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Comparative Analysis of Classification of Biotechnology Licensing Agreements

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Abstract

This article presents a comprehensive classification system for licensing agreements in biotechnology, analyzing diverse license types including exclusive, non-exclusive, sole, and compulsory licenses, alongside specialized mechanisms such as conditional exclusivity, field-of-use restrictions, and geographic limitations. Drawing on international practices across the United States, the European Union, Japan, China, South Korea, and Uzbekistan, the study demonstrates that biotechnology's unique characteristics necessitate sophisticated classification systems that exceed traditional industrial licensing frameworks. The research examines how different license types serve distinct commercial functions, analyzing the role of exclusive licenses in supporting substantial capital investments, the utility of non-exclusive licenses for platform technologies, and the importance of sole licenses in university-industry partnerships. The article proposes legislative reforms for Uzbekistan, introducing sole licensing recognition, differentiating registration requirements by license type, and establishing biotechnology-specific provisions addressing field-of-use restrictions, compulsory licensing, and conditional exclusivity mechanisms.

Keywords: Biotechnology Licensing, Field-of-Use Restrictions, Patent Law, Technology Transfer

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I. Introduction

Licensing agreements constitute the primary legal mechanism through which biotechnology innovations transition from research laboratories to commercial applications, enabling technology transfer, facilitating collaborative development, and supporting the substantial capital investments required for biotechnology product development (Excedr, 2024). Unlike traditional industrial sectors, where licensing often involves mature technologies with established markets, biotechnology licensing frequently occurs at early developmental stages, involving molecular discoveries, research tools, platform technologies, and therapeutic candidates requiring extensive further development before commercial viability can be determined. This distinctive context creates a need for sophisticated classification systems that recognize diverse license types, accommodate multiple simultaneous licensing arrangements for different applications of single technologies, and provide legal frameworks supporting complex commercialization strategies spanning multiple jurisdictions, regulatory systems, and market segments.

Patent rights constitute exclusionary rights by their nature. These rights provide patent holders with the authority to prevent third parties from practicing claimed inventions. More specifically, patents obtained in Uzbekistan grant holder's rights to prevent third parties from manufacturing, using, offering for sale, or selling inventions in Uzbekistan, as well as importing inventions into Uzbekistan, provided third parties have not obtained appropriate authorization from patent holders. Such authorization is termed a license. The word "license" derives from Latin "licentia," literally meaning "freedom" or "liberty," and represents a legal document expressing official permission to do something. In this process, the patent holder (termed licensor) grants certain rights under the patent to another party (licensee). However, a license under no circumstances deprives the licensor of patent ownership. This fact remains valid even though the practical benefits of ownership rights may terminate.

According to Uzbek legal scholar O. Oqyulov, "When property rights are partially transferred, the rights holder retains a certain portion while transferring the remaining portion. Property rights are transferred only on a contractual basis. A contract is concluded between the property rights holder and the person to whom rights are being transferred fully or partially. Unless otherwise provided by law for such contracts, provisions of Civil Code Chapter 26 (Contract concept and terms) and Chapter 28 (Contract modification and termination) apply".

The classification of licensing agreements has received substantial attention in intellectual property scholarship, with established taxonomies distinguishing exclusive from non-exclusive licenses, identifying compulsory licensing mechanisms, and

recognizing various restrictions, including field-of-use, geographic, and temporal limitations. However, existing classification frameworks derive predominantly from traditional industrial contexts, with limited attention to biotechnology's specialized requirements. Biotechnology's extraordinarily long development cycles, substantial capital requirements, complex regulatory approval processes, and potential for multiple therapeutic and diagnostic applications of single molecular discoveries create unique classification challenges requiring specialized analytical frameworks. The interplay between different license types, the emergence of hybrid forms combining exclusive and non-exclusive elements, and the growing importance of conditional exclusivity mechanisms tied to development milestones or market performance warrant systematic examination.

This research gap holds particular significance for countries like Uzbekistan, establishing biotechnology sectors and seeking to develop legal frameworks that facilitate innovation while protecting the legitimate interests of researchers, developers, investors, and public health stakeholders. Uzbekistan's current intellectual property legislation addresses licensing agreements but lacks biotechnology-specific provisions and a detailed classification framework differentiating license types and their appropriate regulatory treatment. Understanding how advanced biotechnology jurisdictions classify licensing agreements and regulate different license types can inform Uzbekistan's legislative development while illustrating broader principles applicable to countries at similar developmental stages.

The primary objective of this study is to develop a comprehensive classification framework for biotechnology licensing agreements, analyzing major license types, examining their distinctive characteristics and commercial functions, and identifying appropriate regulatory approaches for each category. Specific research objectives include: first, examining exclusive, non-exclusive, and sole licenses, clarifying distinctions and analyzing their respective roles in biotechnology commercialization; second, analyzing compulsory licensing mechanisms in biotechnology; third, exploring conditional exclusivity mechanisms linking exclusive rights to performance milestones; fourth, examining field-of-use restrictions including therapeutic area limitations; fifth, analyzing temporal and geographic classifications; and sixth, developing recommendations for Uzbekistan's legal framework.

II. Methodology

This study employs qualitative research methodology centered on comparative legal analysis, combining systematic review of primary legal sources with functional comparison of licensing classification systems across major biotechnology jurisdictions. The research design integrates doctrinal legal analysis examining statutory provisions,

regulatory frameworks, and judicial decisions with functional analysis of how different license types operate in commercial practice (Drozdoff & Fairbairn, 2015). The jurisdictions selected for comparative analysis include the United States, the European Union, Japan, China, South Korea, Russia, and Uzbekistan. These jurisdictions were chosen based on several criteria: economic significance in global biotechnology markets; diversity in legal traditions, including common law and civil law systems; sophistication of biotechnology regulatory frameworks; availability of substantial licensing data; and relevance for Uzbekistan's legal development.

Primary legal sources examined include statutes, regulations, administrative guidelines, and judicial decisions addressing licensing agreements. For the United States, materials included Patent Act provisions (35 U.S.C.), Bayh-Dole Act and implementing regulations (35 U.S.C. §§ 200-212, 1980), Orphan Drug Act provisions (21 U.S.C. § 360aa et seq., 1983), Pediatric Research Equity Act (21 U.S.C. § 355c, 2003), U.S. Department of Justice and Federal Trade Commission intellectual property licensing guidelines (2017), and judicial decisions including De Forest Radio Telephone Co. v. United States (1927). European Union sources included Directive 98/44/EC (1998) on biotechnological inventions particularly Article 12 addressing compulsory licensing, Treaty on the Functioning of the European Union Articles 101-102 on competition law aspects of licensing, Directive 2004/48/EC on enforcement of intellectual property rights, and European Court of Justice jurisprudence including Consten and Grundig v. Commission (1966).

Japanese materials included Patent Act provisions (1959, as amended 2019) and Bio2020 strategy documents. Chinese sources included Patent Law provisions (2020), Civil Code contract provisions, Made in China 2025 strategy documents, and regulatory data protection mechanisms (Tan, Wang & Gu, 2025). South Korean materials included Patent Act provisions (as amended in 2020) and K-Bio/Health Strategy policy documents (Ministry of Health & Welfare, 2019). Russian sources included Civil Code Article 1235 (2006) and related provisions on licensing, including scholarly works on license agreement features (Kupriyanova & Nikolukin, 2019; Demyanenko & Shpak, 2019). Uzbek sources included Civil Code Articles 1036 and 1089 (1996) and Patent Law Article 11 (2001).

Secondary sources included academic literature on biotechnology licensing from specialized journals, industry reports from biotechnology organizations and consulting firms, and legal practice guides addressing licensing agreement drafting and negotiation. Literature sources included works on licensing biotechnology intellectual property in university-industry partnerships (Drozdoff & Fairbairn, 2015), profiting from technological innovation through licensing strategies (Teece, 1986), signal effects and producer reputation in new product marketing through partnerships (Helm & Mark,

2006), specialized guidance on biotechnology patent licensing and field-of-use restrictions, licensing deal structuring elements, and cross-border collaboration challenges. Data collection proceeded systematically through several phases, examining statutory materials, regulatory provisions, judicial decisions, and commercial practice. The analytical framework employed doctrinal analysis of formal legal classifications, functional analysis of commercial purposes, comparative analysis across jurisdictions, and contextual analysis of biotechnology-specific characteristics.

III. Results

A. Exclusive Licenses in Biotechnology

Exclusive licensing represents the most protective form of licensing arrangement, conferring on licensee's rights to practice licensed technology while excluding all others, including patent holders themselves, from the licensed field. Analysis across jurisdictions reveals widespread recognition of exclusive licensing as a distinct category warranting specialized legal treatment, though specific requirements and effects vary. In the United States legal practice, a license agreement is defined through the Copyright Act, Lanham Act, Patent Act, Bayh-Dole Act, and other legislative instruments. As noted in the U.S. Supreme Court's De Forest Radio Telephone Co. v. United States (1927) decision, a license represents the patent holder's waiver of the right to sue through the courts. License granting permission to use, manufacture, or sell a patent object actually signifies the patent holder's waiver of the possibility to pursue infringement through judicial proceedings. That is, through granting a license, the patent holder subsequently loses the right to file a court complaint regarding that patent. Additionally, the Bayh-Dole Act granted universities the right to license inventions obtained through federal grants, which significantly contributed to the biotechnology sector.

In European Union legislation, license agreement is regulated based on Directive 98/44/EC on legal protection of biotechnological inventions and TFEU Articles 101-102. Article 12 of Directive 98/44/EC establishes grounds for compulsory licensing for biotechnological inventions. European Court's Consent and Grundig v. Commission (1966) decision envision that a license agreement should be examined within the framework of competition law. Japanese legislation does not provide a definition or content of a license agreement. However, the Patent Act (1959, as amended 2019) Articles 77-78 regulate patent licensing. Article 77 envisions exclusive licenses, termed registered exclusive licenses, which grant the licensee sole right to use a patented invention and require registration for validity (Saito, 2023). Article 78 establishes non-exclusive (ordinary) licenses, which permit use of the invention without exclusivity rights, and registration is not mandatory for their validity. Furthermore, guidelines adopted within the framework of Japan's 2020 biotechnology strategies clarified field-of-

use restrictions in biotechnology licensing.

According to Article 11 of the China Patent Law, the patent holder has the sole right to use the patent and prohibits unauthorized use. Article 12 states that "Any organization or person using another's patent must conclude a licensing agreement with the patent holder and pay patent fees." Patent Law does not provide a detailed, precise definition of a license agreement term. General principles regulating contracts, including license agreements (which are considered a type of contract), are envisioned in the Chinese Civil Code. The Chinese government envisions a biotechnology licensing policy within the framework of "Made in China 2025" strategy and has introduced regulatory data protection and exclusivity mechanisms for biotechnology products (Tan, Wang & Gu, 2025).

Similar to Japanese and Chinese Patent Laws, the South Korean Patent Act does not provide a precise definition of a license agreement but establishes basic rules regarding exclusive and non-exclusive licenses. While exclusive licenses must be registered, non-exclusive licenses remain valid without registration. Additionally, the South Korean government implements policies to activate biotechnology intellectual property commercialization and technology transfer, including licensing processes, within the framework of "K-Bio/Health Strategy". Unlike the legislation reviewed above, the Russian Federation Civil Code provides a license agreement definition. According to Article 1235(1) of Code, license agreement is civil-legal contract whereby "one party - holder of exclusive right to result of intellectual activity or means of individualization (licensor) grants or undertakes obligation to grant to second party (licensee) right to use such result or means within limits envisioned in agreement". According to this definition, the conclusion of the license agreement does not result in the transfer of exclusive rights to the licensee but only the transfer of a certain portion of exclusive rights in a specified volume. Transfer of specified portion of exclusive rights under license agreement is carried out for a certain time period, after which licensor recovers transferred rights, unlike exclusive right alienation agreement, whereby exclusive right is transferred definitively.

Similar to Russian legislation, Uzbekistan legislation also envisions a license agreement definition. Specifically, according to Civil Code Article 1036, under a license agreement, the party having the exclusive right to the result of intellectual activity or means reflecting distinctive characteristics (licensor) grants permission to another party (licensee) to use the corresponding intellectual property object. Japanese Patent Act Article 77 (1959, as amended 2019) addresses exclusive licenses, requiring registration with the Patent Office for validity and legal effect. Without proper registration, purported exclusive licenses lack legal force. This registration requirement reflects the view that exclusive licensing creates quasi-property rights warranting formal recording and public

notice (Saito, 2023). The statute's original formulation provided that registered exclusive licensees possess exclusive rights to work patented inventions within the scope of their licenses, automatically excluding patent holders themselves. However, the 2019 amendments introduced flexibility allowing parties to reserve usage rights for patent holders through contractual provisions, creating arrangements functionally similar to sole licenses while maintaining exclusive license designation.

Chinese Patent Law (2020) historically provided limited explicit recognition of exclusive licensing, with practice developing through contractual arrangements. Recent amendments strengthen exclusive license provisions, clarifying licensees' rights and providing enhanced legal protection. China's biotechnology licensing market has grown substantially, with exclusive licenses increasingly used for innovative therapeutics and diagnostic technologies. The Made in China 2025 strategy explicitly identifies biotechnology licensing as a priority area for intellectual property system development. South Korean Patent Act (as amended 2020) similarly recognizes exclusive licenses requiring registration, following the Japanese model with adaptations reflecting Korean commercial practices and policy priorities. The K-Bio/Health Strategy adopted by the South Korean government includes provisions supporting biotechnology licensing and technology transfer, recognizing exclusive licensing in attracting investment and supporting product development.

European Union law addresses exclusive licensing through a competition law lens in Articles 101-102 of the Treaty on the Functioning of the European Union, examining whether exclusive arrangements restrict competition. Directive 98/44/EC (1998) on biotechnological inventions establishes a framework for compulsory licensing that implicitly recognizes exclusive licensing as a normal commercial arrangement. European Court of Justice Jurisprudence, including Consent and Grundig v. Commission (1966), establishes principles for evaluating exclusive licensing under competition law. Uzbekistan Civil Code Article 1036 (1996) addresses exclusive licensing in paragraph four's third clause, defining exclusive license as an arrangement where the intellectual property object may be used by the licensee while the licensor retains usage rights but cannot grant licenses to others. This formulation actually describes sole licensing rather than true exclusive licensing as internationally understood. This definitional discrepancy creates potential confusion and may inadequately protect exclusive licensees who expect complete exclusivity, including against patent holders.

According to our research, the legal significance of exclusive licenses in biotechnology substantially differs from classical patent licensing. First, biotechnology products require many years of research and development (average 10-15 years); therefore, exclusivity provides the licensee opportunity to recover necessary investments (WIPO, 2025). Second, due to the regulatory approval process being complex and

expensive (average 100 million - 1 billion dollars), exclusive rights are necessary to incentivize the licensee. Third, the possibility of multi-purpose application of biotechnology products creates a necessity to divide exclusive licenses into various fields (Freeman, 2007).

Civil-legal consequences of exclusivity are very broad, requiring the licensor to significantly restrict its own rights. Exclusive agreements provide the licensee with complete control over the product in a designated market, which increases potential market share and ensures competitive advantage. This is especially important in biotechnology, as exclusive rights play a central role due to the large expenses and efforts necessary for developing molecular targets and drug candidates. Exclusive contracts grant the licensee full control over the product in the designated market, thereby increasing potential market share and providing a competitive advantage.

B. Non-Exclusive Licenses in Biotechnology

Unlike exclusive licenses, in non-exclusive licenses, there may be several licensees, and coordination issues among their rights assume important significance. In non-exclusive license agreements, the licensee may use the licensor's product, but the licensor retains the right to grant similar licenses to other persons. This situation provides licensors opportunity to obtain multiple income sources through several licensees. Non-exclusive licenses have advantages for widely applicable technologies, standardized tools, and research instruments. Because they maximize technology's impact, scope, and income by permitting several users, while encouraging broader dissemination and use. Japanese Patent Act Article 78 (1959, as amended 2019) addresses non-exclusive ordinary licenses, permitting their validity without registration, though providing that registration confers enhanced protection against subsequent patent transferees. This optional registration framework reflects the view that non-exclusive licenses create less need for public recording than exclusive licenses. Unregistered non-exclusive licenses remain valid between licensors and licensees but may not bind third parties who subsequently acquire licensed patents without notice.

United States practice treats non-exclusive licenses primarily as contractual arrangements without specialized statutory provisions. Non-exclusive licensees generally lack standing to sue for patent infringement, relying on licensors to enforce underlying patents. Non-exclusive licensing predominates for certain biotechnology applications, including genetic databases, antibody generation platforms, cell culture media, and laboratory equipment incorporating patented technologies. Chinese Patent Law (2020) addresses non-exclusive licenses primarily through general provisions requiring licensing agreements and royalty payments for patent use. Chinese biotechnology practice increasingly uses non-exclusive licensing for platform technologies and research tools. Made in China 2025 strategy includes initiatives facilitating licensing transactions,

though these focus primarily on exclusive arrangements for core technologies while recognizing non-exclusive licensing's role for enabling technologies.

European Union competition law shapes non-exclusive licensing practice through provisions limiting restrictions on non-exclusive licensees that might constitute anticompetitive restraints. Non-exclusive licenses generally raise fewer competition concerns than exclusive arrangements. European biotechnology practice uses non-exclusive licensing extensively for research tools. Uzbekistan Civil Code Article 1036 (1996) addresses non-exclusive licensing in paragraph four's first clause, terming it a simple non-exclusive license allowing intellectual property use while the licensor retains both usage rights and rights to grant additional licenses. However, current registration requirements treating all licenses identically impose unnecessary burdens on non-exclusive arrangements. Eliminating mandatory registration for non-exclusive licenses while maintaining optional registration for succession protection would reduce administrative burdens and encourage legitimate licensing activity.

C. Sole Licenses: Intermediate Category

The sole license concept manifests as an intermediate state between exclusive and non-exclusive licenses. In this case, it should be separately noted that the licensor itself may also have the right to use its own technology. Such a structure is often applied in cooperation between scientific institutions and industry, where, in a sole license university also retains the right to continue its research. In international practice, besides standard exclusive and non-exclusive forms, legislation expressing separate "sole license" rules is not commonly encountered, as the definition of this license agreement type may vary. Specifically, the Bayh-Dole Act grants universities and other nonprofit organizations the opportunity to retain ownership rights to inventions created based on federal financing and commercialize them through exclusive license agreements with the private sector. Here, although the law commercializes biotechnology objects through exclusive license agreements, it retains the right to conduct research on these inventions. This is essentially a sole license agreement and is widely used in U.S. practice. However, legislation does not specifically provide grounds for a sole license.

However, jurisdictions operating under the United States-Singapore Free Trade Agreement (USSFTA) have such rules or system permitting their establishment on a contractual basis. Indeed, the Singapore Free Trade Agreement states that license agreements are classified into exclusive, non-exclusive, and sole license agreements, and a sole license means a license type granted to only one licensee that restricts the licensor from granting a license to any other person but does not restrict the licensor itself from using the mark (or technology). Notable aspect in our national legislation is that in Civil Code Article 1036 paragraph 4 third clause, right to use an intellectual property object while retaining licensor's usage right but without right to grant license to other persons is

recognized as exclusive license.

Actually, from this norm's content, not exclusive license but sole license content is understood. Because in international practice, an exclusive license is understood as the licensee having exclusive rights through restricting even the licensor itself from using the invention. The sole license agreement provides universities and research institutes opportunity to continue fundamental research while commercializing their scientific developments, and has been showing positive results in the U.S. and other developed countries' practice, it is appropriate to introduce sole license agreement into our national legislation separately from exclusive license agreement and remove licensor's usage right from exclusive license norm. Accordingly, we propose the following amendments and additions to our legislation:

1. **Amendments and additions to the civil code**

It is proposed to state the Uzbekistan Republic Civil Code Article 1036 paragraph 4 in the following version License agreement may envision granting licensee:

- Right to use intellectual property object while retaining licensor's usage right and right to grant license to other persons (simple non-exclusive license);
- Right to use intellectual property object without retaining licensor's usage right, without the right to grant a license to other persons (exclusive license);
- Right to use intellectual property object while licensor itself also has usage right, but license is not granted to other third parties (sole license);
- Other types of licenses permitted by law.

2. **Article 1036¹. Sole license agreement**

To supplement the Civil Code with a new Article 1036¹ in the following version: Under a sole license agreement, the party having exclusive right to the intellectual property object (licensor) grants another party (licensee) the right to use the corresponding object while retaining its own usage right, but with the obligation not to grant a license to third parties. Sole license agreement grants licensee the following rights:

- To use licensed technology for commercial purposes;
- To file a claim against any violation of this right by third parties;
- To conduct exclusive activity in a designated geographic territory.

Licensor assumes the following obligations under the sole license agreement:

- Not to grant a similar license to third parties;
- Not to compete regarding licensee's commercial activity;
- To cooperate with licensee in developing technology.

D. Compulsory Licensing in Biotechnology

Compulsory licensing represents an exceptional category where governmental authorities require patent holders to grant licenses to third parties without voluntary agreement. Biotechnology presents distinctive compulsory licensing issues given the sector's public health significance. Additionally, exclusivity degree changing over time and the application of conditional exclusivity mechanisms are the biotechnology sector's distinctive characteristics. Exclusive agreements demand a higher price compared to non-exclusive agreements. Conditional exclusivity mechanisms provide an opportunity to modify exclusivity rights upon reaching certain stages or indicators, meaning a conditional exclusivity clause establish one party being provided with exclusive rights, but only when certain specified conditions are fulfilled. In practice, exclusivity may not be direct but may be connected with reaching sales indicators, obtaining permission from regulatory authorities, or fulfilling other contractual obligations.

Conditional exclusivity mechanisms are widely applied in international practice. For example, within the framework of the "Orphan Drug Act" (1983) by the U.S. Food and Drug Administration, seven-year market exclusivity is granted to medicines for rare diseases. Additional six-month exclusivity ("Pediatric Exclusivity") for pediatric research also exists, which has been shown to significantly improve children's access to appropriate medicines (Grieve et al., 2005). In the European Union, accelerated review and conditional exclusivity mechanisms for medicines responding to important medical needs have been introduced through the "PRIME" (PRIority MEdicines) scheme.

Furthermore, conditional exclusivity license agreement practice also operates in countries such as Canada, Japan, South Korea (Miller, 2012; Recchia & Jones, 2015), and China. The compulsory licensing mechanism has special significance in biotechnology. Uzbekistan "Law on Inventions, Utility Models and Industrial Designs" Article 11^1 establishes compulsory licensing grounds. Specifically, according to it, if patent holder does not use or insufficiently uses industrial property object within three years from patent registration date or four years from application filing date, whichever ends later, and this leads to insufficient supply of corresponding goods, works, and services in market, any person wishing to use industrial property object may apply to court for compulsory non-exclusive license, i.e., compulsory license, if patent holder refused to conclude license agreement on acceptable commercial terms. However, the biotechnology sector's characteristics are not fully considered in law.

Using the European Union experience is appropriate here. Specifically, according to European Union Directive 98/44/EC of July 6, 1998, on Legal Protection of Biotechnological Inventions Article 12, if a breeder is compelled to violate an existing patent in creating a new plant variety, they may obtain a compulsory license from the patent holder. In exchange, the patent holder also obtains the right to use the new variety.

If the patent holder is compelled to violate existing plant variety rights in using their invention, they may obtain a compulsory license from the variety holder. In exchange, the variety holder also obtains the right to use the patent. It is appropriate to introduce a special compulsory licensing procedure for biotechnological products, specifically to introduce special norms envisioning compulsory licensing when compelled to violate existing patents in implementing biotechnological inventions or during public health emergencies, into the Civil Code.

Furthermore, developing a draft special national legislative document on biotechnology using the experience of the European Union's above-mentioned Directive 98/44/EC serves as an encouraging tool in sector formation and development. Imagining the national biotechnology sector formation without this legislative document is difficult. Therefore, developing our national law-envisioning mechanism for legally regulating biotechnology and inventions in the sector is appropriate and necessary. It should be noted that the license agreement's division into exclusive and non-exclusive licenses causes theoretical debates about its legal nature; specifically, there is no unified approach on this issue throughout Europe. While most countries consider all forms of license agreement as pure contractual-legal transactions, in Germany and Austria, dominant teaching considers only a simple license as such, while an exclusive license is viewed as having quasi-property (or erga omnes), i.e., effect toward everyone (Hilty, 2012).

The practical impact of this difference is that (exclusive) licensee, without these approaches (quasi-property), is theoretically deprived of the right to take legal measures against third parties (for example, in a violation case) and succession protection right when the licensed object is disposed of by licensor. Uzbekistan's legal system belongs to the continental law family and is close to German and Austrian legal traditions in this respect. In this regard, applying hybrid approach in determining legal nature of license agreements in Uzbekistan intellectual property law using European experience is considered appropriate, whereby non-exclusive licenses should be subject to Civil Code's general contract law rules as pure contractual-legal transaction and not mandatory to register with relevant state authority according to our above-given proposal, while exclusive licenses should be viewed as set of rights having quasi-property right elements, affecting third parties, and must be registered with relevant state authority.

According to our research, this issue is not clearly regulated in Uzbekistan legislation, and it is necessary to strengthen mechanisms protecting biotechnology licensees' rights. Exclusive licensees' right to file a claim against third parties is not clearly defined in our national legislation. Therefore, we consider it appropriate to introduce a norm on the licensee's right to file a claim against any violation of this right by third parties in the new Civil Code Article 1036[2] presented above, and the adoption of norms in the following version is considered appropriate:

1. Article 1036[2]. Exclusive licensee's right to claim against third parties

A person who obtained the right to use an intellectual property object under an exclusive license agreement (exclusive licensee) has the right to apply legal protection measures against intellectual property rights violations by third parties independently through court or other means without requiring the licensor's consent. The exclusive licensee's right envisioned in the first part of this article arises when the following conditions are fulfilled:

- License agreement must be concluded as an exclusive license;
- License agreement must be registered with the relevant state authority regarding intellectual property objects;
- Unless otherwise established by license agreement.

The exclusive licensee has the right to apply to the court or other means with the following demands regarding intellectual property rights violations:

- To cease actions constituting rights violations;
- To compensate damages incurred;
- To confiscate income obtained as a result of rights violation;
- Other demands envisioned in legislation.

A non-exclusive (simple) licensee does not have the right to independently claim against third parties but has the right to demand licensor take intellectual property rights protection measures. Provisions of this article may be otherwise regulated by a license agreement, but this regulation must not harm third parties' legitimate rights and interests.

E. Field-of-Use Restrictions and Therapeutic Area Licensing

Now addressing important rules of the license agreement, the licensee's rights boundaries within the license agreement framework assume special significance. These boundaries may be material (production, marketing, user licenses, etc.), geographic (territorial license), quantitative (quota licenses), or time-based. As in most national legal systems, a license agreement is not regulated in detail in international practice. Instead, confidence is expressed in its legality. When biotechnology license agreements are concluded and discussed with academic institutions' participation, they rarely provide easily commercializable product or technology (Drozdoff & Fairbairn, 2015) easily. Often, licensing relationships are established around relatively early-stage technology, where the path leading to the final commercial product is not completely clear. Therefore, understanding both parties' expectations assumes especially important significance in shaping license scope and rights agreement gives to both parties.

Contractual agreements concluded with well-known firms, specifically license agreements, are considered one way for new firms to benefit from technological

innovations using the partner firm's reputation (Helm & Mark, 2006), and represent an important mechanism for profiting from technological innovation through strategic partnerships and collaborations (Teece, 1986). Field-of-use restrictions constitute a mechanism restricting rights regarding biotechnology technologies in various fields. Field-of-use rules limit licensee's rights in licensed technology to designated programs or usage methods in license agreements.

In "Intellectual Property Guidelines for Licensing" issued by the U.S. Federal Trade Commission and Department of Justice in 2017, criteria for evaluating field-of-use restrictions from a competition law perspective are established. According to this guideline, if field-of-use restrictions are based on technological differences and not applied for market division purposes, they do not contradict competition legislation. Because patent rights in the biotechnology sector may be of multiple types, it is customary to grant a license for one field (for example, treating pediatric oncology) but not grant for another field (for example, adult oncology or pediatric autoimmune diseases). In this case, the same patents may be licensed to different parties, each on an exclusive basis but for different field-of-use scopes (Pressman, 2006; Freeman, 2007).

Therapeutic area restrictions manifest as licensing boundaries regarding biotechnology products in treating various diseases. These restrictions are especially important in pharmaceutical production, where a single molecule may be used to treat several diseases. For example, monoclonal antibodies may be used for various oncological diseases, but each therapeutic area may be licensed separately. As concrete example, Roche company's bevacizumab (Avastin) molecule (biological drug substance called monoclonal antibody) has been licensed to different companies for several therapeutic areas: one licensee for colorectal cancer (colon cancer), another licensee for macular degeneration (disease causing loss of eye's central vision ability), and third licensee for other oncological indications (various cancer diseases) (Roche, 2018).

According to our analysis, therapeutic area restrictions provide biotechnology companies following advantages: first, risk distribution risk is also distributed for separate licensees for each therapeutic area; second, specialization each licensee gains deep experience in their area; third, maximum market coverage opportunity for simultaneous development in various areas is created. Market segment licensing includes a mechanism for separately allocating licensing rights regarding pharmaceutical products' different market segments, for example, prescription (Rx) and over-the-counter (OTC) sales. This important mechanism expresses importance, especially when one medicine is sold prescription-based while another is sold without a prescription. Geographic area restrictions express biotechnology licenses' application rights limitation in certain territories. Determining the territory where intellectual property may be used is often considered one of the main issues. An agreement determines where and how the

licensee may use intellectual property. These scopes are often fully defined in agreement on a global scale, covering a selected region (for example, the European Union) or limited within a certain country.

International practice shows that geographic restrictions often differ between developed and developing markets. For example, the MSD (Merck & Co.) company establishes high payment (royalty) rates for developed countries (USA, Europe, and Japan) (5-10%), while offering preferential conditions for developing countries (1-3%) in many license agreements. It should be noted that the territory-based licensing issue is especially important for Uzbekistan, as biotechnology in our country is in the formation stage, and integration into the international market is very important. Cross-border issues include legal complexities in biotechnology licenses' Trans boundary nature. These issues are connected with differences in patent protection in various countries, regulatory requirements, and legal systems. Most biomedicine companies, whether large or small, desire patent protection throughout the world to supply foreign markets or use their assets in creating strategic alliances.

Cross-border issues in biotechnology include: regulatory differences (differences among the FDA, EMA, PMDA, and NMPA), patent rights' territorial nature, parallel import issues, licensing fee (royalty) taxation issues, etc. These issues require special attention in concluding biotechnology license agreements (Covington & Burling, 2024). Parallel import (bringing the same product from another country at a lower price rather than from the official distributor) restrictions manifest as restrictions regarding biotechnology products in various countries. These restrictions are applied to limit licensees' importing products from one country to another, which creates price difference and market division issues (Thomas, 2016).

The parallel import issue is considered a serious debate topic in biotechnology. On one hand, patent holders want to have the opportunity to segment the market to protect their investments. On the other hand, market competition and consumer interests support parallel import (Thomas, 2016). The European Court's exhaustion doctrine has partially resolved this issue. According to the exhaustion doctrine, it is a legal principle restricting intellectual property holders' rights after a product containing their intellectual property object has been legally sold (Moroğlu Arseven, 2021). Under this doctrine, after the first authorized sale is carried out, the intellectual property holder's control over that specific object "exhausts," and the buyer may use, sell, or otherwise dispose of this object without additional permission. Regional licensing agreements include issues of biotechnology rights distribution by regional blocks (EAC, ASEAN, and MERCOSUR). This type of agreement is important for biotechnology companies in developing regional strategies, providing an opportunity to cooperate with partner organizations in various countries.

F. Temporal Classifications

Term licenses express a legal regulation mechanism regarding biotechnology licenses being granted for a certain period. Time restrictions are usually connected with patent term, considering a 20-year protection period in most countries. At the same time, term licenses - these are exclusivity period restrictions with a time necessary to give the licensee a competitive advantage through early market entry. After that, the permission converts to a non-exclusive license, and the market opens for other companies. Terms may differ from several years to much longer periods for products requiring many years of development and/or testing. The following factors should be considered for term licenses in biotechnology: clinical trials duration (usually 5-12 years), regulatory approval process (1-3 years), market entry and commercialization (2-5 years). Therefore, biotechnology licenses being long-term is natural. For example, a full development cycle for monoclonal antibodies may constitute 10-15 years.

Patent expiration impact includes legal issues related to how licensing obligations change when the patent rights term concludes. For example, licenses based only on patent rights are usually terminated when the patent term expires. If a license was granted together with other rights (know-how, copyright), the licensing fee (royalty) amount decreases after the patent term expires. Agreement renewal opportunities occupy an important place in biotechnology licenses, as they determine licensing term extension procedure and conditions. In practice, annual or other recurring licensing fees are often applied as a mechanism encouraging the licensee to practically apply the invention. This approach's essence is that if the licensee does not intend to use the invention for commercial purposes, they cannot pay high amounts of regular payments for a long period.

Termination grounds in biotechnology licensing agreements express a set of legal situations permitting agreement cancellation before the established term. Such grounds include non-practical use of a patent, serious violation of agreement conditions, and non-achievement of established performance indicators, violation of regulatory norms and requirements, as well as situations such as non-provision of public health needs. Thus, special aspects of license agreements in biotechnology substantially differ from classical intellectual property licensing, and these differences are connected with biotechnology products' long development cycle (10-15 years), high expenses (100 million - 1 billion dollars), complex regulatory requirements, and multi-purpose application opportunities. International practice analysis shows that countries with advanced biotechnology experience, specifically the USA, Japan, China, and South Korea, have created special legal regimes by adapting their national legislation to the biotechnology sector needs. For Uzbekistan as well, applying a similar complex approach is necessary, whereby adapting national legislation to international standards, adopting a special biotechnology law

encouraging innovations, and creating a separate legal environment is considered necessary.

IV. Discussion

A. Integration of Classification System with Biotechnology Characteristics

The comprehensive classification system developed through this study integrates multiple dimensions, including exclusivity level, conditionality, field limitations, geographic scope, and temporal parameters, creating a multidimensional framework reflecting biotechnology licensing. Unlike a simple exclusive versus non-exclusive dichotomy, biotechnology licensing requires sophisticated taxonomy accommodating hybrid forms, conditional structures, and multiple simultaneous licenses for different applications of single technologies. Biotechnology's extended development timelines, averaging ten to fifteen years, create a particular need for conditional and performance-based licensing structures. Early-stage licenses, when commercial viability remains uncertain, benefit from milestone-based structures linking continued exclusivity to development progress. Performance requirements reflect biotechnology's sequential development phases.

Substantial capital requirements ranging from one hundred million to one billion dollars for biotechnology product development create an essential role for exclusive licensing, providing commercial protection justifying such investments. Non-exclusive arrangements typically cannot support the requisite capital mobilization for major biotechnology projects. However, some biotechnology applications, including research tools and platform technologies, may be successfully commercialized through non-exclusive licensing. Multiple potential applications of single biotechnology innovations create a compelling case for field-of-use classification systems, enabling licensing of different applications to specialized partners. Field-based licensing maximizes commercial value and development probability by engaging optimal partners for each application.

B. Legislative Framework Implications for Developing Jurisdictions

The classification analysis generates significant implications for legislative framework development in jurisdictions like Uzbekistan, establishing biotechnology sectors. A comprehensive classification system providing clear categories, definitions, and regulatory treatment for diverse license types enhances legal certainty and signals governmental commitment to biotechnology development. Explicit recognition of all major license types, including exclusive, non-exclusive, and sole licenses, represents an essential first step. Uzbekistan's current framework inadequately addresses sole licensing and confuses exclusive with sole categories. Legislative reform introducing a clear three-part classification aligning with international practice would enhance commercial

flexibility and facilitate university-industry technology transfer.

Differentiated registration requirements based on license type balance competing values of public notice against administrative efficiency. Mandatory registration for exclusive and sole licenses provides appropriate protection, while optional registration for non-exclusive licenses reduces burdens on routine transactions. Biotechnology-specific compulsory licensing provisions addressing dependency situations and public health emergencies adapted to the sector's unique characteristics would balance access imperatives with innovation incentives. Specialized provisions modeled on EU Directive 98/44/EC Article 12 addressing dependencies would prevent blocking situations. Recognition and regulation of conditional exclusivity mechanisms would facilitate sophisticated licensing structures aligning with biotechnology development's uncertain nature. Field-of-use licensing provisions establishing validity and enforcement mechanisms would support biotechnology's characteristic pattern.

C. International Harmonization Challenges

The comparative analysis reveals significant diversity in licensing classification and regulation across examined jurisdictions, reflecting different legal traditions and regulatory philosophies. This diversity creates challenges for international biotechnology transactions requiring navigation of multiple legal systems. Terminology variations create confusion even when jurisdictions adopt functionally similar approaches. Harmonization of basic terminology, including standardized definitions, would reduce confusion (Covington & Burling, 2024). Registration requirements vary substantially across jurisdictions. Despite harmonization challenges, international biotechnology licensing's commercial importance creates incentives for continued convergence.

Conclusion

This study has developed a comprehensive classification framework for biotechnology licensing agreements, analyzing major license types, including exclusive, non-exclusive, sole, and compulsory licenses, alongside specialized mechanisms. The analysis demonstrates that biotechnology's unique characteristics necessitate sophisticated classification systems exceeding traditional industrial licensing frameworks. Comparative analysis across the United States, European Union, Japan, China, South Korea, Russia, and Uzbekistan reveals significant diversity in classification approaches. For Uzbekistan, the analysis generates concrete legislative recommendations including amending Civil Code Article 1036 to correct exclusive license definition and introduce sole licensing as distinct category, reforming Article 1089 to differentiate registration requirements, establishing sole licensing framework, conferring enforcement rights on exclusive licensees, incorporating biotechnology-specific compulsory licensing provisions, and establishing field-of-use licensing framework.

The reforms would align Uzbekistan's legislation with international best practices, enhance legal certainty supporting biotechnology investment, accommodate sector-specific needs, and position Uzbekistan competitively in biotechnology markets. The comprehensive classification system offers a template for countries examining their licensing regimes. For developing countries, thoughtful licensing classification framework development can create competitive advantages by providing clear, predictable legal environments supporting biotechnology commercialization.

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