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Trade Secrets as an Effective Mechanism for Protecting Intellectual Property Rights in Biotechnology

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Annotation: This article examines trade secret protection as a critical component of intellectual property strategy in the biotechnology sector. While patent protection remains limited by fixed terms, trade secrets offer indefinite protection provided confidentiality is maintained. The study employs comparative legal analysis to evaluate trade secret frameworks across major jurisdictions including the United States, European Union, China, Japan, and South Korea, with particular attention to Uzbekistan's evolving legal regime. The research demonstrates that biotechnology companies increasingly rely on strategic combinations of protection mechanisms, with trade secrets playing a central role in safeguarding processes, formulas, and genetic information that resist reverse engineering. Findings indicate significant variations in trade secret protection strength across legal systems, from the robust common law framework in the United States to emerging continental European approaches and hybrid Asian-Pacific models. The article concludes that Uzbekistan's current trade secret legislation requires refinement to address biotechnology-specific challenges, including clearer definitions of protectable information types, employee mobility regulations, and specialized mechanisms for digital data and bioinformatics.

Key words: trade secrets, biotechnology, intellectual property protection, comparative law, innovation strategy, legal framework, genetic information, bioinformatics.

1. INTRODUCTION

In contemporary biotechnology, beyond patent protection, civil law protection of other intellectual property types such as trade secrets, trademarks, and copyrights has strategic importance. Each of these protection types possesses its own legal mechanisms and constitutes an integral part of a comprehensive intellectual property strategy for biotechnology companies (Pooley, 2002).

Comparative legal analysis shows that these protection forms have developed to varying degrees in different legal systems. In the United States' common law system, trade secrets enjoy strong protection, while in continental European systems this institution has formed as a newer institution. In Asia-Pacific countries such as Japan, China, and South Korea, distinctive mixed approaches are applied (Png, 2017a; Png, 2017b). To effectively legally regulate relations in rapidly developing fields like biotechnology, Uzbekistan's legal system also faces the necessity of studying international experience in this area and improving national legislation.

Based on our research, the effectiveness of intellectual property protection in biotechnology depends not only on the strength of individual protection types but also on their mutual integration. The success of modern biotechnology companies is often based on strategic combinations of various protection mechanisms. This approach is clearly manifested in the legal practice of developed countries (Rowe, 2007).

While legal protection provided through patents is limited to a certain period, trade secret protection has no fixed time limit and can continue indefinitely as long as information remains confidential. In other words, patents typically remain valid for 20 years, while the validity period of trade secrets ends

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only when the secret is disclosed (Lemley, 2008). This characteristic is especially valuable for biotechnology companies because many biotechnological processes and formulas are difficult to disclose through reverse engineering.

2. METHODS

This study employs a multi-method qualitative research design combining comparative legal analysis, doctrinal research, and case study examination. The research systematically analyzes trade secret protection frameworks across multiple jurisdictions to identify patterns, variations, and best practices applicable to biotechnology contexts.

The research objects encompass trade secret legislative frameworks, biotechnology-specific applications, judicial precedents, and corporate practices of major biotechnology companies.

3. RESEARCH RESULTS

In international legal scholarship, the development of the trade secrets institution has passed through several stages. Initially, this field of law was considered based on principles of fair competition and commercial ethics, but later it was reinterpreted as an intellectual property concept (Lemley, 2008). Laws related to trade secrets in practice became not just protecting certain technologies, but a comprehensive institution protecting any type of information. Initially, in the United States, this institution formed as part of the unfair competition doctrine (Bone, 1998), while in Europe it evolved into a new independent legal category.

In the continental European legal system, trade secrets were initially considered within the framework of personal rights, but later were recognized as a separate legal institution (Aplin & Davis, 2020). Article 39 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) regulates trade secrets as “information that is not generally known or easily accessible, has commercial value due to its confidentiality, and for which appropriate measures are taken to maintain confidentiality” and establishes minimum protection standards (TRIPS Agreement, 1994).

Theoretically, trade secret protection aims to ensure balance between economic efficiency and innovation incentives. Trade secret protection is aimed at increasing the overall efficiency of the innovation ecosystem, and appropriate trade secret protection mechanisms encourage innovators and their competitors to invest more effectively in innovative activities (Lemley, 2008). However, some researchers note that strengthening legal protection of trade secrets may restrict knowledge exchange, with evidence from certain U.S. states showing that strengthening trade secret protection resulted in a nearly 40% decrease in patents the following year (Png, 2017a; Png, 2017b).

In the United States, trade secrets are primarily regulated by two main legal instruments: the Uniform Trade Secrets Act (UTSA) and the Defend Trade Secrets Act (DTSA) enacted in 2016 (Defend Trade Secrets Act, 2016).

According to UTSA, a trade secret constitutes information satisfying the following conditions: first, information not generally known and not readily ascertainable through proper means; second, information possessing economic value from not being disclosed or used (Uniform Trade Secrets Act, 1985).

DTSA’s distinctive feature is that it enables trade secret disputes to be heard in federal courts and provides powerful protection tools such as ex parte seizure of property or evidence without prior notice to the respondent (Defend Trade Secrets Act, 2016). This proves particularly important in biotechnology where competitor disputes frequently possess interstate character.

In American judicial practice, the Economic Espionage Act (1996) provides for criminal liability and is specifically directed against trade secret theft by foreign entities (Economic Espionage Act, 1996).

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Principles established in American judicial practice find wide application in biotechnology. For example, in E.I. Du Pont de Nemours & Co. v. Kolon Industries, the U.S. District Court for the Eastern District of Virginia found trade secret theft proven on September 14, 2011, and the jury decided to award damages of $919.9 million in favor of DuPont. In this case, the court recognized that chemical fiber production technology, specifically Kevlar manufacturing technology constituted a trade secret and demonstrated that its unlawful acquisition led to significant financial liability (E.I. Du Pont de Nemours & Co. v. Kolon Industries, 2014).

In the European Union, the Trade Secrets Directive (2016/943/EU) adopted in 2016 establishes common minimum standards for EU member states regarding trade secrets regulation. This directive encompasses civil law protection tools against unlawful acquisition, use, and disclosure of trade secrets (EU Trade Secrets Directive, 2016).

The Directive defines trade secret as information that is "confidential (i.e., not generally known or readily accessible), has commercial value due to its confidentiality, and has been subject to reasonable steps by the confidentiality holder to maintain its confidentiality" (EU Trade Secrets Directive, 2016). This definition, unlike the American definition, specifically emphasizes the "reasonable measures" requirement.

In Germany, the Trade Secrets Protection Act (Gesetz zum Schutz von Geschäftsgeheimnissen - GeschGehG) adopted in 2019 finds wide application in biotechnology (GeschGehG, 2019). German legislation, from the perspective of trade secret relationships, regulates employee mobility more liberally than American legislation.

In France, new provisions of the Commercial Code (Code de commerce) establish strong mechanisms for protecting trade secrets while maintaining balance with employees' professional freedom (Aplin & Davis, 2020).

Following the **United Kingdom's** exit from the European Union (Brexit), it retained its independent trade secrets legislation, creating complexity for biotechnology companies (Aplin & Davis, 2020).

In Japan, the Unfair Competition Prevention Act (UCPA) protects "trade secrets." Trade secrets are defined as technical or business information possessing the following characteristics: first, kept secret; second, useful for business activities such as production or marketing methods; and third, not publicly known (UCPA Article 2(6)) (Japan UCPA, 1993).

While information not meeting the trade secret definition is not protected under UCPA, if parties have agreed in contract to protect such information as confidential, such information may be protected through contract under the Civil Code or other contract-related laws (Matsuo, 2019). Japanese legislation considers trade secrets in biotechnology particularly within the know-how (manufacturing secrets) category.

In China, the Anti-Unfair Competition Law updated in 2019 significantly strengthened trade secret protection (China Anti-Unfair Competition Law, 2019). According to Chinese law, trade secrets are "technical information and business information not known to the public, possessing commercial value, and subject to confidentiality measures by the rights holder." China's distinctive feature is that it provides separate protection for traditional Chinese medicine information (Zang & Zhou, 2020).

In South Korea, the Unfair Competition Prevention and Trade Secret Protection Act (UCPA) improved in 2018 introduced special protection mechanisms for biotechnology companies (Korea UCPA, 2018).

Most legislation pays special attention to the reverse engineering issue in biotechnology and clearly defines legal limitations in this field.

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The Law of the Republic of Uzbekistan "On Trade Secrets" (September 11, 2014, No. O'RQ-374) defines trade secret as "information in science, technology, production, finance, economics, and other fields that has commercial value due to being unknown to third parties, is not freely available on a legal basis, and whose owner takes measures to protect its confidentiality" (Uzbekistan Law on Trade Secrets, 2014).

According to Article 4 of the law, a trade secret must meet the following requirements: possess actual or potential commercial value for its owner due to being unknown to third parties; not be generally known or publicly accessible according to legislation; be ensured by confidentiality protection measures; not possess state secret characteristics and other secrets protected by law (Uzbekistan Law on Trade Secrets, 2014).

In our opinion, while Uzbekistan's legislation encompasses basic trade secret concepts, biotechnology-specific characteristics are not adequately considered. Specifically, special protection mechanisms for genetic information, bioinformatics algorithms, and biotechnological processes are not provided in legislation. Article 5 of the law lists information types that cannot constitute trade secrets, but no clarity is provided regarding biotechnology-specific information types (Uzbekistan Law on Trade Secrets, 2014).

Comparison with foreign legislation indicates that Uzbekistan's legal framework requires improvement in the following aspects:

- Clearly defining biotechnology-specific trade secret types
- Regulating employee mobility
- Creating special protection mechanisms for digital data and bioinformatics

In the biotechnology context, trade secrets encompass a wide range including microorganism cultivation techniques, separation and purification processes, pharmaceutical substance and formula methods (Rowe, 2007).

For example, Genentech's recombinant insulin production process has been protected as a trade secret since the 1980s, providing the company with significant competitive advantage (Rowe, 2007). In this process, genetic modification of E. coli bacteria (bacteria living in human and animal intestines), fermentation conditions, protein purification methods, and quality control protocols constitute trade secrets.

Amgen's erythropoietin (EPO) (a hormone stimulating red blood cell formation) production technology represents another classic example. The company protects its CHO (Chinese Hamster Ovary) cell usage technology, cell cultivation conditions, and downstream processing methods as trade secrets. Roche's experience in monoclonal antibody (laboratory-created biological drug consisting of one type of antibody molecule) production encompasses a 30-year knowledge accumulation.

In European practice, hundreds of trade secrets are maintained at Novartis's biotechnology center located in Switzerland. In Japan, Takeda protects hundreds of trade secrets for its fermentation technologies. In China, BeiGene has registered trade secrets for its CAR-T cell therapy.

4. DISCUSSION

The comparative analysis reveals significant variations in trade secret protection strength across jurisdictions. The United States demonstrates the most robust framework with comprehensive federal legislation (DTSA) and established common law principles (Defend Trade Secrets Act, 2016; Uniform Trade Secrets Act, 1985).

The European Union presents a more harmonized landscape following the 2016 Directive, though implementation varies across member states (EU Trade Secrets Directive, 2016; Aplin & Davis, 2020).

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German legislation emphasizes balanced protection with attention to employee rights (GeschGehG, 2019), while French law provides strong employer protections.

Asian-Pacific jurisdictions exhibit hybrid approaches. Japan integrates trade secrets within unfair competition law (Japan UCPA, 1993; Matsuo, 2019), while China's recent legislative strengthening indicates recognition of trade secrets' economic importance (China Anti-Unfair Competition Law, 2019; Zang & Zhou, 2020).

Several challenges emerge as particularly acute in biotechnology contexts:

- Unlike mechanical inventions, biotechnological processes often resist reverse engineering, making trade secret protection especially valuable (Lemley, 2008; Rowe, 2007).
- Biotechnology's specialized workforce creates tension between trade secret protection and professional mobility. German legislation's more liberal approach contrasts with stricter American enforcement (GeschGehG, 2019; Aplin & Davis, 2020).
- Strengthened trade secret protection may restrict knowledge exchange. Evidence from U.S. states shows correlation between enhanced protection and decreased patent filings (Png, 2017a; Png, 2017b).
- Modern biotechnology generates massive datasets requiring adaptation of traditional frameworks (Rowe, 2007).

The research demonstrates that optimal strategies integrate trade secrets with patents, copyrights, and trademarks. Major biotechnology companies strategically combine these mechanisms: patenting core inventions while maintaining complementary processes as trade secrets (Rowe, 2007; Pooley, 2002).

Based above analysis Uzbekistan's framework requires:

1. Legislative clarification regarding genetic information, cell lines, and biological materials as protectable subject matter
2. Clearer guidelines balancing employer interests against employee rights
3. Specific provisions addressing cybersecurity and electronic information controls
4. Strengthened remedies appropriate to biotechnology contexts

5. CONCLUSION

This study demonstrates that trade secret protection constitutes an effective mechanism for intellectual property protection in biotechnology. The indefinite protection duration, coupled with biotechnology processes' resistance to reverse engineering, positions trade secrets as strategic complements to patent protection.

Comparative analysis reveals significant implementation variations despite core principle consistency. The United States offers the most robust framework, the European Union has created baseline harmonization, and Asian-Pacific jurisdictions demonstrate rapid evolution.

Practical applications by major companies demonstrate strategic value for protecting processes and formulations extending decades beyond patent terms.

For Uzbekistan, biotechnology-specific provisions must be incorporated, employee mobility frameworks require clarification, and digital information protection mechanisms need development. These improvements are essential for fostering robust innovation ecosystems while balancing proprietary interests against knowledge dissemination needs.

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