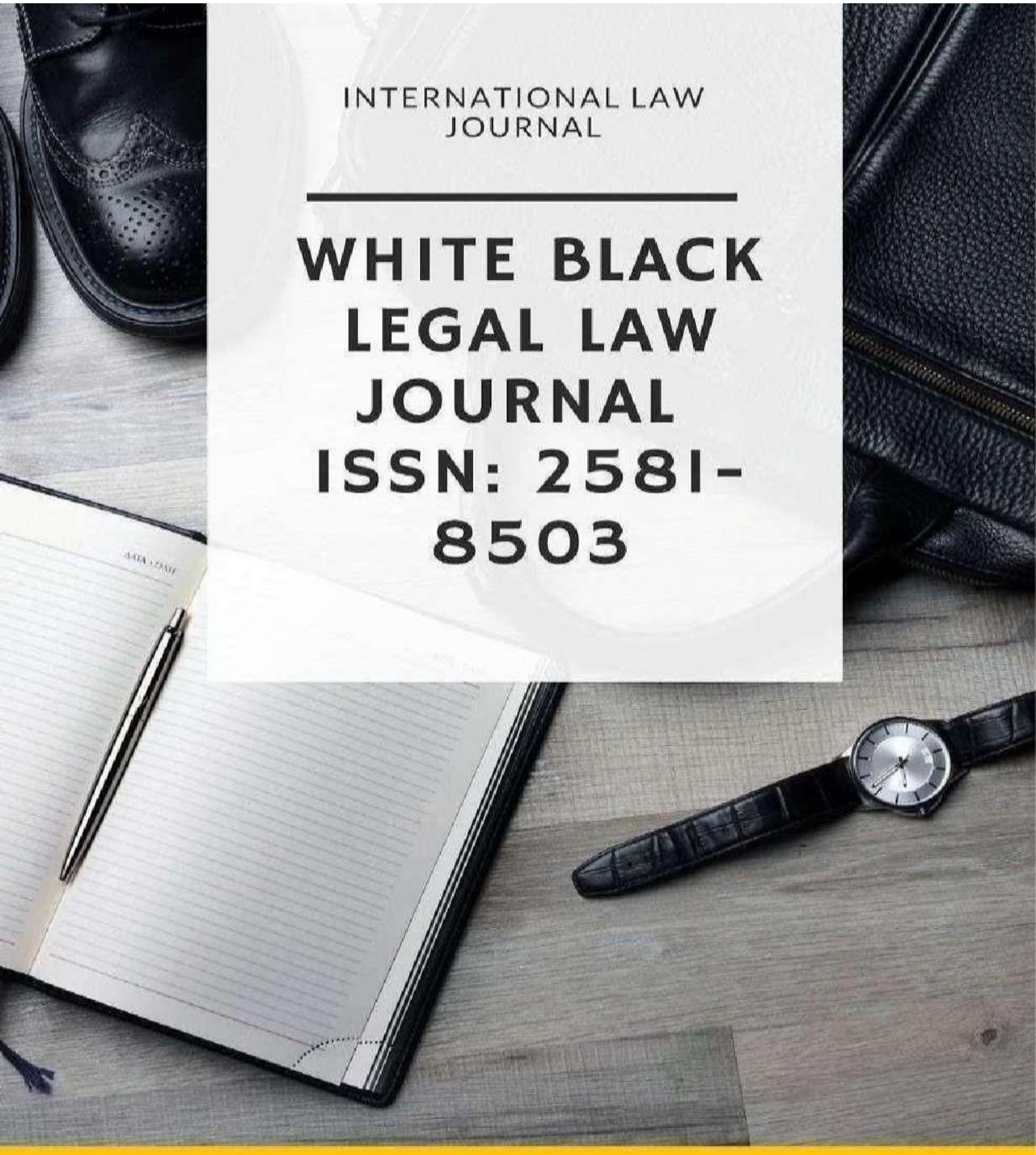

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ABOUT US

WHITE BLACK LEGAL is an open access, peer-reviewed and refereed journal providededicated to express views on topical legal issues, thereby generating a cross current of ideas on emerging matters. This platform shall also ignite the initiative and desire of young law students to contribute in the field of law. The erudite response of legal luminaries shall be solicited to enable readers to explore challenges that lie before law makers, lawyers and the society at large, in the event of the ever changing social, economic and technological scenario.

With this thought, we hereby present to you

LEGAL CHALLENGES IN PATENTING FORENSIC DNA TECHNOLOGY: A CRITICAL LEGAL ANALYSIS.

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Abstract:

DNA technology is a revolutionary power that has led the way in transforming forensic investigation, allowing a unique level of accuracy and objectivity while working on criminal cases. But legal problems arise from the patent-issuing practice of requiring novelty and non-obviousness patents involving DNA analysis kits and processes. **Methods**: *Methodology* adopted is legal and doctrinal based on rigorous analysis and reviewing of research papers, articles, judgments, statistical studies, and reports that are related to the legal challenges pertaining to the *Patenting Forensic DNA Technology.* Thus, this interdisciplinary and doctrinal legal research paper aims at shedding light on the area where patent law intersects with forensic DNA technology with a pragmatic approach to solutions based on the cutting-edge research; and further examines the complexities relating to biological materials' patents, ethical dilemmas that emerge due to ownership of genetic information and implications for law enforcement accessibility as well as justice systems. We conclude with a call for interdisciplinary dialogue by science into the law to strike an appropriate balance that fosters continued innovation on this critical forensic tool while ensuring broad access.

Keywords: DNA technology, forensics, patenting, legal challenges, ethical considerations, law enforcement.

1. **Introduction:**

The development of this technique has been instrumental to the achievements of modern forensic science since it afforded a novel method for identifying one person among millions based on their unique DNA profile: DNA analysis has transformed the landscape of criminal justice by exonerating innocent prisoners, revealing who committed crimes that would never have been solved otherwise and augmenting meritless cases against defendants. Nonetheless, all of these technologies will involve the creation and exploitation of intellectual property (IP) in the form of patents. In our paper we address the above-mentioned potential legal roadblocks that could be put in front of patenting forensic DNA technology and analyze whether granting patents within these bounds is a good solution from a social standpoint, taking into consideration interests related to stimulating innovation as well as maintaining justice-based equal access to this important tool.

2. **Patenting Challenges in Forensic DNA Technology:**

2.1. Complexities of Patenting Biological Material: DNA differs from most inventions in that DNA sequences are naturally occurring biological materials. "Experimental results show that patent eligibility requirements often rule out products of nature, which can make specific DNA markers or small segments of genetic code unpatentable. “The situation is particularly complicated due to the nature of biological materials and conflict between intellectual property rights and definition of biological matter. Here's a breakdown of the key challenges:

2.2. Patent Eligibility:

2.3. Products of Nature vs. Inventions: Patent law typically grants protection for inventions, not discoveries. Since biological materials like DNA sequences exist naturally, there's a question of whether they qualify as inventions.

2.4. Isolation vs. Purification: Isolating a specific DNA sequence from a cell might be considered patentable if it demonstrates a substantial difference from its natural state. However, simply purifying an existing molecule might not be enough for

patent protection. The isolation of DNA sequences primarily focuses on extracting DNA from a biological sample, aiming to obtain the genetic material in its pure form for downstream applications like sequencing and genotyping.(1) This process involves breaking down cell membranes and removing impurities to yield high-quality DNA suitable for various molecular biology techniques (2). On the other hand, DNA purification concentrates on refining the isolated DNA further to enhance its quality by eliminating contaminants that could interfere with enzymatic reactions during molecular analyses(3). Different methods, such as mechanical lysis-based, enzymatic lysis-based, and kit-based approaches, are employed for DNA isolation and purification, with variations in efficiency and outcomes based on the chosen method. Ultimately, while DNA isolation aims to extract genetic material from a sample, DNA purification strives to refine and enhance the quality of the isolated DNA for accurate molecular analyses.

3. **Functionality vs. Information:**

3.1. Focus on Function: Patents are typically granted for inventions with a specific utility or function. Patenting a DNA sequence for its role in a diagnostic test might be easier than patenting the sequence itself without a defined function. Patenting a DNA sequence for its role in a diagnostic test can be a complex process influenced by various factors. While patents on gene sequences can cover the link between a disease and mutations, the actual technology for identifying mutations may not be patented(4). The U.S. Patent and Trademark Office suggests that DNA-related inventions can be patentable if they meet specific criteria like utility and novelty(5). The National Society of Genetic Counsellors advocates for the widespread granting of DNA-sequence patents, the exemption of non-commercial research from patent enforcement, and the establishment of licensing criteria that promote the interests of consumers and participants in genetic research.(6). Recent legal decisions have also made it more feasible to patent gene sequences, enhancing the potential for patenting DNA sequences for diagnostic purposes(7). However, global trends show a decline in DNA patent filings, indicating evolving debates and regional disparities in patenting activities(8)

3.2. Information vs. Application: DNA sequences are essentially information encoded within the molecule. Patenting the information itself might be difficult but patenting a method for using that information (e.g., in a genetic test) could be more feasible. The legal implications of patenting DNA sequences versus methods that utilize them are multifaceted. Patenting gene sequences can impact accessibility to genetic research tools, innovation, and clinical practice, potentially hindering the free flow of academic knowledge and stifling genetic innovation(9). Recent US Supreme Court cases, such as *Mayo v. Prometheus and Association for Molecular Pathology v. Myriad Genetics*, have ruled that isolated DNA sequences are not patentable, while cDNA may still be eligible for patents if distinct from naturally occurring DNA(1 0). The debate over DNA patenting continues in the US, with ongoing discussions on the need to redefine patentable subject matter to modulate the effects of upstream patenting(4). Additionally, legislative efforts, like the Patent Amendment Bill in Australia, reflect global concerns over the patentability of DNA and biological materials(11)

4. Distinguishing Novelty and Non-Obviousness:

4.1. Novelty: For a patent to be granted, the invention must not have been previously known. However, as more and more genetic information becomes known, proving that a particular sequence was new can be difficult. Hence, the assessment of novelty within specific DNA-sequences for patent eligibility has obviously been complicated by several factors including: the existence and escalation of genetic variants (VUS); and; an appropriate test for determining whether DNA is patentable(12). Addressing these challenges may involve improving the interpretation of variants, restricting the calling or reporting of VUSs, semiquantitative subclassification and stratifying VUS based on likelihood to be pathogenic, and providing extensive counselling efforts. However, the various legal systems already serve an important role in defining where the boundaries of patentability are and clarifying ambiguities regarding current standards, such as that addressed by High Court decision on patent claims for DNA sequences. To unravel these complexities and help provide clear parameters for determining when DNA

sequences are or are not “new”, collaboration between the scientific community and the legal systems overseeing patents will ultimately be required.

4.2.Non-Obviousness: It is worth considering that the invention should not be an obvious modification of something already known. Thus, once again, it may be complex to prove the non-obviousness of a slightly modified DNA sequence in comparison to those that already exist. Simultaneously, it can be said that the problem of the complexity of DNA sequences, especially when non-obviousness has to be proven to a slightly modified sequence, is a complex issue. The duplications, rearrangements, and novel functions that create complexity in the mammalian genome can be generated by the same order of elements can also be present but are much simpler elsewhere, argues N.F. Lander. Therefore, it is complicated to work with noncoding DNA because of the repetitiveness and the absence of distinct features.(13). There are multiple techniques and strategies available for evaluating the intricacy of DNA sequences, such as statistical analysis, dictionary-based methods, and structural approaches. These approaches are essential for discerning and categorizing structural patterns in DNA sequences(14). Regions corresponding to genes have consistently different complexity measures than those regions that do not have any gene associated with them(15).

5. Ethical Considerations:

5.1. Ownership of Genetic Information is partly determined by the following question: who owns the genetic information which resides in these DNA sequences? Do you think people should ultimately be able to decide what happens with their DNA data when it comes to patents as well? This had ethical implications regarding the commodification of genetic data. this issue of patent is complex and multi-faced. there concerns that while the DNA patenting is broadly justified, but also has been allowed overbroadly(16). Scientists suggests that DNA sequence information in patents should be made publicly available to accelerate innovation(17). The anthropological examination of the commercialization of the human body and the notion of 'embodiment' is valuable in scrutinizing the discussion surrounding DNA

as a form of ownership. (18). The inclusion of a critical perspective in the DNA patenting discussion emphasizes the importance of considering the integrity of the body and self-identity. These perspectives indicate that individuals should be able to influence the use of their DNA data in patenting to safeguard their rights and interests.(19).

5.2. Biopiracy and Access to Genetic Resources: It also reflects worries that companies are patenting genetic resources in developing countries with little or no money going back to fund fair compensation and benefit-sharing. But it also does raise questions around biopiracy, and equitable access to genetic biodiscovery. This raises the more complex and multi-dimensional issue of biopiracy and equitable access to genetic diversity Developing countries and their inherent indigenous communities do not secure rightful share of benefits from unwarranted access to resources and this phenomena could be classified as biopiracy(20). The United Nations' Convention on Biological Diversity formally recognized the sovereignty of Nation States to control their biodiversity and genetic resources(21). The principles of common heritage of mankind and global commons warrant increased attention (22). In sum the voices that speak from these perspectives elucidate the imperative of a more just use and sharing genetic resources approach. All these intricacies just make clearer the constant controversy over patenting life forms of any kind. With a better understanding of genetics and application in this field, the legal framework for patenting is likely to evolve further.

5.3. Ethical Considerations in Ownership and Privacy: The ownership of genetic information used in forensic analysis raises ethical concerns. Should individuals have a say in how their DNA data is used, or can it be patented and controlled by private companies? This raises questions about privacy rights and potential discrimination based on genetic profiling. The commercial aspect of sharing genetic and health data gives rise to concerns about the rights of the individuals whose data is being shared and the equitable distribution of benefits (23). Further complications of the issue has been created by discussing the legal and ethical concerns

surrounding the patenting and licensing of genetic material, particularly in the context of genetic testing(24). These papers collectively underscore the need for a more nuanced and transparent approach to the ownership and control of genetic information, one that prioritizes the rights and autonomy of individuals.

6. **Impact on Law Enforcement and Justice Systems:** Patenting DNA technology creates a potential barrier to access for law enforcement agencies. High licensing fees for patented kits or processes could limit the use of DNA analysis in investigations, particularly in resource-constrained jurisdictions(25). This could hinder access to justice for victims and raise concerns about the equal application of the law.

6.1. Case Study: The AmpFℓSTR® Identifiler® PCR Amplification Kit (Illustrative Example):

*The AmpFℓSTR® Identifiler® PCR Amplification Kit, developed by Thermo Fisher Scientific***,** is a widely used example of a patented DNA analysis kit in forensics. This kit allows scientists to analyse Short Tandem Repeats (STRs), which are repetitive sequences of DNA that vary in length between individuals. By amplifying and analysing these STRs at multiple locations (loci) across the genome, a unique DNA profile can be generated for identification purposes. The kit includes all the necessary reagents and primers to amplify 15 core CODIS (Combined DNA Index System) STR loci and the Amelogenin gender marker in a single PCR reaction. Amplified STR fragments are then separated by size using capillary electrophoresis and visualized for analysis. The resulting DNA profile can be compared to known suspect profiles or evidence samples to identify individuals or link them to crime scenes.

6.2. Legal Challenges with the Patent:

The patent for the AmpFℓSTR® Identifiler® Kit has faced legal challenges surrounding the patentability of specific aspects:

6.3. Patenting of Biological Material: An important obstacle is in the process of patenting the STR loci due to their inherent nature as naturally occurring DNA sequences. An inherently existing DNA fragment that has simply been "separated"

is not eligible for patent protection. (26). Patent law frequently excludes natural products, which leads to inquiries regarding whether isolated and amplified STRs meet the criteria for being patentable innovations. The Supreme Court's ruling in Association for Molecular Pathology v. Myriad Genetics has added complexity to this problem by determining that isolated naturally occurring DNA segments cannot be patented.

6.4. Non-Obviousness: Another issue pertains to the "non-obviousness" prerequisite for patents. Detractors contend that the identification and enhancement of Short Tandem Repeats (STRs) for forensic examination was a clear and logical progression of preexisting technology during the period when the patent application was submitted.

6.5.Relevant Court Cases:

Association for Molecular Pathology v. Myriad Genetics (2013): This significant Supreme Court judgment established that human genes are not eligible for patent protection. Although the Identifiler Kit does not directly patent genes, it brings attention to the continuing discussion regarding the potential to patent isolated biological components.

Athena Diagnostics v. Thermo Fisher Scientific (2008): Athena Diagnostics initiated a legal action against Thermo Fisher, alleging patent infringement related to a rival STR diagnostic kit. The focus of the case revolved around the particular primers and amplification techniques employed in the kits, rather than the STR loci themselves.

These legal battles demonstrate the complexities of patenting in forensic DNA technology. While companies invest heavily in developing these kits, the patenting of biological materials and the boundaries of non-obviousness remain contested issues.

7. Balancing Innovation and Justice:

Finding a balanced approach requires collaboration between scientists, legal scholars, and policymakers. Potential solutions include:

7.1.Narrow Tailoring of Patents: Patents could be granted for specific applications of DNA technology, such as methods for analyzing specific genetic markers, rather than broad claims on the DNA sequences themselves(27).

7.2. **Open-Source Licensing Models:** Examining open-source licensing arrangements may promote innovation while guaranteeing wider availability of forensic DNA technology for law enforcement organizations. The application of DNA in forensic science is undergoing tremendous advancements, with the emergence of novel technologies like massively parallel sequencing and forensic genomics, which are broadening the range of DNA analysis.(28). However, these advancements raise significant legal and policy issues, particularly in the context of privacy and civil liberties(29). Moreover, the involvement of scientific stakeholders in the formulation of anticipatory governance discussions is essential for the conscientious and moral utilization of new technologies. (30).

7.3. **Alternative Incentive Mechanisms:** Grants or prizes dedicated to certain forensic applications could offer alternate motivations to inventors, avoiding the need for conventional patenting methods. However, while selecting an incentive mechanism, it is important to take into account the informative functions of each option. Grants, tax credits, and prizes are especially helpful in minimizing social-welfare expenses and addressing challenges in imperfect capital markets.(31). In settings where individuals other than the creator of an invention receive knowledge regarding the quality of the innovation, utilizing systems that make use of market information can effectively give suitable motivations. Offering awards could be one possible approach.(32)

Conclusion:

Without question, DNA technology has revolutionized criminal investigations and the rule of law. Solving the legal issue of patenting will also require an interdisciplinary approach to deal with a problem that must be solved: One which protects innovators' rights at the same time it secures objective interpretation and implementation of law. Please see the article for factors that are relevant in balancing encouraging further development of forensic science while safeguarding access to an essential tool by establishing a culture of cooperation across scientific and legal community lines.

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