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Contemporary Application Issues of Patent Theories in Biotechnology

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Annotation

This article provides an in-depth analysis of the application challenges of patent theories in biotechnology. The primary objective is to identify adaptation problems of classical patent theories (incentive, natural rights, social contract, and economic efficiency theories) to the specific characteristics of biotechnology and propose solutions. The research employs comparative legal, analytical, and systematic approaches. The application of Kenneth Arrow's incentive theory, John Locke's natural rights theory, social contract theory, and economic efficiency theory in the biotechnology context is examined. The main finding demonstrates that classical patent theories do not fully function in biotechnology due to specific characteristics such as self-replication capabilities of living organisms, genetic variability, and anticommons problems. Additionally, the length of innovation cycles for biotechnological inventions, high costs and risks significantly affect patent investments, patent cliff phenomena, and Eroom's law impact are demonstrated. Research findings can be applied in patent law reform, creating special legal regimes for biotechnology, and developing balanced patent policy for developing countries like Uzbekistan. The conclusion emphasizes the necessity of reconsidering traditional patent paradigms for biotechnology and developing specialized legal instruments.

Keywords: biotechnology patents, incentive theory, natural rights, social contract, anticommons problem, genetic materials, living organisms, patent policy, innovation system, legal regime.

1. Introduction

The role of biotechnology in contemporary global development is increasingly prominent. The fundamental characteristic of this field lies in its direct connection to life's most basic mysteries - DNA structure and genetic materials. Consequently, the legal regulation of biotechnological inventions necessitates a comprehensive reconsideration of traditional patent theories.

The theoretical foundations of intellectual property rights in biotechnology are formed around several major legal theories, each possessing unique application characteristics in the context of inventions related to living organisms and genetic materials. The application of patent theories in biotechnology presents considerable complexity, primarily stemming from the distinctive nature of biologically-based technologies.

According to the World Intellectual Property Organization (WIPO) definition, a patent is an absolute right granted by the government for inventions that are novel, involve an inventive step, and are industrially applicable (WIPO, 2011). However, this classical definition raises fundamental questions when applied to biotechnology.

The article's primary objective is to identify application problems of classical patent theories in biotechnology and propose balanced solutions for developing countries like Uzbekistan. The central challenge addressed is determining pathways for establishing patent systems that accommodate biotechnological specificities.

For developing nations such as Uzbekistan, this issue holds particular significance, as the correctly chosen legal regime in biotechnology directly impacts national innovation system development.

2. Materials and Methods

The research analyzed classical patent theories (incentive, natural rights, social contract, and economic efficiency theories) within the biotechnology context. Each theory's specific application characteristics, problems, and limitations in biotechnology were identified.

The study employed comparative legal, systematic analysis, systematic approach, and expert evaluation methods. Biotechnology patent legislation and theoretical foundations served as the research object.

3. Research Results

3.1 Application of Incentive Theory in Biotechnology

Incentive theory represents one of the crucial theoretical foundations for patent protection in biotechnology. Kenneth Arrow (1962) in his work "Economic Welfare and the Allocation of Resources for Invention" demonstrated the patent system's role in resolving the paradox of knowledge production requiring substantial investment while replication demands minimal costs. According to Arrow's theory, patent protection serves as an essential incentive mechanism for innovation, as inventors must have opportunities to recover their investments.

This theory remains particularly relevant in the biotechnology context, as genetic research and new biotechnological product development requires billions of dollars in investment. Research by DiMasi, Grabowski, and Hansen (2016) showed that developing new pharmaceutical preparations requires an average of $2.6 billion and 10-15 years. However, independent analysis by Prasad and Mailankody (2017) determined this figure to be $648 million, indicating ongoing debates about costs.

The nature of biotechnology research demonstrates that successful projects in this field require not only substantial financial investments but also long-term, high-risk research activities. Empirical research by Budish, Roin, and Williams (2015) shows that more investment is directed toward late-stage cancer drugs with faster market access potential compared to early-stage cancer drugs requiring lengthy clinical trials.

The application of incentive theory in biotechnology raises several serious problems. The balance between patent duration and social benefits becomes more complex in biotechnology (Nordhaus, 1969). When patent rights are established over genetic materials and living organisms, these rights fundamentally differ from traditional patent objects. Living organisms possess self-replication capabilities, leading to strengthened patent monopoly effects. As noted by Yelpaala (2000), biotechnology inventions' primary objective is often "controlling pathways to products rather than products themselves."

3.2 Limitations of Natural Rights Theory in Biotechnology

Natural rights theory, based on John Locke's labor theory, creates fundamental contradictions when applied to biotechnology. Locke (1689) in the second part of his "Two Treatises of Government" developed the principle of "mixing labor with nature." According to this theory, "everyone has property in his own person... The labor of his body and the work of his hands are properly his."

Adam Mossoff (2009) applied this classical approach to modern intellectual property rights, noting that Locke's theory allows justifying patents as natural rights.

However, applying natural rights theory to biotechnology creates serious theoretical and practical problems. The first problem is that the concept of applying labor to genetic materials and living organisms remains unclear. Critical analyses of Locke's theory by Jeremy Waldron (1988) show that the "mixing labor" argument lacks clear boundaries when applied to genetic materials.

The second problem relates to indigenous peoples' and traditional communities' natural rights over genetic resources. As noted by James Boyle (2008), the concept of genetic commons and converting public domain genetic information to private property creates significant debates. This issue is particularly relevant for Uzbekistan, given the country's rich biodiversity and traditional agricultural culture.

Third, the fundamental condition of Locke's theory - the "enough and as good left for others" principle (Lockean proviso) - faces violation in the biotechnology context. Modern biotechnology achievements have eliminated the natural limitations Locke envisioned (Yelpaala, 2000). A single genetic invention can establish monopolies over entire species or biological processes.

3.3 Social Contract Theory Problems

Social contract theory explains the patent system as an agreement between society and inventors, holding special significance in the biotechnology context. According to this theory, in exchange for patent grants, inventors must disclose their discoveries and benefit society. The US National Research Council (2003) in "Patents in the Knowledge-Based Economy" notes that "the patent system's primary purpose is to encourage inventive activity by granting exclusive rights to prevent others from making, using, or selling in exchange for disclosing invention details."

Applying social contract theory in biotechnology has unique characteristics. Disclosure requirements for biotechnology patents become considerably more complex than traditional mechanical inventions. Describing genetic sequences, protein structures, and biological processes requires specialized knowledge and experience.

The quid pro quo principle also presents unique problems in biotechnology. According to this patent system principle, inventors should provide new knowledge to society in exchange for monopoly rights. However, some research (Bera, 2016) suggests that biotechnology patents sometimes limit themselves to reexpressing natural processes without providing sufficient scientific novelty.

3.4 Economic Efficiency Theory Contradictions

Economic efficiency theory views the patent system as a tool for enhancing innovation efficiency, but this theory creates serious contradictions in the biotechnology context. The OECD (2004) report "Patents, Innovation and Economic Efficiency" notes that patents "often help strengthen incentives for invention, technology disclosure, and commercialization, while simultaneously imposing costs on society through monopoly rents and barriers to knowledge use."

The "deadweight loss" problem holds particularly serious significance in biotechnology. Patent monopolies in vital pharmaceutical and biomedical products maintain high prices, limiting access for broad population segments. Research by Scotchmer and Green (1990) showed that balancing dynamic efficiency (encouraging innovation) and static efficiency (widespread use of existing technology) requires special regulatory mechanisms in biotechnology patent policy.

Research by Gilbert and Shapiro (1990) on optimal patent breadth design reached an important conclusion: excessive patent protection strengthens not only specific firms' patent portfolio values but also encourages competitors into "patent races," complicating innovation systems. This problem often manifests as the "tragedy of the anticommons" in biotechnology.

4. Analysis of Research Results

4.1 Unique Characteristics of Biotechnological Inventions

One primary characteristic of biotechnological inventions is the complexity of working with living systems. The self-replication capability of biological materials creates complexity sources for biotechnological inventions. As correctly noted by Rebecca Eisenberg (2001), "biological material can be patented at one moment but may change or mutate the next minute."

Biological variability and batch-to-batch differences directly affect patent claim definition. As noted by John Duffy (2009), "the unpredictable nature of biological systems directly impacts enablement requirements for biotechnology patents."

The Diamond v. Chakrabarty (1980) case holds fundamental significance in this field. The US Supreme Court decision established that genetically modified bacteria could be patented. According to Jordan and colleagues (2022), the Supreme Court ruling determined that "human-made bacteria can be patented under patent laws as such inventions constitute manufacture or composition of matter."

4.2 Innovation Cycle Length and Patent Duration Problems

Biotechnology product development typically spans 15-20 years. This process includes clinical trials, regulatory approvals, and manufacturing setup phases. This duration makes patent protection adequacy relevant, as patent terms are typically 20 years, with significant portions consumed before market entry.

The pharmaceutical industry has witnessed declining innovation activity in recent decades. According to Scannell and colleagues' (2012) analysis, new drug development efficiency has halved every 9 years over the past 60 years. This phenomenon is explained as "Eroom's law" (reverse of "Moore's law," describing the exponential increase in new drug development costs and time while the number of approved new drugs relative to R&D expenditures decreases).

Continuation applications and patent family management strategies provide continuous patent protection throughout long development cycles. These strategies are particularly important for fields with long-term innovation processes like biotechnology and pharmaceuticals (Lemley and Moore, 2004).

The patent cliff phenomenon and biotechnology companies' strategies for preparing for patent expiration are also significant. Patent cliff refers to the rapid revenue decline following sharp competition increases in company product markets after pharmaceutical patent protection expires. Research by Hughes, Moore, and Snyder (2002) demonstrates that patent cliffs significantly impact biotechnology companies' financial results.

4.3 High Cost and Risk Analysis

The high-risk, high-reward nature plays an important role in evaluating biotechnology patents. Research by Hall and Harhoff (2012) shows that biotechnology patent value distribution is highly skewed, with many patents remaining uncommercial.

Sunk costs and biotechnology R&D failure rates directly affect patent investment decisions. According to FDA (2018) data, only 12% of preparations successfully passing clinical trials reach market.

Patent portfolio diversification strategies and risk management approaches occupy special positions. The von Minden and Gonzalez (2024) report notes that for early-stage biotechnology companies, being patent owners or in the process of obtaining patent licenses holds strategic significance.

4.4 Anticommons Problem and Social Consequences

The tragedy of the anticommons in biotechnology represents one of the most pressing issues in modern patent systems. Research by Heller and Eisenberg (1998) shows that multiple separate patents slow innovative activity, particularly evident in biotechnology.

The anticommons problem manifests in various forms in biotechnology. First, thousands of patent applications have been filed for genes and gene fragments, particularly expressed sequence tags (ESTs) since the 1990s. The Craig Venter and NIH project resulted in private organizations also popularizing EST patenting. As noted by Sherkow and Greely (2015), such patents result in multiple independent right holders having legal control over identical gene fragments, creating patent barriers so strong over resources that they may hinder scientific research and innovation.

Second, research results and data are also being patented. This practice contradicts the scientific community's traditional openness principle and slows scientific research. This situation resembles individual ownership of every grain of sand on a beach (Yelpaala, 2000).

Third, patenting research tools in biotechnology creates problems. For example, patenting fundamental research tools like polymerase chain reaction (PCR) makes subsequent research more expensive and slows scientific development.

Empirical research by Walsh, Arora, and Cohen (2003) analyzed anticommons problems' impact on biotechnology research. Results showed that issuing numerous patents for genes and gene sequences creates the necessity of obtaining hundreds of licenses for major genetic projects.

5. Conclusions

Analysis of patent theory applications in biotechnology demonstrates that traditional patent theories do not fully accommodate biotechnology's unique characteristics. The following directions are important for developing countries like Uzbekistan:

First, creating a hierarchical norms system is necessary. This system should include three levels: things that cannot be property objects (e.g., human genome sequences), things that may be property objects but are not patentable (e.g., basic research tools), and inventions that may be patentable but are not granted patents for ethical reasons (e.g., human cloning technologies).

Second, creating a biotechnology-specific patent system is needed. Abandoning the "one size fits all" approach and developing separate legal regimes adapted to biotechnology characteristics is necessary. This regime should include special measures to address anticommons problems and preserve the scientific community's traditional openness principles.

Third, shaping patent policy considering Uzbekistan's national interests and development needs is important. This includes balancing national biotechnology sector development, protecting traditional knowledge, and encouraging international cooperation.

Fourth, introducing compulsory licensing mechanisms into national legislation and ensuring access to vital biotechnology products is necessary. This mechanism can be particularly applied to biotechnology inventions in medicine.

Fifth, developing international cooperation in biotechnology and facilitating technology transfer is important. This is necessary for enhancing Uzbekistan's biotechnology capacity and attracting foreign investments.

Research results demonstrate that fundamental reconsideration of patent systems in biotechnology is necessary. Traditional patent paradigms are insufficient for this field and require special approaches. Developing balanced patent policy for Uzbekistan holds strategic significance for strengthening national innovation systems and developing biotechnology sectors.

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