.S. Apex Court, in a groundbreaking ruling sided with Chakrabarty, deciding that genetically modified microorganisms could be legally patented under Section 101 of the Patent Act. The Court concluded that Chakrabarty's genetically modified bacterium, despite being a product of nature, was eligible for patent protection as it was a man-made microorganism with distinct features compared to its natural counterparts. The Court stressed that Chakrabarty's discovery went beyond simply finding something existing; it entailed the development of a distinct bacterium with special characteristics through human involvement.

Evaluation of the ruling: The Supreme Court of the United States determined that a living, artificially produced microorganism is not naturally occurring and can therefore be eligible for a patent. The court declared that the vitality of microorganisms is unimportant in terms of patent law. The court acknowledged that recombinant DNA technology is a contentious field and suggested that Congress, not the court, should be responsible for balancing the conflicting values and interests involved.

Importance: The Diamond v. Chakrabarty case set an important example in patent law by confirming that genetically modified organisms (GMOs) could be patented, opening the door for the patenting of biotechnological inventions. It acknowledged the importance of human involvement in developing new microorganisms and broadened the range of patentable material to encompass living beings altered by genetic manipulation. The ruling inspired creativity in the biotechnology sector and initiated discussions regarding the moral, societal, and financial consequences of patenting living organisms.

b. Dimminaco AG vs Controller of Patents and Designs (2002) I.P.L.R. 255 (Cal)

2.2. Gene and Indian Patent System:

The *Dimminaco AG vs Controller of Patents and Designs* case in the Calcutta High Court in 2002 was the initial case to challenge the legal rules concerning gene patenting.

Facts: The company applied for a patent for a process aiming to develop a Bursitis vaccine, which resulted in the creation of living organisms. However, the patent application was rejected by the Patents Office, arguing that the process did not meet the criteria of a "process of manufacture" under the Indian Patents Act due to the resulting living product being considered a natural occurrence.

Ruling: In its ruling, the court overturned the Patents Office decision, stating that patenting a production method, even if it results in a life form, is legally permissible. Revisions to the Patents Act in 2002 allowed for a patent in the microbiological and biological processes. However, natural DNA cannot be patented under Indian law, following Sections *3(c)* and *3(j)* of the Patents Act.

Analysis of the after-effects: Until 2013, the Indian Patents Office allowed patents for isolated genomic DNA. However, the 2013 Indian Biotechnology Guidelines reclassified isolated DNA as a "discovery," making it ineligible for patents under Sections *3(c)* and *3(d)* of the Indian Patents Act. This classification considers standalone DNA to be a new form of a known material without increased effectiveness and, therefore not patentable. The status of cDNA's patent eligibility is uncertain due to its artificial derivation from natural

material. Indian patent law lacks clear standards on the level of human intervention required for natural objects to be patentable, despite restrictions in Sections *3(c)*, *3(d)*, and *3(e)* of the Indian Patents Act.

The Act defines an "invention" as a new commercially applicable product or process with an inventive component. Indian patent law aligns with US law in not granting patents for natural products and outlines categories of inventions ineligible for patent protection based on policy principles in Section 3 of the Indian Patents Act.

For brevity, a table has been provided to understand the difference in the parts:

Sections	Before Amendment	After Amendment (2005)
3(c)	Simply finding a different version of a substance that is already known, without any improved effectiveness, is not eligible for a patent.	Same as before: New form must enhance efficacy.
3(d)	A new form of a known substance is patentable only if it enhances efficacy.	Stricter criterion: Enhanced efficacy required for new forms and new uses of known substances.
3(e)	Mere discovery of new properties or new uses for known substances, efficacy enhancement is required.	Same as before: Enhanced efficacy needed for new properties or uses.
2(1)(j)	Definition of “invention”: New product, process, or inventive step with industrial applicability.	The definition remains unchanged: Encompasses new products, processes, and inventive steps with industrial use.

Table 1: A table showing the difference between sections before and after amendments

2.3 Patent eligibility- Gene and Genetic Technology:

Eligibility of genes and genetic technology for patents. Here is an analysis of important elements:

- **Is it possible to patent genes themselves?**

It is typically not allowed but, in many nations, naturally, isolated genes are typically not eligible for patents. This is because they are seen as creations of nature rather than creations of humans. Exceptional cases and restrictions are placed in a few nations that permit patents on separated genes under certain circumstances.

- **Specified Function:** The gene should possess a recognized purpose, rather than simply being a random sequence (e.g., UK). For an isolated gene to be considered patentable, it must show inventiveness that would not be apparent to someone with expertise in genetics in countries like the EU, India, Canada, and Brazil. cDNA, or complementary DNA, is a type of synthetic DNA that could potentially be eligible for patents in certain countries like the US.
- How do Genetic Technologies fit into the picture? It is more probable for patents to be approved for inventions that come from genes. For example: Genetically Modified Organisms (GMOs): Changing the genetic composition of an organism may qualify for a patent in numerous nations.
- Gene usage techniques can be patented, even if the gene sequence is not patented. Tools for diagnosis that utilize genes could potentially be eligible for patents.

Methods of treating diseases by manipulating genes through gene therapies may be eligible for patents.

- Biopiracy is a concern that arises when genetic resources are gathered from communities without obtaining proper permissions or agreements for sharing benefits.

  Gene patents can restrict access to medical care if the cost of genetic tests or treatments becomes prohibitively high.

3. Ownership of Genetic Data- Investigating Genetic Data Ownership: How Data-sharing Institutes, Biobanks, and Informed Consent Shape the Landscape

Personalized medicine utilizes genetic information to develop tailored treatments, improve health outcomes, and identify disease-linked variations through DNA analysis. The debate over data ownership continues, with individuals seeking control over their genetic data while researchers argue for shared access to advanced scientific knowledge. Genetic data is also valuable commercially for predicting disease risks and optimizing drug treatments. Balancing data ownership and research needs is crucial for the transformative impact of genetic data in the healthcare and pharmaceutical industries.

3.1 The US Department of Veterans Affairs operates the Million Veteran Program (MVP):

This program gathers genetic information and health data from more than 850,000 US military veterans. The original objective was to comprehend the genetic foundation of different health issues impacting veterans, like PTSD, traumatic brain injury, and cardiovascular disease. Nevertheless, the project has broadened its focus on research to encompass fields such as cancer, mental health, and the efficacy of drugs. This illustration demonstrates how genetic data gathered for particular reasons can be applied to wider research fields with appropriate consent protocols.

3.2 The UK Biobank is a biorepository in the United Kingdom:

This resource is a biomedical database with a vast amount of genetic and health data collected from more than 500,000 people in the UK. At first, the main attention was on studying the genetic and environmental factors that play a role in common diseases such as cancer, heart disease, and diabetes. Yet, scientists have utilized the UK Biobank information for various research projects, such as creating innovative diagnostic instruments, investigating the impact of ageing, and uncovering connections between genetics and mental health disorders.

These instances demonstrate how data-sharing institutions can use genetic information for different research objectives beyond the original intention, as long as it adheres to the rules of informed consent.

4. Strategies for Equitable Access in Low-Resource Settings:

4.1 Access to new healthcare technologies and treatments is vital for improving global health outcomes, especially in resource-constrained areas. However, various licensing methods and access barriers often impede the realization of these benefits. High licensing costs set by patent holders can make necessary medical treatments unaffordable.

4.2 Encouraging patent holders to collaborate with non-profits allows for generic drug production at lower costs, improving treatment accessibility. Open-source licensing fosters innovation and collaboration in healthcare solutions. Technology transfer initiatives boost healthcare sustainability by sharing expertise in low-resource areas.

4.3 Public-Private Partnerships: Encouraging collaborations between governments, NGOs, and pharmaceutical companies can combine resources and knowledge to address access challenges and enhance health results in resource-limited areas.

Setups like this help in bringing resources to patients who have low incomes:

4.4 MPP, also known as the Medicines Patent Pool:

Established by UNITAID in 2010, the Medicines Patent Pool (MPP) works to improve access to essential medicines in resource-limited areas. Through agreements with pharmaceutical companies, the MPP enables the production of affordable generic versions of patented drugs, expanding treatment options for diseases such as HIV/AIDS, pediatric formulations, and hepatitis C.

4.5 The Open-Source Malaria Initiative (OSMI) 2007, is an endeavour focused on creating open-source solutions for malaria:

The Open-Source Malaria Initiative promotes transparency and innovation in addressing healthcare challenges in under-resourced areas through a partnership between public and private sectors, creating new drug discovery tools and diagnostics for malaria.

4.6 CHAI, which stands for the Clinton Health Access Initiative:

CHAI, founded by ex-President Bill Clinton, negotiates with drug companies to lower the prices of vital medications for HIV/AIDS and malaria. By advocating for reduced costs, CHAI increases the availability of life-saving treatments in resource-limited countries, ensuring essential drugs are accessible to those in need.

5. International Perspective on Gene Patenting: A Look at Contrasting Approaches

Gene patenting grants exclusive rights to isolated genes and their uses, promoting research in genetics but raising concerns about limited access to testing and treatments if patents are too restrictive. Global nations have diverse approaches to gene patenting, with some emphasizing an 'inventive step' and careful distinction between discovery and invention to address the complexity of the issue.

5.1 United Kingdom:

Case Study: *Human Genome Sciences Inc v Eli Lilly and Company [2011] UKSC 51*

The UK Supreme Court favoured Human Genome Sciences Inc., ruling that the patent for the Neutrokine-α gene sequence was valid under the European Patent Convention. This decision reversed previous invalidations by lower courts and emphasized the importance of clear and consistent laws in biotechnology. The UK follows EPC rules for gene patenting, allowing patents for genes to meet novelty, inventorship, and industrial applicability criteria. However, debates have arisen over patenting genetic material from human embryos and stem cells.

5.2 The United States of America

The United States has a strong gene patenting system in place, where the USPTO awards patents for genes and genetic sequences that are considered novel, useful, and not obvious. Nevertheless, the United States has faced notable legal obstacles concerning the ability to patent genes, especially in instances like the Association for Molecular Pathology v. Myriad Genetics.

Case Study- *Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 186 L. Ed. 2d 124 (2013).*

Myriad Genetics patented cancer-linked genes and techniques for drug efficacy and genetic test analysis. The US Supreme Court's 2013 ruling on Myriad Genetics' patents for BRCA1 and BRCA2 genes stated that patents cannot be granted for naturally occurring genomic DNA, while synthetic DNA is eligible for patent protection. This decision voided patents for genes like Myriad's but supported patents for synthetic DNA. It also permitted the patenting of new techniques for gene control.

5.3 Canada

Canadian laws are relatively lenient when it comes to gene patenting, as the Canadian Patent Act controls the eligibility of genetic inventions for patents. Yet, Canada has encountered discussions and legal disputes concerning the ability to patent genes and genetic sequences, specifically about the requirements of usefulness and lack of obviousness.

Case Study: *The Harvard Oncomouse Incident*

In 2002, the Canadian Supreme Court allowed for the patenting of genetically modified animals like the Harvard Oncomouse. This decision established a new precedent for gene patents in Canada, sparking ethical debates about the patenting of transgenic animals with DNA from other species. The case also highlighted differences in patent rulings between countries like the US and Europe.

5.4 China

China has taken a careful stance on gene patenting, as stated in the Chinese Patent Law which outlines the specific types of inventions that cannot be patented, such as genetic material from human embryos and stem cells. Yet China's position on gene patents has changed over the years, as the nation is now more aware of the significance of biotechnology and innovation.

Case Study: *BGI Genomics: Collection of Patents from BGI Genomics*

A top biotech company in China has developed a significant collection of patents that span across different areas of genomic sequencing and analysis technologies. The patents held by the company demonstrate China's increasing focus on innovation in biotechnology and its measures to enhance intellectual property rights in genetics.

5.5 Japan

Japan has a strong gene patenting system which is regulated by the Japanese Patent Act and determines the patent eligibility of genetic inventions. Japan has actively encouraged biotechnology and innovation, with the government backing genetics research and development.

Case Study: *RIKEN's Genome Editing Technology Study*

RIKEN Institute developed CRISPR-Cas9 for precise gene editing in various organisms, showcasing Japan's commitment to genetic research and healthcare advancements. Scientists at RIKEN BDR created the first genetically modified marsupial, an opossum model, to study their unique traits. Despite challenges like opossums' extended breeding cycle and territorial behaviour, the team successfully transferred edited embryos using piezoelectric technology, resulting in albino offspring. This breakthrough in genetic engineering highlights RIKEN's innovation in developing advanced tools for genetic research and biotechnology applications.

5.6 Australia.

Australia's gene patenting laws are relaxed under the Patents Act 1990, allowing for patenting of genetic innovations. Judiciary clarified gene patenting, including isolated nucleic acids, through Myriad Genetics.

Case Study: *Genetic Technologies Limited* secured a patent for introns, sparking a debate on patenting non-coding DNA sequences and their impact on genetic research. The Federal Court ruled that isolated nucleic acids are patentable due to human intervention. Biotechnology patents cover various genetic materials from humans, animals, plants, and microorganisms, crucial for the industry. The Australian legal system continues to navigate the complexities of gene patenting in the biotech sector.

Reliability: The decision upholds the Australian Patent Office's tradition of issuing patents for genetic material. Considerations regarding infringement: The case prompts questions on the level of separation needed for nucleic acid to violate a patent claim.

6. CONCLUSION AND SUGGESTIONS:

The *Diamond v. Chakrabarty* case represented a major change in patent law by establishing a standard for granting patents to genetically modified living organisms. The arrival of gene patents has sparked discussions regarding the ownership of genes or genetic material, as some believe these patents impede research and creativity.

Genetic data, an important resource for studying diseases, requires a careful equilibrium between privacy and the greater good. Data-sharing organizations and biobanks are essential in this effort, gathering various genetic data, preserving genetic samples, and establishing strong governance systems to protect this data. Key components in safeguarding donor privacy include obtaining informed consent, anonymizing data, and allowing donors to revise their consent for future research.

Biobanks store genetic samples with informed consent to protect donor privacy. Consent forms outline risks, and benefits, and allow modifications. Anonymization preserves privacy, and options for changing consent are available for future research. Responsible data governance will promote ethical genetic data use, transparency, and benefit-sharing. Stakeholder collaboration will shape data ownership, with organizations creating rules for data access and research. Nevertheless, the consequences of this choice go beyond the realm of law, bringing up ethical and healthcare issues.

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